

The Stock Exchange of Hong Kong Limited and the Securities and Futures Commission take no responsibility for the contents of this Application Proof, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this Application Proof.

Application Proof of



SHENZHEN HEPALINK PHARMACEUTICAL GROUP CO., LTD.

(深圳市海普瑞藥業集團股份有限公司)

(A joint stock company incorporated in the People's Republic of China with limited liability)

(the “Company”)

WARNING

The publication of this Application Proof is required by The Stock Exchange of Hong Kong Limited (the “Exchange”)/the Securities and Futures Commission (the “Commission”) solely for the purpose of providing information to the public in Hong Kong.

This Application Proof is in draft form. The information contained in it is incomplete and is subject to change which can be material. By viewing this document, you acknowledge, accept and agree with the Company, its sponsor, advisers or member of the underwriting syndicate that:

(a) this document is only for the purpose of providing information about the Company to the public in Hong Kong and not for any other purposes. No investment decision should be based on the information contained in this document;

(b) the publication of this document or supplemental, revised or replacement pages on the Exchange’s website does not give rise to any obligation of the Company, its sponsor, advisers or members of the underwriting syndicate to proceed with an offering in Hong Kong or any other jurisdiction. There is no assurance that the Company will proceed with the offering;

(c) the contents of this document or supplemental, revised or replacement pages may or may not be replicated in full or in part in the actual final listing document;

(d) the Application Proof is not the final listing document and may be updated or revised by the Company from time to time in accordance with the Listing Rules;

(e) this document does not constitute a prospectus, offering circular, notice, circular, brochure or advertisement offering to sell any securities to the public in any jurisdiction, nor is it an invitation to the public to make offers to subscribe for or purchase any securities, nor is it calculated to invite offers by the public to subscribe for or purchase any securities;

(f) this document must not be regarded as an inducement to subscribe for or purchase any securities, and no such inducement is intended;

(g) neither the Company nor any of its affiliates, advisers or underwriters is offering, or is soliciting offers to buy, any securities in any jurisdiction through the publication of this document;

(h) no application for the securities mentioned in this document should be made by any person nor would such application be accepted;

(i) the Company has not and will not register the securities referred to in this document under the United States Securities Act of 1933, as amended, or any state securities laws of the United States;

(j) as there may be legal restrictions on the distribution of this document or dissemination of any information contained in this document, you agree to inform yourself about and observe any such restrictions applicable to you; and

(k) the application to which this document relates has not been approved for listing and the Exchange and the Commission may accept, return or reject the application for the subject public offering and/or listing.

If an offer or an invitation is made to the public in Hong Kong in due course, prospective investors are reminded to make their investment decisions solely based on the Company’s prospectus registered with the Registrar of Companies in Hong Kong, copies of which will be distributed to the public during the offer period.

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

IMPORTANT

IMPORTANT: If you are in any doubt about any of the contents of this document, you should obtain professional independent advice.



Hepalink

SHENZHEN HEPALINK PHARMACEUTICAL GROUP CO., LTD.
(深圳市海普瑞藥業集團股份有限公司)

(A joint stock company incorporated in the People’s Republic of China with limited liability)

[REDACTED]

Number of [REDACTED] under the [REDACTED]	[REDACTED] H Shares (subject to the [REDACTED])
Number of [REDACTED]	[REDACTED] H Shares (subject to adjustment)
Number of [REDACTED]	[REDACTED] H Shares (subject to adjustment and the [REDACTED])
[REDACTED]	[REDACTED] per H Share, plus brokerage of 1.0%, SFC transaction levy of 0.0027% and Hong Kong Stock Exchange trading fee of 0.005% (payable in full on application in Hong Kong dollars and subject to refund)
Nominal value	RMB1.00 per H Share

[REDACTED]

Joint Sponsors

(in alphabetical order)

**Goldman
Sachs**

Morgan Stanley

[REDACTED]

[REDACTED]

Hong Kong Exchanges and Clearing Limited, The Stock Exchange of Hong Kong Limited and Hong Kong Securities Clearing Company Limited take no responsibility for the contents of this document, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this document.

A copy of this document, having attached thereto the documents specified in the paragraphs headed “Documents Delivered to the Registrar of Companies in Hong Kong” and “Documents Available for Inspection” in Appendix VII to this document, has been registered by the Registrar of Companies in Hong Kong as required by Section 342C of the Companies (Winding up and Miscellaneous Provisions) Ordinance, Chapter 32 of the Laws of Hong Kong. The Securities and Futures Commission of Hong Kong and the Registrar of Companies in Hong Kong take no responsibility as to the contents of this document or any other documents referred to above.

The [REDACTED] is expected to be fixed by agreement between the [REDACTED] (on behalf of the [REDACTED]) and us on the [REDACTED]. The [REDACTED] is expected to be on or around [REDACTED] (Hong Kong time) and, in any event, not later than [REDACTED] (Hong Kong time). The [REDACTED] will be not more than HK\$[REDACTED] and is currently expected to be not less than HK\$[REDACTED] per [REDACTED]. If, for any reason, the [REDACTED] is not agreed by [REDACTED] (Hong Kong time) between the [REDACTED] (on behalf of the [REDACTED]) and us, the [REDACTED] will not proceed and will lapse.

Applicants for [REDACTED] are required to pay, on application, the [REDACTED] of HK\$[REDACTED] for each [REDACTED] together with brokerage fee of 1.0%, SFC transaction levy of 0.0027% and Hong Kong Stock Exchange trading fee of 0.005%, subject to refund if the [REDACTED] as finally determined is less than HK\$[REDACTED].

The [REDACTED], on behalf of the [REDACTED], and with our consent may, where considered appropriate, reduce the number of [REDACTED] and/or the indicative [REDACTED] range below that is stated in this document (which is HK\$[REDACTED] to HK\$[REDACTED]) at any time prior to the morning of the last day for lodging applications under the [REDACTED]. In such a case, notices of the reduction in the number of [REDACTED] and/or the indicative [REDACTED] range will be published in the [South China Morning Post] (in English) and the [Hong Kong Economic Times] (in Chinese) as soon as practicable following the decision to make such reduction, and in any event not later than the morning of the day which is the last day for lodging applications under the [REDACTED]. Such notices will also be available on the website of our Company at www.hepalink.com and on the website of the Hong Kong Stock Exchange at www.hkexnews.hk. Further details are set forth in “Structure of the [REDACTED]” and “How to Apply for the [REDACTED]” in this document.

We are incorporated in the PRC. Potential [REDACTED] should be aware of the differences in the legal, economic and financial systems between the PRC and Hong Kong and that there are different risk factors relating to [REDACTED] in PRC-incorporated businesses. Potential [REDACTED] should also be aware that the regulatory framework in the PRC is different from the regulatory framework in Hong Kong and should take into consideration the different market nature of the H Shares. Such differences and risk factors are set out in “Risk Factors,” “Appendix IV—Summary of Principal Legal and Regulatory Provisions” and “Appendix V—Summary of Articles of Association” to this document.

The obligations of the [REDACTED] under the [REDACTED] are subject to termination by the [REDACTED] (on behalf of the [REDACTED]) if certain grounds arise prior to 8:00 a.m. on the [REDACTED]. See “[REDACTED]” of this document.

The [REDACTED] have not been and will not be registered under the U.S. Securities Act or any state securities law in the United States and may be [REDACTED] and [REDACTED] only (a) in the United States to “Qualified Institutional Buyer” in reliance on Rule 144A or another exemption from, or in a transaction not subject to, registration under the U.S. Securities Act and (b) outside the United States in offshore transactions in reliance on Regulation S under the U.S. Securities Act.

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

CONTENTS

This document is issued by our Company solely in connection with the [REDACTED] and the [REDACTED] and does not constitute an [REDACTED] to sell or a solicitation of an [REDACTED] to subscribe for or buy any security other than the [REDACTED]. This document may not be used for the purpose of, and does not constitute, an [REDACTED] to sell or a solicitation of an [REDACTED] to subscribe for or buy any security in any other jurisdiction or in any other circumstances. No action has been taken to permit a [REDACTED] of the [REDACTED] or the distribution of this document in any jurisdiction other than Hong Kong. The distribution of this document and the [REDACTED] and sale of the [REDACTED] in other jurisdictions are subject to restrictions and may not be made except as permitted under the applicable securities laws of such jurisdictions pursuant to registration with or authorization by the relevant securities regulatory authorities or an exemption therefrom.

You should rely only on the information contained in this document and the [REDACTED] to make your [REDACTED] decision. We have not authorized anyone to provide you with information that is different from that contained in this document. Any information or representation not included in this document must not be relied on by you as having been authorized by us, the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], any of our or their respective directors or advisors, or any other person or party involved in the [REDACTED]. Information contained on our website, located at www.hepalink.com, does not form part of this document.

Expected Timetable	i
Contents	iii
Summary	1
Definitions	16
Glossary of Technical Terms	29
Forward-looking Statements	40
Risk Factors	42
Waivers and Consents from Strict Compliance with the Hong Kong Listing Rules	106
Information about this Document and the [REDACTED]	112
Directors, Supervisors and Parties Involved in the [REDACTED]	117
Corporate Information	120
Industry Overview	122
Regulatory Environment	145
History, Development and Corporate Structure	211
Business	223
Relationship with the Controlling Shareholders	313
Connected Transaction	318
Directors, Supervisors and Senior Management	319
Share Capital	331
Substantial Shareholders	334
Financial Information	336
Future Plans and Use of [REDACTED]	392

CONTENTS

[REDACTED]	394
Structure of the [REDACTED]	404
How to Apply for the [REDACTED]	413
Appendix I—Accountants’ Report	I-1
Appendix II— [REDACTED]	II-1
Appendix III—Taxation and Foreign Exchange	III-1
Appendix IV—Summary of Principal Legal and Regulatory Provisions	IV-1
Appendix V—Summary of Articles of Association	V-1
Appendix VI—Statutory and General Information	VI-1
Appendix VII—Documents Delivered to the Registrar of Companies in Hong Kong and Available for Inspection	VII-1

SUMMARY

This summary aims to give you an overview of the information contained in this document. As it is a summary, it does not contain all the information that may be important to you and is qualified by its entirety by, and should be read in conjunction with, the full text of this document. You should read this document in its entirety before you decide to [REDACTED] in the [REDACTED].

There are risks associated with any [REDACTED] in the [REDACTED]. We set out some of the particular risks in [REDACTED] in the [REDACTED] in the section headed “Risk Factors” in this document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED].

OVERVIEW

Driven by our innovations across the industry value chain, our mission is to become a leading global pharmaceutical company targeting high-mortality diseases with significant unmet medical needs.

We are a leading China-based pharmaceutical company with global businesses in pharmaceutical, innovative biotech and CDMO sectors. We ranked the first by both export value and export volume of injectable finished doses in 2018 among China-based pharmaceutical companies, with major sales into the EU market.

Founded by a group of seasoned polysaccharide-chemists with scientific insights and profound understanding of immunology, we have built up a portfolio of both leading drugs in the anticoagulant and antithrombotic therapeutic areas and innovative drug candidates focusing on diseases with an immune system disorder axis, including oncology, autoimmune, metabolic and other areas. These diseases are among the largest unmet medical needs globally and represent the leading causes of morbidity and mortality.

Our leading drugs, Inhixa, Neoparin and Prolongin are three different brands of enoxaparin sodium injection which in total have been approved in 36 countries and sold in 15 countries. We have also supplied enoxaparin sodium injection to our customers in 13 other countries. We are the only China-based pharmaceutical company with cumulative sales of enoxaparin sodium injections in the EU exceeding 100 million doses. Enoxaparin is the “gold standard” anticoagulant and antithrombotic drug for various indications, such as venous thromboembolism (VTE) and pulmonary embolism (PE), with huge market demands and significant growth potential. According to Frost & Sullivan, the global usage of enoxaparin exceeded 763.2 million syringes/vials in 2018, and is expected to reach 1,444.3 million syringes/vials in 2024. Its usage in China was 41.9 million syringes/vials in 2018, which is expected to increase at a CAGR of 47.5% to 431.7 million syringes/vials in 2024.

We are the largest China-based and fourth largest global manufacturer and marketer of enoxaparin sodium injection, with a global market share of 5.4%, based on 2018 worldwide sales according to Frost & Sullivan. In China we are the second largest supplier in the enoxaparin injection market with a market share of 11.3%, second only to the originator firm, according to Frost & Sullivan. We implement localized and differentiated marketing strategies in the three major enoxaparin markets, the EU, China and the U.S. Our marketing strategies incorporate a combination of direct sales, distributor network and supply agreement partnerships. Our effective marketing efforts have resulted in rapid growth of our enoxaparin injection sales. In the EU, sales volume of our enoxaparin sodium injection grew by 164% to 47.8 million syringes/vials in 2018 from 18.1 million syringes/vials in 2017,

SUMMARY

and grew by 105% to 60.2 million syringes/vials in the nine months ended September 30, 2019 from 29.4 million syringes/vials in the nine months ended September 30, 2018. In China, sales volume of our enoxaparin sodium injection grew by 81% to 5.8 million syringes/vials in 2018 from 3.2 million syringes/vials in 2017, and grew by 28% to 4.1 million syringes/vials in the nine months ended September 30, 2019 from 3.2 million syringes/vials in the nine months ended September 30, 2018. We expect our Prolongin to be the first enoxaparin approved based on Quality Consistency Evaluation (QCE) in China, further solidifying our competitive advantage to capture the fast growth of enoxaparin in the China market.

We are the largest provider of heparin API with a global market share of 40.7%, larger than the second and third market players combined, based on 2018 global revenue according to Frost & Sullivan. We also have exclusive access to over 50% of the traceable heparin raw materials in China and over 40% in the U.S. in 2018, which ensures sufficient supply of high quality heparin raw materials. With 90.8% of our revenue generated from markets outside PRC in 2018, we are continuously expanding our strong global footprint to additional overseas markets, such as Southeast Asia, Middle East and South America.

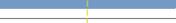
We have established a fully integrated business model covering the heparin industry value chain from supply of raw materials, manufacturing of APIs to the sales of enoxaparin finished doses. Based on such unique business model, we have developed our state-of-the-art supply chain management and world-class facilities with proprietary manufacturing technologies, rigorous quality control standards and large-scale manufacture capability. Through our integrated supply chain management, we have access to a significant portion of the traceable crude heparin globally, which ensures safety, reliability and stability for the supply of our heparin raw materials. Our manufacturing processes and facilities comply with the CGMP requirements in the EU, the U.S. and China, and follow rigorous manufacturing and quality control standards. We have accumulated extensive manufacturing expertise and know-how including our proprietary extraction, purification and virus and bacteria inactivation technologies, which we believe will further solidify our long-term competitiveness in the global enoxaparin market. We are one of the few China-based pharmaceutical companies which are able to produce commercialized biological drugs on a large scale. Our world-leading facilities enable us to efficiently manufacture biopharmaceutical products in large volumes while consistently ensure high quality. We believe our unique business model together with state-of-the-art supply chain management and world-class facilities serve as the cornerstones of our leading position in the global enoxaparin market.

Based on our profound understanding of immune response mechanisms, we have strategically constructed a robust portfolio of both exclusive development and commercial rights in Greater China for first-in-class clinical stage drug candidates and self-developed first-in-class drug candidate. These pipeline drugs are being developed to address the significant unmet medical demands in oncology, cardiovascular, inflammation and autoimmune areas. We place great importance in nurturing our partners and provide strong support to them in various areas including clinical development through our CDMO platform and equity investment. For example, Oregovomab, an immune-oncology antibody candidate being developed for first-line treatment of ovarian cancer in combination with chemotherapy, has shown a significant prolongation of median progression-free survival (median PFS 41.8 months vs. 12.2 months in patients treated by chemo-alone, $p=0.0027$) in a phase II trial. It also showed a significant improvement in overall survival (OS) ($p=0.0043$). We own 38.74% equity interest

SUMMARY

in the developer company of Oregovomab as well as its exclusive development and commercial rights in Greater China.

As of the Latest Practicable Date, we have exclusive development and commercial rights in Greater China for five drug candidates, among which two are in phase III global clinical trials and two are in phase II global trials. We are also developing a self-discovered proprietary oncology drug candidate currently at preclinical stage. We believe we are able to leverage our manufacturing, marketing and distribution capabilities of enoxaparin and industry experience to successfully develop and commercialize our innovative drug pipeline. The following chart summarizes the development status of our pipeline drugs as of the Latest Practicable Date:

Drug Candidate	Target / Mechanism of Action	Indications	Partner Company	Hepalink Shareholding	Development and Commercial Rights Owned by (Regions)	IND	Ph1	Ph2	Ph3	MRCT ¹ Participated by Hepalink
Oregovomab	Immunological stimulation after binding to CA125 antigen	Primary late-stage ovarian cancer	OncoQuest	38.74%	OncoVent ² (Greater China)					☆
		Recurrent late-stage ovarian cancer (Oregovomab+Hiltonol)								☆
		Recurrent late-stage ovarian cancer (Oregovomab+PD-1 Inhibitor nivolumab)								☆
		Recurrent late-stage ovarian cancer (Oregovomab+PARP Inhibitor niraparib)								☆
mAb-AR20.5	Immunological stimulation after binding to MUC1 antigen	Pancreatic cancer								☆
AR-301	α-toxin released by Gram-positive staphylococcus aureus	Staphylococcus aureus pneumonia	Aridis	9.86%	Shenzhen Arimab ³ (Greater China)					★
AR-101	Gram-negative pseudomonas aeruginosa O11 serum	Pseudomonas aeruginosa pneumonia								☆
RVX-208	BD2 domain of BET family member	Type 2 diabetes with coronary heart disease	Resverlogix	38.80%	Hepalink (Greater China)					
		Chronic Kidney Disease								
		New Indication								☆
H1710	Heparanase (HPA)	Pancreatic cancer	Hepalink (In-house)	100%	Hepalink (Global)					

 Hepalink initiated the trials
 The companies Hepalink invested initiated the clinical trials
 The company Hepalink invested plans to initiate the clinical trials for new indication based on the ph3 clinical data of Type 2 diabetes with coronary heart disease
 Hepalink has initiated the China portion MRCT¹
 Hepalink plans to initiate the respective China portion MRCTs¹ once entered pivotal phase

¹ MRCT refers to multi-regional clinical trials, which involves more than one independent center in enrolling and following clinical trial participants. It is widely conducted by many global pharmaceutical companies to reduce the time lag of launching innovative drugs in different regions.
² We directly hold 54.00% equity interest in OncoVent and are entitled to additional economic interest through our investee companies which hold 40.00% of its equity interest in total.
³ We directly hold 51.00% equity interest in Shenzhen Arimab and are entitled to additional economic interest through our investee company which holds the remaining 49.00% of its equity interest.

We operate a fast-growing CDMO business through two platforms, Cytovance, a CDMO platform enabling the development and manufacture of recombinant pharmaceutical products and critical non-viral vectors and intermediates for gene therapy, and SPL, a CDMO platform enabling the development and manufacture of pharmaceutical products from natural sources, to capture the growth opportunities in the global biopharmaceutical sector. Our CDMO business ranks among the top three China-owned biologics CDMO operators based on 2018 revenue according to Frost & Sullivan. Our CDMO revenue grew by 69.1% from RMB324.3 million in 2017 to RMB548.5 million in 2018 and grew by 41.2% from RMB356.5 million for the first nine months in 2018 to RMB503.2 million for the first nine months in 2019. Our customer base ranges from multinational pharmaceutical giants to midsize, small and virtual biotech companies. With continuous investments in capabilities, capacity and innovation, the dual CDMO platform addresses diverse customer needs while leveraging over 45 years of combined experience of Cytovance and SPL in the development and manufacture of large molecule pharmaceutical products for innovative biologically based therapeutics. In addition to supporting a multitude of customer drug pipelines, our own product pipeline is aptly enabled and enhanced by the dual CDMO platform strategy. By addressing the capacity shortage and technological challenge in the CMC process, our CDMO platform empowers our customers to develop drugs from

SUMMARY

concept to commercial manufacturing stage and ensures CDMO capacities for the development of our own pipeline drugs. Benefiting from the global growth in the biopharmaceutical sector, our CDMO business has contributed to our rapid growth and diversified our revenue source. As of the Latest Practicable Date, we had 39 on-going projects and a backlog of US\$62.1 million, which represents the total amount of contracted service fees pending milestone delivery. The following table shows the status of our on-going projects as of the Latest Practicable Date:

<u>Biologics development stage</u>	<u>Number of on-going projects</u>
Pre-IND	
—Drug discovery	2
—Preclinical development	10
Clinical trial	
—Early-phase (phase I & II) clinical development	20
—Late-phase (phase III) clinical development	4
Commercial manufacturing	<u>3</u>
Total	<u><u>39</u></u>

Our revenue increased by 69.7%, from RMB2,828.2 million in 2017 to RMB4,799.8 million in 2018, and decreased by 5.3%, from RMB3,306.7 million for the nine months ended September 30, 2018 to RMB3,132.2 million for the nine months ended September 30, 2019. Our net profit increased by 156.1% from RMB240.9 million in 2017 to RMB617.0 million in 2018, and increased by 59.6% from RMB469.4 million for the nine months ended September 30, 2018 to RMB749.0 million for the nine months ended September 30, 2019.

OUR STRENGTHS

We believe the following strengths have contributed to our success and differentiated us from our competitors:

- strategic focus on attractive therapeutic areas with both commercialized drugs of significant growth potential and first-in-class clinical stage pipeline drugs;
- “gold standard” anticoagulant and antithrombotic drug with outstanding safety profile;
- fully integrated business model to enhance profitability;
- well positioned to be the global leader in the enoxaparin market with effective marketing strategies in the major markets worldwide;
- a robust portfolio of first-in-class clinical stage drug candidates for the China market;
- a fast-growing CDMO business focusing on a vast spectrum of recombinant and naturally derived large molecule and gene therapy products; and
- seasoned polysaccharide-chemists founders and experienced management team with strategic insight and proven ability to lead our success.

SUMMARY

OUR STRATEGIES

To achieve our goal to become a global leading pharmaceutical company, we intend to pursue the following strategies:

- continue to expand our market share of enoxaparin to become the leader in the global heparin industry;
- maximize the commercial value of our first-in-class pipeline drugs in China by leveraging our local insight and vast experience in global operation;
- further expand and develop our CDMO business and build a world-leading CDMO platform;
- expand our business and strengthen our core competencies through acquisitions and strategic investments; and
- develop our Pingshan Industrial Park into a world-class manufacture base for pharmaceutical products.

OUR BUSINESS

The following table sets forth a breakdown of our revenue by our products and services during the Track Record Period.

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue
Sale of goods								
Finished dose pharmaceutical products	381,197	13.5	1,045,643	21.8	605,142	18.3	720,891	23.0
API	1,846,129	65.3	2,752,386	57.3	2,003,884	60.6	1,690,020	54.0
Others ⁽¹⁾	217,124	7.7	385,403	8.0	310,762	9.4	193,398	6.2
Subtotal	2,444,450	86.4	4,183,432	87.2	2,919,788	88.3	2,604,309	83.1
CDMO services	324,308	11.5	548,469	11.4	356,542	10.8	503,161	16.1
Others ⁽²⁾	59,467	2.1	67,906	1.4	30,418	0.9	24,701	0.8
Total	2,828,225	100.0	4,799,807	100.0	3,306,748	100.0	3,132,171	100.0

Notes:

(1) Other products mainly include pancreatin API.

(2) Other business mainly includes manufacture and marketing service, processing service, technical support service and other services.

SUMMARY

OUR PHARMACEUTICAL PRODUCTS

We manufacture and sell anticoagulant and antithrombotic finished dose pharmaceutical products, including enoxaparin sodium injection and heparin sodium injection and their relevant APIs. The following table sets forth selective information relating to our products as of the Latest Practicable Date:

<u>PRODUCT TYPE</u>	<u>PRODUCTS</u>	<u>APPROVAL FOR SALES IN CHINA</u>	<u>APPROVAL FOR SALES IN THE EU</u>	<u>APPROVAL FOR SALES IN THE U.S.</u>	<u>APPROVAL FOR SALES IN OTHER MAJOR COUNTRIES*</u>	<u>APPLICATION OF APPROVAL FOR SALES IN OTHER MAJOR COUNTRIES*</u>
FINISHED DOSE PHARMACEUTICAL PRODUCTS	Enoxaparin sodium injection	Prolongin— approved by the NMPA for five strengths in 2005	Inhixa— approved by the EMA in 2016 for five strengths and in 2018 for multi-dose vials and high strengths Neoparin— approved in Poland in 2016 for five strengths and in 2018 for multi-dose vials and high strengths	Filed an ANDA under the FDA’s review for enoxaparin sodium injection for seven strengths	Brazil, Colombia, Pakistan, Chile, Bolivia, Vietnam, Ecuador, Paraguay, Myanmar, Madagascar, Jordan, Sri Lanka, Philippines, Nicaragua, United Arab Emirates	Canada, Saudi Arabia, Singapore, Malaysia, Switzerland, Israel, Montenegro, El Salvador, Costa Rica, Panama, Uzbekistan, Honduras
	Heparin sodium injection	—	—	Four ANDAs approved for nine respective strengths by FDA	—	—
API PRODUCTS	Heparin sodium API	Approved by the NMPA in 2002	Approved by the EDQM in 2008 and renewed in 2013	Authorized supplier of heparin sodium API for the manufacture of several heparin products	Authorized supplier in Japan, Turkey, India, Italy, Brazil, South Korea, Mexico, Canada	Authorized supplier in Russia
	Enoxaparin sodium API	Approved by the NMPA in 2005	—	Filed DMF and under the FDA’s review as the manufacturer referenced in a customer’s ANDA for enoxaparin sodium injection Filed DMF and under the FDA’s review of our ANDA for enoxaparin sodium injection for seven strengths	Authorized supplier in Turkey, Brazil, Morocco, Uruguay, South Korea, Bangladesh, Paraguay, Colombia, India, Peru	Authorized supplier in Vietnam, Algeria, Russia, Saudi Arabia, Mexico, Thailand, Malaysia, Jordan

* Marketing approvals of our products in these countries are held by third parties.

OUR INNOVATIVE DRUG BUSINESS

We have obtained exclusive development and commercial rights in Greater China for five pipeline drugs, among which two are currently in phase III clinical trials and two are in phase II

SUMMARY

clinical trials. We are also developing a self-discovered proprietary oncology drug candidate currently at preclinical stage. The following are our late clinical stage drug candidates:

- **Oregovomab:** Oregovomab, an anti-idiotypic murine monoclonal antibody, is an immunoncology drug candidate being developed by OncoQuest, in which we hold approximately a 38.74% equity interest. It has completed a phase II clinical trial as a first-line treatment combined with chemotherapy in patients with advanced primary ovarian cancer. Phase II clinical trial have proven the safety and efficiency of Oregovomab in such combined treatment regime for advanced primary ovarian cancer patients. The combination of Oregovomab and chemotherapy leverages the effects of chemotherapy without additional toxicity. Phase II clinical results have shown a significant prolongation of median PFS, with a median PFS of 41.8 months, compared with 12.2 months in patients treated by chemotherapy alone ($p=0.0027$). It also showed a significant improvement in OS ($p=0.0043$). OncoQuest is currently in discussion with the FDA regarding pivotal phase III trial plan. We plan to participate in the phase III MRCT of Oregovomab for such combined treatment. Oregovomab has Orphan Drug Designation from the FDA and EMA. Oregovomab is also being evaluated in a phase II clinical trial in combination with an investigational stage immune booster (poly ICLC / Hiltonol) for patients with advanced recurrent ovarian cancer, a phase Ib/IIa clinical trial in combination with PD-1 inhibitor (nivolumab) as a novel combination immunotherapy treatment for patients with recurrent ovarian cancer, and a phase II clinical trial as a combined treatment with a PARP inhibitor (niraparib) for patients with recurrent ovarian cancer.
- **AR-301 (Salvecin):** AR-301 is a fully human monoclonal IgG1 antibody (mAb) that specifically targets *S. aureus* alpha-toxin. It is being developed by Aridis (NASDAQ: ARDS) in which we hold approximately 9.86% equity interest. It is currently being evaluated in a global phase III clinical study as an adjunctive therapy to standard of care antibiotics in patients diagnosed with ventilator associated pneumonia (VAP) caused by *S. aureus*. Results of a Phase I/II trial have shown that patients treated with AR-301 consistently demonstrated less time spent under mechanical ventilation and higher rates of *S. aureus* eradication as compared to those treated with antibiotics alone. AR-301 was granted Fast Track Designation by the FDA and Orphan Drug Designation by the EMA. We are conducting a phase III clinical trial in China as part of the global MRCT of AR-301.
- **RVX-208 (Apabetalone):** RVX-208 is an inhibitor of BET transcriptional regulators with selectivity for the second bromodomain. RVX-208 has completed phase III clinical trial (BETonMACE) in combination with standard of care to reduce major adverse cardiovascular events among high-risk cardiovascular disease patients with type 2 diabetes mellitus, recent acute coronary syndrome, and low levels of high-density lipoprotein (HDL). It is being developed by Resverlogix (TSE: RVX) in which we held a 38.80% equity interest as of the Latest Practicable Date.

Our CDMO Services

We operate our CDMO business through two platforms, Cytovance and SPL. The two platforms give our customers access to a truly unique assemblage of CMC services for supporting the vast spectrum recombinant and naturally derived large molecule pharmaceutical products and critical non-viral vectors and intermediates for gene therapy. Both platforms offer services across the drug development lifecycle from late discovery lead selection to clinical CGMP-compliant manufacture and commercial supply, including R&D services, manufacturing services, quality assurance, and program

SUMMARY

management. In addition to dealing with fee-for-service and commercial supply contracts, our CDMO platform also enables us to rapidly develop our own diverse innovative drug pipeline. Our CDMO business is led by Jesse McCool, Cytovance’s chief technology officer, who has the relevant experience in the CDMO industry.

Cytovance specializes in the development and manufacture of large molecule pharmaceutical products, with a 12-year track record of working with over 130 different recombinant products, such as monoclonal antibodies, antibody fragments, bispecific antibodies, cytokines, fusion proteins, vaccines and other recombinant proteins. Cytovance has expertise in both mammalian cell culture and microbial fermentation and possesses integrated single-use technologies for production and purification. In addition, Cytovance supports the rapidly growing gene therapy sector by supplying customers with high quality pDNA.

SPL provides services in the development and manufacturing of large molecule pharmaceutical products derived from natural sources such as pancreatic enzymes, heparin and heparin derivatives. SPL has extensive track record of working on naturally derived pharmaceutical products and has developed core competencies such as developing complex and scalable processes for the extraction, isolation and purification of naturally derived materials.

Our CDMO business has a global and diversified customer base, consisting of leading global pharmaceutical companies as well as small- to mid-sized biotechnology companies and start-ups. We enjoy a high level of customer loyalty and industry referrals. We provided services to 49, 53 and 43 customers in the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, respectively, including 5 out of the 10 largest pharmaceutical companies globally. During the Track Record Period, our CDMO services enabled approximately 20 regulatory filing milestones, including INDs, NDAs, BLAs or amendments. As a further testament to value created by the CDMO platform, several of our customers were acquired by large pharmaceutical companies such as Synageva BioPharma Corp. which was purchased by Alexion Pharmaceuticals, Inc. in 2015, Five Prime Therapeutics, Inc. which was purchased by Bristol-Myers Squibb Company in 2015, Selexys Pharmaceuticals Corporation which was purchased by Novartis International AG in 2016, ARMO Biosciences, Inc. which was purchased by Eli Lilly and Company in 2018 and Synthorx Inc which was purchased by Sanofi in 2019.

SALES AND MARKETING

We implement differentiated and localized sales and marketing strategies which are suitable for our various pharmaceutical products in different markets. We use a combination of academic marketing by our in-house sales and marketing team and collaboration with a network of independent distributors and third-party promoters to generate market demands for our products. We directly market our CDMO services to pharmaceutical and biotechnology companies by actively participating in trade conferences, trade shows and scientific conferences.

We have an experienced and specialized in-house sales and marketing team with international exposure. The head of our sales and marketing department has more than 25 years of experiences in the field, and our overseas sales and marketing team is led by Wen Shi, vice president of our business development, who has vast experience in the pharmaceutical industry. Our sales and marketing efforts are characterized by a strong emphasis on academic promotion, in order to promote and strengthen the awareness and recognition of our products and our brand among medical professionals. Besides our in-house academic marketing, we also rely on third-party promoters and distributors to market our

SUMMARY

products, especially enoxaparin sodium injection, by leveraging their local connection and marketing network. Each of our distributors and third-party promoters has its own sales force that focuses on marketing in its designated territory, which expands our marketing coverage and deepens our marketing penetration while allowing us to maintain operational flexibility and optimize our resource allocation. For more information, please see “Business—Sales and Marketing.”

CUSTOMERS

In 2017 and 2018 and the nine months ended September 30, 2019, the aggregate sales to our five largest customers were RMB1,707.8 million, RMB2,873.8 million and RMB1,549.3 million, representing 60.4%, 59.9%, and 49.5% of our revenue for the same periods, respectively. Sales to our largest customer for the same periods were RMB1,126.9 million, RMB1,804.7 million and RMB896.3 million, representing 39.8%, 37.6% and 28.6% of our revenue for the same periods, respectively. For more information, please see “Business—Customers.”

SUPPLIERS

In 2017, 2018 and the nine months ended September 30, 2019, purchases from our five largest suppliers in aggregate accounted for 32.8%, 22.5% and 20.2% of our total purchases (including value added tax), respectively, and purchases from our largest supplier accounted for 9.6%, 9.3% and 7.0% of our total purchases for the same periods (including value added tax), respectively. During the Track Record Period, our purchases mainly include raw materials, machines and equipment and services from third parties such as syringes, crude heparin and porcine small intestines. For more information, please see “Business—Raw Materials and Suppliers.”

PROPERTIES AND FACILITIES

As of the Latest Practicable Date, we owned seven properties in China, primarily in Shenzhen, Linyi and Chengdu, and three properties overseas, primarily in the U.S. We owned in total gross floor area of approximately 48,845 sq.m. for production facilities, including 4,458 sq.m. in Hepalink Nanshan facility, 6,848 sq.m. in Techdow Nanshan facility and 8,852 sq.m. in SPL. We also owned gross floor area of 4,207 sq.m. for R&D activities, 12,307 sq.m. for housing, 11,469 sq.m. for storage and 27,185 sq.m. for office space and other general administrative use. As of the Latest Practicable Date, we leased six properties from third parties, primarily in Shenzhen, China and Oklahoma, U.S. We leased gross floor area of 23,999 sq.m., including 6,129 sq.m. for production facilities, 2,261 sq.m. for R&D activities, 10,095 sq.m. for storage and 5,513 sq.m. for office space and other general administrative use.

SUMMARY OF CONSOLIDATED FINANCIAL INFORMATION

The following is a summary of our consolidated financial information as of and for the years ended December 31, 2017 and 2018, and as of and for the nine months ended September 30, 2018 and 2019, extracted from the Accountants’ Report set out in Appendix I to this document.

We acquired Topknow in May 2018. As the acquisition of Topknow constitutes a business combination under common control, the consolidated financial statements of the Company were prepared as if Topknow had been combined throughout the Track Record Period. For the details of our acquisitions and disposals, please refer to “History, Development and Corporate Structure” to this document.

SUMMARY

Summary of Consolidated Statement of Profit or Loss

The table below sets forth our consolidated statements of profit or loss with line items in absolute amounts and as percentages of our revenue for the periods indicated derived from our consolidated statements of profit or loss set out in the Accountants’ Report included in Appendix I to this document:

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue
Revenue	2,828,225	100.0	4,799,807	100.0	3,306,748	100.0	3,132,171	100.0
Cost of sales	(1,976,442)	(69.9)	(2,926,275)	(61.0)	(2,037,569)	(61.6)	(2,069,583)	(66.1)
Gross profit	851,783	30.1	1,873,532	39.0	1,269,179	38.4	1,062,588	33.9
Other income and gains . . .	209,701	7.4	308,150	6.4	317,777	9.6	740,238	23.6
Selling and distribution expenses	(192,201)	(6.8)	(37,710)	(7.7)	(240,505)	(7.3)	(292,569)	(9.3)
Administrative expenses . . .	(435,629)	(15.4)	(497,735)	(10.4)	(343,676)	(10.4)	(365,580)	(11.7)
Impairment losses on financial assets	(10,884)	(0.4)	(12,454)	(0.3)	(13,404)	(0.4)	(14,676)	(0.5)
Other expenses	(2,707)	(0.096)	(366)	(0.008)	(68)	(0.002)	(477)	(0.015)
Finance costs	(183,268)	(6.5)	(229,207)	(4.8)	(170,519)	(5.2)	(200,693)	(6.4)
Share of profits and losses of associates	(79,710)	(2.8)	(305,003)	(6.4)	(233,915)	(7.1)	(41,797)	(1.3)
Profit before tax	157,085	5.6	765,207	15.9	584,869	17.7	887,034	28.3
Income tax credit/(expense)	83,807	3.0	(148,244)	(3.1)	(115,424)	(3.5)	(138,061)	(4.4)
Profit for the year/period	240,892	8.5	616,963	12.9	469,445	14.2	748,973	23.9
Attributable to:								
Owners of the parent	238,904	8.4	640,194	13.3	479,041	14.5	763,586	24.4
Non-controlling interests . .	1,988	0.1	(23,231)	(0.5)	(9,596)	(0.3)	(14,613)	(0.5)
Earnings per share attributable to equity holders of the parent								
Basic								
—for profit for the year/period	<u>RMB0.19</u>		<u>RMB0.51</u>		<u>RMB0.38</u>		<u>RMB0.61</u>	
Diluted								
—for profit for the year/period	<u>RMB0.19</u>		<u>RMB0.51</u>		<u>RMB0.38</u>		<u>RMB0.61</u>	

SUMMARY

Summary of Consolidated Statements of Financial Position

	As at 31 December		As at
	2017	2018	30 September
	RMB'000	RMB'000	RMB'000
Total non-current assets	7,995,387	8,236,874	9,339,287
Total current assets	6,213,469	5,607,404	5,853,542
Total assets	14,208,856	13,844,278	15,192,829
Total current liabilities	3,946,852	4,690,579	5,717,213
Total non-current liabilities	2,208,235	2,877,366	2,269,544
Total liabilities	6,155,087	7,567,945	7,986,757
Total assets less current liabilities	10,262,004	9,153,699	9,475,616
Net assets	8,053,769	6,276,333	7,206,072
Share capital	1,247,202	1,247,202	1,247,202
Reserves	6,584,962	4,852,410	5,834,153
Non-controlling interests	221,605	176,721	124,717
Total equity	8,053,769	6,276,333	7,206,072

KEY FINANCIAL RATIOS

The following table sets forth certain of our key financial ratios for the periods or as of the dates indicated.

	Year ended December 31, / As of December 31,		Nine months ended September 30, / As of September 30,	
	2017	2018	2018	2019
Gross margin ⁽¹⁾	0.30	0.39	0.38	0.34
Current ratio ⁽²⁾	1.57	1.20	N/A	1.02
Gearing ratio ⁽³⁾	0.61	0.76	N/A	0.87
Leverage ratio ⁽⁴⁾	0.43	0.55	N/A	0.53

Notes:

- (1) Gross margin equals gross profit divided by revenue for the year/period.
- (2) Current ratio equals current assets divided by liabilities as of the end of the year/period.
- (3) Gearing ratio equals total financial indebtedness (including interest-bearing bank and other borrowings and lease liabilities) divided by total equity as of the end of the year/period.
- (4) Leverage ratio equals total liabilities divided by total assets as of the end of the year/period.

OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, our Controlling Shareholders, namely Leren Technology, Feilaishi, Jintiantu, Mr. Li and Ms. Li, held in aggregate approximately 73.96% of the issued Shares of our Company. Following completion of the [REDACTED], our Controlling Shareholders will hold in aggregate approximately [REDACTED]% of the issued Shares of our Company (assuming the [REDACTED] is not exercised). Our Controlling Shareholders and their respective close associates are not interested in any business, other than our Group, which competes or is likely to compete, directly or indirectly, with our Group’s business pursuant to Rule 8.10 of the Listing Rules. Please see “Relationship with the Controlling Shareholders” for more details.

SUMMARY

RECENT DEVELOPMENTS

Save as disclosed in the document, our Directors confirm, as of the date of this document, that there has been no material adverse change in our financial or trading position, indebtedness, mortgage, contingent liabilities, guarantees or prospects of our Group since September 30, 2019, the end of the period reported on in the Accountants’ Report set out in Appendix I to this document.

[REDACTED] EXPENSES

The total [REDACTED] expenses (including [REDACTED]) are estimated to be approximately HK\$[REDACTED], assuming the [REDACTED] is not exercised and based on an [REDACTED] of HK\$[REDACTED] (being the mid-point of our [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]). These [REDACTED] expenses mainly comprise legal and other professional fees paid and payable to the professional parties, commissions payable to the [REDACTED] and printing and other expenses for their services rendered in relation to the [REDACTED] and the [REDACTED].

As of September 30, 2019, the [REDACTED] expenses (excluding [REDACTED]) incurred were [REDACTED]. We estimate that additional [REDACTED] expenses of RMB[REDACTED] (including [REDACTED] of RMB[REDACTED] million, assuming the [REDACTED] is not exercised and based on the mid-point of our [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]) will be incurred by our Company, of which approximately RMB[REDACTED] is expected to be charged to our consolidated statement of profit or loss and approximately RMB[REDACTED] is expected to be charged against equity upon the [REDACTED].

[REDACTED]

FUTURE PLANS AND USE OF [REDACTED]

We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED]

SUMMARY

[REDACTED] is exercised and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED] in this documents. We intend to use the net [REDACTED] we will receive from the [REDACTED] for the following purposes, subject to changes in light of our evolving business needs and changing market conditions:

- approximately [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], for improving our capital structure and repaying existing debt, including our loan facility of RMB588 million at China Merchants Bank for the acquisition of Topknow, US\$30.7 million at Ping An Bank of China and US\$42.5 million at Bank of China due in June 2020, February 2021 and July 2020 respectively, and interest rate of 4.785%, 3 month libor+1.5% and 3 month libor+1.3%, respectively. For more details, see “Financial Information—Indebtedness”.
- approximately [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], for our expansion of the sales and marketing network and infrastructure in the EU and other global markets.
- approximately [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], for expanding our development and manufacturing capacity and broadening our product and services offering of Cytovance.
- approximately [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], for investment in innovative drugs.

The allocation of the [REDACTED] used for the above will be adjusted in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the indicative [REDACTED] range. If the [REDACTED] is fixed at HK\$[REDACTED] per H Share, being the high end of the indicative [REDACTED] range, our net [REDACTED] will be (i) increased by approximately HK\$[REDACTED], assuming the [REDACTED] is not exercised; and (ii) increased by approximately HK\$[REDACTED], assuming the [REDACTED] is exercised in full. In such circumstances, we currently intend to use such additional [REDACTED] to increase the net [REDACTED] applied for the same purposes as set out above on a pro rata basis. If the [REDACTED] is fixed at HK\$[REDACTED] per H Share, being the low end of the indicative [REDACTED] range, our net [REDACTED] will be (i) decreased by approximately HK\$[REDACTED], assuming the [REDACTED] is not exercised; and (ii) decreased by approximately HK\$[REDACTED] million, assuming the [REDACTED] is exercised in full. In such circumstances, we currently intend to reduce the net [REDACTED] applied for the same purposes as set out above on a pro rata basis.

If the [REDACTED] is exercised in full, the additional net [REDACTED] that we will receive will be approximately HK\$[REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range. The Company may be required to issue up to an aggregate of [REDACTED] additional Shares pursuant to the [REDACTED].

To the extent that the net [REDACTED] of the [REDACTED] re not immediately required for the above purposes or if we are unable to put into effect any part of our development plan as intended, we may hold such funds in short-term deposits so long as it is deemed to be in the best interests of the Company. In such event, we will comply with the appropriate disclosure requirements under the Listing Rules.

SUMMARY

DIVIDEND POLICY

We declared and paid dividends of RMB311.8 million, RMB56.1 million and RMB124.7 million to our then Shareholders for the years ended December 31, 2017 and 2018, and the nine months ended September 30, 2019, respectively. Except as disclosed in this section, we had not made any payment of, or set any payment schedule for, dividends as of the Latest Practicable Date.

After the [REDACTED], we may declare and pay dividends mainly by cash or by stock that we consider appropriate. At the end of each financial year, distribution of dividends will be formulated by our Board, and will be subject to shareholders’ approval. Decisions to declare or to pay any dividends in the future, will depend on, among other things, the company’s profitability, operation and development plans, external financing environment, costs of capital, the company’s cash flows and other factors that our Directors may consider relevant.

Pursuant to our Dividends Distribution Plan (2018-2020) approved by our Board, we, in principle, declare and distribute our dividends once a year. The accumulated cash dividends we pay in the past three years shall be no less than 30% of the average annual distributable profit in the respective period. We are also able to declare interim dividends subject to our profitability and capital requirements. When the Board considers that our stock price does not align with the total amount of our outstanding shares, or when the Boards considers appropriate, we can propose and carry out a stock dividend distribution plan, provided that the above requirements of cash dividend distribution are satisfied. For more information, please see “Financial Information—Dividend Policy.”

RISK FACTORS

There are certain risks involved in our operations and in connection with the [REDACTED], many of which are beyond our control. These risks can be categorized into (i) risks relating to our business and industry; (ii) risks relating to conducting business in the PRC; and (iii) risks relating to the [REDACTED]. We believe the most significant risk we face include:

- We are largely dependent on sales of our two products, enoxaparin sodium injection and heparin sodium API;
- Failure to attain market acceptance among the medical community would have a material adverse impact on our operations and profitability;
- The retail prices of certain of our products are subject to price control or downward adjustment by the government authorities or other pricing pressure;
- Sales of our enoxaparin sodium injection products depend on the reimbursement policies of the governmental authorities and health insurers. Failure to obtain or maintain adequate medical insurance coverage and reimbursement for our pharmaceutical products could limit our ability to market those products and decrease our ability to generate revenue;
- If our products are not manufactured to the necessary quality standards, it could harm our business and reputation, and our revenue and profitability could be adversely affected;
- If we suffer substantial disruption to any of our production sites or encounter problems in manufacturing our products, our business and results of operations could be adversely affected;
- Fluctuations in prices of our raw materials may have a material adverse effect on us if we are not able to transfer the cost increase to our customers;

SUMMARY

- If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed;
- Our CDMO business is dependent on our customers’ spending on and demand for outsourced biologics discovery, development and manufacturing. A reduction in spending or demand could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects;
- If we or parties on whom we rely fail to comply with the laws and regulations related to, or maintain the necessary licenses for, the development, production, sales and distribution of our products, our ability to conduct our business could be materially impaired; and
- Goodwill comprises a substantial portion of our total assets; if we determine our goodwill to be impaired, it would adversely affect our financial position.

A detailed discussion of all the risk factors involved are set out in the section headed “Risk Factors” in this document. You should read the whole section carefully before you decided to [REDACTED] in the [REDACTED].

DEFINITIONS

In this document, unless the context otherwise requires, the following terms and expressions have the meanings set forth below.

“A Shares”	domestic shares issued by the Company, with a nominal value of RMB1.00 each, which are subscribed for or credited as paid in Renminbi and are listed for trading on the Shenzhen Stock Exchange
“ANVISA”	National Health Surveillance Agency of Brazil
	[REDACTED]
“Aridis”	Aridis Pharmaceuticals, Inc., a public company incorporated in the U.S. on April 24, 2003, and listed on the NASDAQ (stock code: ARDS) in which we held approximately 9.86% equity interest as of the Latest Practicable Date
“Articles of Association” or “Articles”	the articles of association of our Company, as amended, which shall become effective on the [REDACTED] , a summary of which is set out in Appendix V to this document
“associate(s)”	has the meaning ascribed to it under the Listing Rules
“BfArm”	German Federal Institute for Drugs and Medical Devices
“Board” or “Board of Directors”	the Board of Directors of our Company
“Business Day” or “business day”	a day on which banks in Hong Kong are generally open to the public for normal banking business and which is not a Saturday, Sunday or public holiday in Hong Kong
“CAGR”	compound annual growth rate
“CCASS”	the Central Clearing and Settlement System established and operated by HKSCC
“CCASS Clearing Participant”	a person admitted to participate in CCASS as a direct clearing participant or general clearing participant
“CCASS Custodian Participant”	a person admitted to participate in CCASS as a custodian participant
“CCASS Investor Participant”	a person admitted to participate in CCASS as an investor participant who may be an individual, joint individuals or a corporation

DEFINITIONS

“CCASS Participant”	a CCASS Clearing Participant, a CCASS Custodian Participant or a CCASS Investor Participant
“CDE”	Center for Drug Evaluation of NMPA (國家食品藥品監督管理總局藥品審評中心)
“Chengdu Sunrace”	Chengdu Sunrace Co., Ltd. (成都深瑞畜產品有限公司), a company incorporated in the PRC with limited liability on November 19, 2009, in which we held 96.4% equity interest as of the Latest Practicable Date
“China” or “the PRC”	the People’s Republic of China, excluding, for the purpose of this document, Hong Kong, Macau and Taiwan
“CNIPA”	National Intellectual Property Administration, PRC (國家知識產權局)
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Companies (Winding up and Miscellaneous Provisions) Ordinance”	the Companies (Winding up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Company”, “our Company”, “Issuer” or “Hepalink”	Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司), whose predecessor was named as Shenzhen Hepalink Industrial Development Company Limited (深圳市海普瑞實業發展有限公司) and incorporated in the PRC in April 1998. Its name was changed to Shenzhen Hepalink Biotechnology Company Limited (深圳市海普瑞生物技術有限公司) in January 2001 and it was further renamed as Shenzhen Hepalink Pharmaceutical Company Limited (深圳市海普瑞藥業有限公司) in September 2002. In December 2007, upon approval by the Ministry of Commerce, it was restructured into a sino-foreign joint-stock company and was renamed as Shenzhen Hepalink Pharmaceutical Co., Ltd (深圳市海普瑞藥業股份有限公司) and then further renamed as Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司) in February 2017. The A Shares of the Company are listed on the Shenzhen Stock Exchange (stock code: 002399)
“Company Law” or “PRC Company Law”	Company Law of the People’s Republic of China (《中華人民共和國公司法》), as amended and adopted by the Standing Committee of the Tenth National People’s Congress on October 27, 2005 and effective on January 1,

DEFINITIONS

	2006, as amended, supplemented or otherwise modified from time to time, which was further amended on October 26, 2018
“Connected Person(s)”	has the meaning ascribed to it under the Listing Rules
“Controlling Shareholder(s)”	has the meaning ascribed to it under the Hong Kong Listing Rules and, unless the context requires otherwise, refers to Mr. Li, Ms. Li, Leren Technology, Feilaishi and Jintiantu
“CRO”	contract research organization
“CSO”	contract sales organizations
“CSRC”	the China Securities Regulatory Commission (中國證券監督管理委員會)
“Cytovance”	Cytovance Biologics, Inc., a limited liability company incorporated in the State of Delaware, United States on March 11, 2011, and a wholly-owned subsidiary of our Company
“Director(s)”	director(s) of our Company
“ECM”	a three-dimensional network of extracellular macromolecules that provide structural and biochemical support to surrounding cells
“EDQM”	European Directorate for the Quality of Medicines
“EIT Law”	Enterprise Income Tax Law of the People’s Republic of China (中華人民共和國企業所得稅法), as amended, supplemented or otherwise modified from time to time
“EMA”	European Medicines Agency
“EU”	the European Union
“Exchange Participant(s)”	a person: (a) who, in accordance with the Listing Rules, may trade on or through the Hong Kong Stock Exchange; and (b) whose name is entered in a list, register or roll kept by the Hong Kong Stock Exchange as a person who may trade on or through the Hong Kong Stock Exchange
“Feilaishi”	Urumqi Feilaishi Equity Investment Co., Ltd. (烏魯木齊飛來石股權投資有限公司), a company incorporated in the PRC with limited liability on August 1, 2007 and a Controlling Shareholder
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market, research and consulting company

DEFINITIONS

“Frost & Sullivan Report”	the report commissioned by the Company and independently prepared by Frost & Sullivan, a summary of which is set forth
“GDP”	gross domestic product [REDACTED]
“GPO”	group purchasing organization
“Greater China”	PRC, Hong Kong, Macau and Taiwan [REDACTED]
“Group”, “our Group”, “we”, “our” or “us”	our Company and its subsidiaries, and their respective predecessors and, in the context of “our products”, including products sold under our brand name and our products the marketing approvals of which are held by third parties
“GS Pharma”	GS Direct Pharma Limited, a company incorporated in Mauritius on July 17, 2007 and an Independent Third Party [REDACTED]
“H Shares”	overseas listed foreign shares in the share capital of our Company with a nominal value of RMB1.00 each, which are to be subscribed for and traded in HK dollars and are to be listed on the Hong Kong Stock Exchange
“Hepalink (Hong Kong)”	Hepalink (Hong Kong) Limited (海普瑞 (香港) 有限公司), a company incorporated in Hong Kong on November 23, 2010 and a wholly-owned subsidiary of our Company
“Hepalink USA”	Hepalink USA Inc., a limited liability company incorporated in the State of Delaware, United States, on October 25, 2013 and a wholly-owned subsidiary of our Company
“Hepatunn”	Chengdu Hepatunn Pharmaceutical Co., Ltd. (成都市海通藥業有限公司), a company incorporated in the PRC with limited liability on December 7, 2010, and an Independent Third Party as of the Latest Practicable Date
“HighTide”	HighTide Therapeutics, Inc., a company incorporated in the Cayman Islands with limited liability on February 28, 2018 and an associate company of our Company, in which we held approximately 47.02% equity interest as of the Latest Practicable Date

DEFINITIONS

[REDACTED]

“HK\$”, “HKD” or “HK dollars”	Hong Kong dollars, the lawful currency of Hong Kong
“HKSCC”	Hong Kong Securities Clearing Company Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
“HKSCC Nominees”	HKSCC Nominees Limited, a wholly owned subsidiary of HKSCC
“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong Listing Rules” or “Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (as amended from time to time)

[REDACTED]

“Hong Kong Stock Exchange”, “HKSE” or “Stock Exchange”	The Stock Exchange of Hong Kong Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
--	--

[REDACTED]

DEFINITIONS

[REDACTED]

“IAS”	International Accounting Standards
“IASB”	International Accounting Standards Board
“IFRS”	International Financial Reporting Standards, which include standards, amendments and interpretations promulgated by the International Accounting Standards Board and the International Accounting Standards and interpretation issued by the International Accounting Standards Committee
“Independent Third Party(ies)”	party(ies) not connected with us within the meaning of the Hong Kong Listing Rules to the knowledge of our Directors after all reasonable enquiries

[REDACTED]

“INVIMA”	Colombia National Food and Drug Surveillance Institute
----------	--

DEFINITIONS

[REDACTED]

“Jintiantu” Urumqi Jintiantu Equity Investment Partnership (Limited Partnership) (烏魯木齊金田土股權投資合夥企業 (有限合夥)), an investment fund established in the PRC on August 10, 2007 and a Controlling Shareholder

[REDACTED]

“Joint Sponsors” Goldman Sachs (Asia) L.L.C. and Morgan Stanley Asia Limited

“Latest Practicable Date” [January 14, 2020], being the latest practicable date for the purpose of ascertaining certain information contained in this document prior to its publication

“Leren Technology” Shenzhen Leren Technology Co., Ltd. (深圳市樂仁科技有限公司), a company incorporated in the PRC with limited liability on August 2, 2007 and a Controlling Shareholder

[REDACTED]

“Listing Committee” the Listing Committee of the Hong Kong Stock Exchange

[REDACTED]

“Macau” the Macau Special Administrative Region of the PRC

“Main Board” the stock market (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with the Growth Enterprise Market of the Hong Kong Stock Exchange

“Mandatory Provisions” the “Mandatory Provisions for Articles of Association of Companies to be Listed Overseas” (《到境外上市公司章程必備條款》), as amended, supplemented or otherwise

DEFINITIONS

modified from time to time, for inclusion in the articles of association of companies incorporated in the PRC to be listed overseas (including Hong Kong), which were promulgated by the former Securities Commission of the State Council (國務院證券委員會) and the former State Commission for Restructuring the Economic Systems (國家經濟體制改革委員會) on August 27, 1994

“Ministry of Finance” or “MOF”	Ministry of Finance of the PRC (中華人民共和國財政部)
“Ministry of Commerce” or “MOFCOM”	Ministry of Commerce of the PRC (中華人民共和國商務部)
“Mobren Transport”	Mobren Transport Inc., a limited liability company incorporated in the State of Iowa, United States on December 23, 1997 and a wholly-owned subsidiary of our Company
“Mr. Bu”	Mr. BU Haihua (步海華), an Executive Director, secretary to the Board and company secretary
“Mr. Li”	Mr. LI Li (李鋸), an Executive Director, Chairman of the Board and a Controlling Shareholder
“Ms. Li”	Ms. LI Tan (李坦), an Executive Director and a Controlling Shareholder
“Mr. Shan”	Mr. SHAN Yu (單宇), an Executive Director
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“NDRC Shenzhen Branch”	Development and Reform Commission of Shenzhen Municipality
“NMPA”	China National Medical Products Administration (國家藥品監督管理局), successor to the China Food and Drug Administration (國家食品藥品監督管理總局)
“NPC”	National People’s Congress of the PRC (中華人民共和國全國人民代表大會)
“OEM”	Original Equipment Manufacturer

[REDACTED]

DEFINITIONS

[REDACTED]

“Official Reply”	the “Official Reply of the State Council on Adjusting the Provisions Governing Matters Including the Application of the Notice Period for the Convening of Shareholders’ General Meetings by Companies Listed Overseas” (國務院關於調整適用在境外上市公司召開股東大會通知期限等事項規定的批復), promulgated by the State Council on October 17, 2019
“Office for Registration of Medicinal Products”	Medical Devices and Biocidal Products in Poland
“OncoQuest”	OncoQuest Inc., a private company incorporated in Alberta, Canada on March 25, 2015, in which we held 38.74% of the shares as of the Latest Practicable Date
“OncoVent”	Shenzhen OncoVent Biomedical Technology Co., Ltd. (深圳昂瑞生物醫藥技術有限公司), a company incorporated in the PRC with limited liability on July 26, 2016, and a subsidiary of our Company, in which we held 54% equity interest as of the Latest Practicable Date
	[REDACTED]
“Pingshan Industrial Park”	Pingshan Industrial Park, a production site located within the National Biopharmaceutical Industry Base in Pingshan, Shenzhen, China
“PRC GAAP”	the PRC Accounting Standards and Accounting Regulations for Business Enterprises (《中國企業會計準則》) promulgated by the MOF on February 15, 2006 and its supplementary regulations, as amended, supplemented or otherwise modified from time to time
“PRC government” or “State”	the central government of the PRC, including all governmental subdivisions (including provincial, municipal and other regional or local government entities) and instrumentalities

DEFINITIONS

“PRC legal advisor”	Tian Yuan Law Firm
	[REDACTED]
“province”	a province or, where the context requires, a provincial level autonomous region or municipality, under the direct supervision of the central government of the PRC
“QDII”	Qualified Domestic Institutional Investor (合格境內機構投資者)
“QFII”	Qualified Foreign Institutional Investor (合格境外機構投資者)
“QIB” or “Qualified Institutional Buyer”	a qualified institutional buyer within the meaning of Rule 144A
“Regulation S”	Regulation S under the U.S. Securities Act
“Resverlogix”	Resverlogix, a public company incorporated in Canada on August 17, 2000, and listed on the Toronto Stock Exchange (stock code: RVX) in which we held approximately 38.80% of the shares as of the Latest Practicable Date
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“Rule 144A”	Rule 144A under the U.S. Securities Act
“SAFE”	State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
“Sanofi”	Sanofi S.A., a multinational pharmaceutical company listed on Euronext Paris (stock code: SAN)
“Scientific Protein Laboratories”	Scientific Protein Laboratories LLC, a limited liability company incorporated in the State of Delaware, United States on January 22, 2004, and a wholly-owned subsidiary of our Company

DEFINITIONS

“Securities and Futures Ordinance” or “SFO”	Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Securities Law”	the Securities Law of the People’s Republic of China (中華人民共和國證券法), as amended, supplemented or otherwise modified from time to time
“SFC”	the Securities and Futures Commission of Hong Kong
“Shandong Ruisheng”	Shandong Ruisheng Biotechnology Co., Ltd. (山東瑞盛生物技術有限公司), a company incorporated in the PRC with limited liability on July 15, 2010, and a wholly-owned subsidiary of our Company
“Share(s)”	ordinary share(s) in the share capital of the Company with a nominal value of RMB1.00 each, comprising A Shares and H Shares
“Shareholder(s)”	holder(s) of the Share(s)
“Shenzhen Arimab”	Shenzhen Arimab Biomedical Co., Ltd., a company incorporated in the PRC with limited liability on July 2, 2018, in which we held 51% equity interest as of the Latest Practicable Date
“Shenzhen Stock Exchange”	the Shenzhen Stock Exchange (深圳證券交易所)
“Shenzhen Stock Exchange Listing Rules”	the Rule Governing the Listing of Shares on the Shenzhen Stock Exchange (《深圳證券交易所股票上市規則》), as amended from time to time
“Shenzhen Techdow”	Shenzhen Techdow Pharmaceutical Co., Ltd. (深圳市天道醫藥有限公司), a company incorporated in the PRC with limited liability on June 29, 2004, and a wholly-owned subsidiary of our Company
“Shuidi Shichuan”	Urumqi Shuidi Shichuan Equity Investment Partnership (Limited Partnership) (烏魯木齊水滴石穿股權投資合夥企業(有限合夥)), an investment fund established in the PRC on August 3, 2007 and a shareholder of our Company
“Special Regulations”	the Special Regulations of the State Council on the Overseas Offering and Listing of Shares by Joint Stock Limited Companies (《國務院關於股份有限公司境外募集股份及上市的特別規定》), promulgated by the State Council on August 4, 1994, as amended from time to time
“SPL”	SPL Acquisition Corp., a limited liability company incorporated in the State of Delaware, United States on

DEFINITIONS

	July 13, 2006, and a wholly-owned subsidiary of our Company
“sq.m”	square meter
	[REDACTED]
“State Council”	State Council of the People’s Republic of China (中華人民共和國國務院)
“subsidiary(ies)”	has the meaning ascribed to it in section 15 of the Companies Ordinance
“Supervisor(s)”	member(s) of our Board of Supervisors
“Supervisory Committee”	the supervisory committee of our Company
“Takeover Code”	the Hong Kong Code on Takeovers and Mergers
“Techdow (Hong Kong)”	Techdow (Hong Kong) Limited (天道醫藥(香港)有限公司), a company incorporated in Hong Kong on May 22, 2013 and a wholly-owned subsidiary of our Company
“TGA”	Therapeutic Goods Administration of Australia
“Topknow”	Shenzhen Topknow Industrial Development Co., Ltd. (深圳市多普樂實業發展有限公司), a company incorporated in the PRC with limited liability on June 7, 2000 and a wholly-owned subsidiary of our Company
“Track Record Period”	the two years ended December 31, 2018 and the nine months ended September 30, 2019
“U.K.” or “United Kingdom”	the United Kingdom of Great Britain and Northern Ireland, its territories, its possessions and all areas subject to its jurisdiction
	[REDACTED]
“U.S.” or “United States”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“U.S. FDA” or “FDA”	the U.S. Food & Drug Administration of the U.S. Department of Health and Human Services
“U.S. Securities Act”	the United States Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder

DEFINITIONS

“US\$” or “US dollar(s)” United States dollar(s), the lawful currency of the United States

“VAT” value-added tax

[REDACTED]

“Yingshi Information” Hunan Yingshi Information Technology Co., Ltd. (湖南應時信息科技有限公司), a company incorporated in the PRC with limited liability on July 5, 2007 and an Independent Third Party

“Yuanzheng Investment” Shenzhen Yuanzheng Investment Development Co., Ltd. (深圳市源政投資發展有限公司), a company incorporated in the PRC with limited liability on June 30, 1994, and an Independent Third Party

In this document, the terms “associate”, “close associate”, “connected person”, “core connected person”, “connected transaction”, “controlling shareholder” and “substantial shareholder” shall have the meanings given to such terms in the Hong Kong Listing Rules, unless the context otherwise requires.

Certain amounts and percentage figures included in this document have been subject to rounding. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them. Any discrepancies in any table or chart between the total shown and the sum of the amounts listed are due to rounding.

For ease of reference, the English names of the PRC established companies or entities, laws or regulations are translation and/or transliteration of their Chinese names and have been included in this document for identification purposes only. In the event of any inconsistency between the Chinese names and their English translations and/or transliterations, the Chinese versions shall prevail.

GLOSSARY OF TECHNICAL TERMS

“ACCF”	American College of Cardiology Foundation
“acute coronary syndrome”	a set of signs or symptoms due to decreased blood flow in the coronary arteries such that part of the heart muscle is unable to function properly or dies, which often causes severe chest pain or discomfort
“ADCC”	antibody-dependent cell-mediated cytotoxicity, a mechanism of cell-mediated immune defense whereby an effector cell of the immune system actively lyses a target cell
“AE”	adverse event, any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment
“AHA”	American Heart Association
“AMPK”	adenosine monophosphate-activated protein kinase, an enzyme that plays a role in cellular energy homeostasis, largely to activate glucose and fatty acid uptake and oxidation when cellular energy is low
“ANDA”	Abbreviated New Drug Application, an application made in the United States for approval of a generic equivalent to an existing approved drug
“ANDS”	Abbreviated New Drug Submission, a submission filed in Canada for approval of a generic drug
“antibiotics”	a substance, such as penicillin or streptomycin, produced by or derived from certain fungi, bacteria and other microorganisms, or produced by chemical processes that can destroy or inhibit the growth of other microorganisms; widely used in the prevention and treatment of infectious diseases
“anticoagulant”	a class of drugs that work to prevent the coagulation (clotting) of blood and can be used <i>in vivo</i> as a medication for thrombotic disorders or in medical equipment which contact blood, such as test tubes, blood transfusion bags, and renal dialysis equipment
“anti-idiotypic”	an antibody that binds to the antigen-combining site of another antibody either suppressing or enhancing the immune response
“antithrombin III”	a kind of glycoprotein produced by the liver that inactivates several enzymes of the coagulation system

GLOSSARY OF TECHNICAL TERMS

“API”	active pharmaceutical ingredients, any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.
“autoimmune diseases”	diseases that arise from an abnormal immune response of the body against substances and tissues normally present in the body
“Baxter Incident”	an incident in 2008, where contamination in the heparin sodium API used in the heparin sodium injections sold by Baxter caused serious acute hypersensitivity reactions in patient
“BBR”	berberine, a compound extracted from several plants including European barberry, goldenseal, goldthread and Oregon grape
“BDL”	bile duct ligation, a surgical method used to induce liver fibrosis
“BE test”	pharmacokinetic testing to determine the similarity of two drugs that share the same desired outcome for patients
“BET”	bromodomain and extraterminal domain, a family of proteins that recognize acetylated chromatin through their bromodomains and help in regulating gene expression
“biosimilar”	a follow-on version of innovator biopharmaceuticals which are separately developed after patents protecting the innovator biopharmaceuticals have expired and have similar quality, safety and efficacy as the innovator biopharmaceuticals
“BLA”	Biologics License Application, a request from FDA for permission to introduce, or deliver for introduction, a biologic product into interstate commerce
“BRD”	Bromodomains, a family of evolutionary conserved protein-interaction modules that play key functions in chromatin organization and regulation of gene transcription
“CA125”	Carbohydrate Antigen 125, a protein that in humans is encoded by the MUC16 gene

GLOSSARY OF TECHNICAL TERMS

“cardiovascular”	pertaining to the heart and blood vessels
“CCR5”	a protein on the surface of white blood cells that is involved in the immune system as it acts as a receptor for chemokines
“CD4”	Cluster of Differentiation 4, a glycoprotein found on the surface of immune cells such as T helper cells
“CD8”	Cluster of Differentiation 8, a transmembrane glycoprotein that serves as a co-receptor for the T-cell receptor
“CDMO”	Contract Development and Manufacturing Organization, a CMO that, in addition to comprehensive drug manufacturing services, also provide process development and other drug development services in connection with its manufacturing services
“Centralized Authorization Procedure”	a market authorization procedure in the EU, which allows the marketing-authorization holder to market the medicine and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorization
“CGMP”	Current Good Manufacturing Practice, regulations enforced by the FDA on pharmaceutical and biotech firms to ensure that the products produced meet specific requirements for identity, strength, quality and purity
“CHD”	Coronary heart disease, a type of disease that develops when the major blood vessels that supply your heart with blood, oxygen and nutrients (coronary arteries) become damaged or diseased
“chemoimmunotherapy”	chemotherapy combined with immunotherapy
“chemotherapy”	treatment of cancer with chemical substances, chosen based on the type or stage of cancer
“CHF”	a chronic progressive condition that affects the pumping power of heart muscles
“CHO cell”	Chinese hamster ovary cell, an epithelial cell line derived from the ovary of the Chinese hamster, often used in biological and medical research and commercially in the production of therapeutic proteins
“CHP”	Chinese Pharmacopoeia, an official compendium of drugs compiled by the Pharmacopoeia Commission of the Ministry of Health of the PRC

GLOSSARY OF TECHNICAL TERMS

“CKD”	Chronic Kidney Disease, a slowly progressive (months to years) decline in the kidneys’ ability to filter metabolic waste products from the blood
“Class C”	a level of cleanroom cleanliness based on a number of particles of a certain size per cubic metre
“CLD”	cell line development
“CMC”	Chemistry and Manufacturing Control, chemistry, manufacturing and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“CSO”	contract sales organization, a company that provide a series of services and solutions related to pharmaceutical marketing and sales activities under contracts with pharmaceutical or biotech companies
“CVD”	cardiovascular disease, a class of diseases that involve the heart or blood vessels
“depolymerisation”	the process of converting a polymer into a monomer or a mixture of monomers
“DM”	diabetes mellitus, a disorder in which blood sugar (glucose) levels are abnormally high because the body does not produce enough insulin to meet its needs
“DTRPAP”	a synthetic peptide derived from Human MUC1, which corresponds to amino acid
“DVT”	deep vein thrombosis, which occurs when a blood clot forms in one or more of the deep veins in human body, usually in legs
“E. coli”	a kind of bacteria normally live in the intestines of healthy people and animals
“endotoxin”	a type of pyrogen and a component of the exterior cell wall of Gram-negative bacteria
“enoxaparin” or “enoxaparin sodium”	an anticoagulant medication used to treat and prevent DVT and pulmonary embolism including during pregnancy and following certain types of surgery
“enzymolysis”	decomposition catalyzed by an enzyme

GLOSSARY OF TECHNICAL TERMS

“EP standards”	European Pharmacopoeia standards, a catalog which lists all the reference standards officially valid for uses prescribed in the European Pharmacopoeia monographs, promulgated by EDQM
“EudraVigilance”	a system for managing and analyzing information on suspected adverse reactions to medicines which have been authorized or being studied in clinical trials in the EEA, which is operated by EMA
“factor IIa”	an enzyme formed in shed blood that converts fibrinogen into fibrin by hydrolyzing peptides of L-arginine
“factor Xa”	activated factor X, an enzyme of the coagulation cascade which is synthesized in the liver and requires vitamin K for its synthesis
“Fast Track Designation”	a designation by FDA of an investigational drug for expedited review to facilitate development of drugs which treat a serious or life-threatening condition and fill an unmet medical need
“Fc γ ”	a tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system. This property allows antibodies to activate the immune system
“fibrin”	a fibrous, non-globular protein involved in the clotting of blood, which is formed by the action of the protease thrombin on fibrinogen which causes it to polymerize
“fibrosis”	the formation of excess fibrous connective tissue in an organ or tissue in a reparative or reactive process
“generic drug”	a drug that is no longer under patent protection, which may be produced by any manufacturer which follows good manufacturing protocols
“glycoprotein”	proteins having covalently bound carbohydrate, which play a part in important cellular functions like cell-cell recognition, immune functions, and pathogen identification. Glycoproteins have a close association with serious human diseases like cancer, rheumatoid arthritis, and immunodeficiency diseases
“glycosaminoglycan”	a family of high sulfated, complex, polydisperse linear polysaccharides that display a variety of important biological roles
“Grade A”	a grade of cleanroom, which represents the local zone for high risk operations
“Grade B”	a grade of cleanroom, which represents the background environment for Grade A zone in case of aseptic preparation and filling

GLOSSARY OF TECHNICAL TERMS

“Grade C”	a grade of cleanroom, which represents clean area for carrying out less critical stages in the manufacture of sterile products
“GxP”	general abbreviation for the “good practice” quality guidelines and regulations. The “x” stands for various specific fields, including “M” for “Manufacturing,” “C” for “Clinical,” “D” for “Distribution,” “E” for “Engineering,” and “L” for “Laboratory,” etc.
“HAMA”	human anti-mouse antibodies, an antibody found in humans which reacts to immunoglobins found in mice
“HAP”	hospital-acquired pneumonia, a lung infection that develops in people who have been hospitalized, typically after about 2 days or more of hospitalization
“heparanase”	an enzyme that acts both at the cell-surface and within the extracellular matrix to degrade polymeric heparan sulfate molecules into shorter chain length
“heparin”	an anticoagulant used to decrease the clotting ability of the blood and help prevent harmful clots from forming in blood vessels, including heparin sodium and heparin calcium
“heparin sodium”	the sodium salt form of heparin
“HDL”	high-density lipoprotein, one of the major groups of lipoproteins, which are complex particles composed of multiple proteins which transport all fat molecules (lipids) around the body within the water outside cells
“hypercholesterolemia”	the presence of high levels of cholesterol in the blood
“IC”	immune complex, a molecule formed from the integral binding of an antibody to a soluble antigen
“ICH”	International Council for harmonization of Technical Requirements for Pharmaceuticals for Human Use
“IFN- γ ”	a dimerized soluble cytokine that is the only member of the type II class of interferons
“IgG1”	one type of the most common class of antibody, Immunoglobulin G, which includes IgG1, IgG2, IgG3 and IgG4
“immunology”	a branch of biology that covers the study of immune systems in all organisms
“immunotherapy”	the treatment of disease by activating or suppressing the immune system

GLOSSARY OF TECHNICAL TERMS

“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“IRB”	a committee that applies research ethics by reviewing the methods proposed for research to ensure that they are ethical
“K-M analysis”	Kaplan-Meier analysis, a non-parametric statistic used to estimate the survival function from lifetime data
“LDL-c”	low-density lipoprotein cholesterol, the amount of cholesterol which is estimated to be contained with low-density lipoprotein particles, using a formula on average
“LMWH”	low molecular weight heparin, a class of antithrombotic agents with relatively more anti-Xa activity, greater bioavailability at low doses, longer half-life, and more predictable anticoagulant response when administered in fixed doses, compared with unfractionated heparin
“LPS”	lipopolysaccharide is an integral component of the <i>P. aeruginosa</i> cell envelope
“lymphocyte”	white blood cells that are also one of the body’s main types of immune cells
“mAb”	an antibody generated by identical immune cells that are all clones of the same parent cell
“MACE”	major adverse cardiac events, a composite endpoint frequently used in cardiovascular research, comparable to the composite endpoint all-cause mortality
“mega”	a unit prefix in metric system of units denoting a factor of one million
“methotrexate”	a chemotherapy agent and immune system suppressant used to treat cancer, autoimmune diseases, ectopic pregnancy, and for medical abortions
“MRCT”	multi-regional clinical trial
“meropenem”	a broad-spectrum antibiotic used to treat a variety of bacterial infections
“MRSA”	methicillin-resistant <i>S. aureus</i> , a type of staph bacteria that has become resistant to the effects of many common antibiotics

GLOSSARY OF TECHNICAL TERMS

“MSC”	mesenchymal stem cells, multipotent stromal cells that can differentiate into a variety of cell types
“MSSA”	methicillin-sensitive <i>S. aureus</i> , a type of staph bacteria that is not resistant to certain antibiotics
“MUC1”	a membrane-associated glycoprotein detected in most epithelial tissues and is highly expressed in the pancreas and breast
“NASH”	non-alcoholic steatohepatitis, the liver inflammation and damage caused by a buildup of fat in the liver
“NDA”	New Drug Application, the vehicle in the United States through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing
“NFLD” or “NAFLD”	non-alcoholic fatty liver disease, a very common disorder and refers to a group of conditions where there is accumulation of excess fat in the liver of people who drink little or no alcohol
“NRDL”	China’s National Reimbursement Drug List
“oncology”	the study and treatment of tumors
“orphan drug”	a pharmaceutical agent that has been developed specifically to treat a rare medical condition
“Orphan Drug Designation”	a designation to medicines developed for rare condition
“OS”	overall survival, the length of time from either the date of diagnosis or the start of treatment for a disease, such as cancer, that patients diagnosed with the disease are still alive.
“p”	P-value, the probability of obtaining test results at least as extreme as the results actually observed during the statistical hypothesis test, assuming that the null hypothesis is correct
“P. aeruginosa”	opportunistic pathogens that frequently cause hospital-acquired infections, particularly in ventilator patients, burn patients, and patients with chronic debility
“PAI”	FDA pre-approval inspection, which is performed to contribute to FDA’s assurance that a manufacturing establishment named in a drug application is capable of manufacturing a drug, and that submitted data are accurate and complete

GLOSSARY OF TECHNICAL TERMS

“pancreatin”	a combination of digestive enzymes (proteins), which are normally produced by the pancreas and are important for digesting fats, proteins, and sugars
“PARP”	poly (ADP-ribose) polymerase, a family of proteins involved in numerous cellular processes, mostly involving DNA replication and transcriptional regulation, which plays an essential role in cell survival in response to DNA damage
“PCI”	percutaneous coronary intervention, a non-surgical procedure used to treat narrowing of the coronary arteries of the heart
“PCSK9”	proprotein convertase subtilisin/kexin type 9, an enzyme encoded by the PCSK9 gene in humans on chromosome 1
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages. The normal function of PD-1 is to turn off the T cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body. When PD-1 on the surface of a T cell attaches to certain proteins on the surface of a normal cell or a cancer cell, the T cell turns off its ability to kill the cell
“pDNA”	a small, circular, double-stranded DNA molecule that is distinct from a cell’s chromosomal DNA
“PFS”	progression-free survival, the length of time during and after the treatment of a disease that a patient lives with the disease but it does not get worse
“pharmacovigilance”	the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem
“PK”	pharmacokinetics, a branch of pharmacology dedicated to determine the fate of substances administered to a living organism
“poly (I:C)”	polyinosinic:polycytidylic acid, an immunostimulant used in the form of its sodium salt to simulate viral infections
“polymerization”	a process of reacting monomer molecules together in a chemical reaction to form polymer chains or three-dimensional networks
“polysaccharide”	long chains of carbohydrate molecules

GLOSSARY OF TECHNICAL TERMS

“PSC”	primary sclerosing cholangitis, inflammation with progressive scarring and narrowing of the bile ducts in and outside the liver
“pulmonary embolism”	the blocking of an artery of the lung by a collection of solid material brought through the bloodstream, usually a blood clot or rarely other material
“puromycin”	an antibiotic protein synthesis inhibitor which causes premature chain termination during translation
“QCE”	quality consistency evaluation, a process conducted by NMPA to evaluate quality consistency of composition and clinical efficacy between the generic drug and originator drug
“RCT”	reverse cholesterol transport, a multi-step process resulting in the net movement of cholesterol from peripheral tissues back to the liver first via entering the lymphatic system, then the bloodstream
“RegIII α ”	regenerating islet-derived protein 3 alpha, also known as PAP, a protein encoded by the REG3A gene
“SAE”	serious adverse event, any untoward medical occurrence in a patient during clinical trials that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect
“S. aureus alpha-toxin”	the major cytotoxic agent released by bacterium <i>S. aureus</i> and first identified member of the pore forming beta-barrel toxin family
“SOC”	standard of care, treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
“STEMI”	ST-elevation myocardial infarction, a type of heart attack during which one of the heart’s major arteries is blocked
“T cell”	a type of lymphocyte which develops in the thymus gland and plays a central role in the immune response
“TEAE”	treatment emergent adverse event, undesirable events not present prior to medical treatment, or an already present event that worsens either in intensity or frequency following the treatment

GLOSSARY OF TECHNICAL TERMS

"thrombosis"	formation of a blood clot inside a blood vessel, obstructing the flow of blood through the circulatory system
"TTCP"	time to clinical progression, the length of time from the date of diagnosis or the start of treatment for a disease until the disease starts to get worse or spread to other parts of the body.
"UDCA"	ursodexychoic acid, one of the secondary bile acids, which are metabolic byproducts of intestinal bacteria
"USP"	United States Pharmacopeia, a pharmacopeia for the United States published annually by the United States Pharmacopeial Convention
"VAP"	ventilator associated pneumonia, a type of lung infection that occurs in people who are on mechanical ventilation breathing machines in hospitals
"VTE"	venous thromboembolism, a blood clot that starts in a vein

FORWARD-LOOKING STATEMENTS

We have included in this document forward-looking statements. Statements that are not historical facts, including statements about our intentions, beliefs, expectations or predictions for the future, are forward-looking statements.

This document contains forward-looking statements and information relating to us and our subsidiaries that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this document, the words "aim," "anticipate," "believe," "could," "aim," "expect," "going forward," "intend," "may," "ought to," "plan," "project," "seek," "should," "will," "would," "vision," "aspire," "target," "schedules," and the negative of these words and other similar expressions, as they relate to us or our management, are intended to identify forward-looking statements. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the risk factors as described in this document, some of which are beyond our control and may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks and uncertainties facing us which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- our operations and business prospects;
- our ability to maintain relationship with, and the actions and developments affecting, our major customers and suppliers;
- future developments, trends and conditions in the industries and markets in which we operate;
- general economic, political and business conditions in the markets in which we operate;
- changes to the regulatory environment in the industries and markets in which we operate;
- our ability to maintain the market leading positions;
- our product candidates under development or planning;
- the actions and developments of our competitors;
- our ability to effectively contain costs and offer competitive prices;
- the ability of third parties to perform in accordance with contractual terms and specifications;
- our ability to retain senior management and key personnel, and recruit qualified staff;
- our business strategies and plans to achieve these strategies, including our expansion plans;
- our ability to defend our intellectual rights and protect confidentiality;
- change or volatility in interest rates, foreign exchange rates, equity prices, trading volumes, commodity prices and overall market trends;
- capital market developments; and
- our dividend policy.

FORWARD-LOOKING STATEMENTS

By their nature, certain disclosures relating to these and other risks are only estimates and should one or more of these uncertainties or risks, among others, materialize, actual results may vary materially from those estimated, anticipated or projected, as well as from historical results. Specifically but without limitation, sales could decrease, costs could increase, capital costs could increase, capital investment could be delayed and anticipated improvements in performance might not be fully realized.

Subject to the requirements of applicable laws, rules and regulations, we do not have any and undertake no obligation to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events or otherwise. As a result of these and other risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect or at all. Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to the cautionary statements in this section.

In this document, statements of or references to our intentions or those of the Directors are made as of the date of this document. Any such information may change in light of future developments.

All forward-looking statements contained in this document are qualified by reference to the cautionary statements set out in this section.

RISK FACTORS

You should carefully consider all of the information in this document, including the following risk factors before making any [REDACTED] decision in relation to the [REDACTED]. Our business, financial condition or results of operations could be materially and adversely affected by any of these risks. The market price of the [REDACTED] could fall significantly due to any of these risks, and you may lose all or part of your [REDACTED].

We believe that there are certain risks involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to our business and industry; (ii) risks relating to conducting business in the PRC; and (iii) risks relating to the [REDACTED].

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

Risks Relating to Sales and Distribution of Our Products

We are largely dependent on sales of our two products, enoxaparin sodium injection and heparin sodium API.

We are largely dependent on sales of two products: enoxaparin sodium injection and heparin sodium API. If we are unable to maintain the sales volumes, pricing levels or profit margins of these two core products, our revenue and profitability could be adversely affected. Sales of enoxaparin sodium injection accounted for 11.0%, 20.5% and 23.0% of our total revenue in 2017, 2018 and the nine months ended September 30, 2019, respectively. Sales of heparin sodium API accounted for 59.2%, 52.6% and 46.6% of our total revenue in 2017, 2018 and the nine months ended September 30, 2019, respectively. We expect that sales of enoxaparin sodium injection and heparin sodium API will continue to comprise a substantial portion of our total revenue in the near future. Any reduction in sales or profit margins of enoxaparin sodium injection and heparin sodium API will thus have a direct negative impact on our business, financial condition and results of operations.

Many of the factors discussed in this section below could adversely affect sales of enoxaparin sodium injection and heparin sodium API, including but not limited to, pricing pressured caused by government policies, market acceptance among the medical community, inclusion or removal from the respective medical insurance coverage in the countries we sell these products, disruptions in manufacturing or distribution, issues with product quality or side effects and disputes over intellectual property. Moreover, despite our efforts, we may be unable to develop or acquire new products that would diversify our business and reduce our dependence on enoxaparin sodium injection and heparin sodium API, or to do so in a competitive manner.

Failure to attain market acceptance among the medical community would have a material adverse impact on our operations and profitability.

The commercial success of our products depends upon the degree of market acceptance they achieve among the medical community, particularly physicians and hospitals. Physicians may not prescribe or recommend our products to patients, and procurement departments of hospitals may not purchase our products. The acceptance of any of our products among the medical community will depend upon several factors, including:

- the safety and effectiveness of the product;
- the effectiveness of our efforts to market our products to hospitals and physicians;

RISK FACTORS

- the product’s cost effectiveness;
- the prevalence and severity of side effects; and
- the product’s perceived advantages and disadvantages relative to competing products or treatments.

If our products fail to attain market acceptance among the medical community, our operations and profitability would be adversely affected.

The retail prices of certain of our products are subject to price control or downward adjustment by the government authorities or other pricing pressure.

Pharmaceutical products covered by governmental insurance are generally subject to price control by relevant regulatory authorities in major EU countries. The regulatory authorities in certain EU countries typically sets a list price upon negotiation with each company, as the ceiling price of retail price and the allowable reimbursement under national medical insurance. Even in countries without such list price, the government may fix a reimbursement price that limits the reimbursable amount under the national medical insurance. Specifically, our enoxaparin sodium injection has been covered by the national medical insurance in eight countries. Upon launching of our enoxaparin sodium injection product in most major countries, we enter into price negotiation with the respective governmental authority. A lengthy price negotiation process may delay the entry of our pharmaceutical products into the EU market and increase our costs, which may adversely affect our revenue and profitability. Moreover, in certain EU countries, the list price or the reimbursement price of biosimilar drugs is required to be lower than the respective originator drugs, including enoxaparin sodium injection. There may be other pricing downward measures or adjustments implemented by certain authorities. Such control and downward adjustments on the maximum retail price or reimbursement amount of our enoxaparin sodium injection in the EU could increase pricing pressure and negatively impact our revenue and profitability.

In China, pursuant to a notice issued by seven PRC state agencies, including the NDRC and the NMPA, government price controls on pharmaceutical products were lifted effective as of June 1, 2015, except for narcotic drugs and psychotropic drugs of category I. As a result, prices of pharmaceutical products are currently determined mainly by market competition through the centralized tender process at the provincial level, without being subject to price ceilings set by the NDRC. However, there is no assurance that such market-based pricing mechanism will result in higher product pricing compared to government-controlled pricing, as competition from other manufacturers, particularly those offering the same products at more competitive prices may force us to lower price of our enoxaparin sodium injection and may also impact the prices of our drug candidates once commercialized in China. We believe that this policy change provides more incentives for manufacturers to develop new products, and encourage more multinational pharmaceutical companies to enter the PRC market. As a result, we may face greater competition from other pharmaceutical companies. Any changes in price control policies, which we may not be able to predict or control, could create uncertainties affecting our product prices, revenue and profitability.

PRC government authorities have implemented policies that aim to further increase the affordability of pharmaceutical products. In an opinion issued in February 2015, the General Office of the State Council encouraged public hospitals to consolidate their demands and to play a more active role in the procurement of pharmaceutical products. The collective procurement of public hospitals will be improved through the centralized purchase of drugs. All drugs used by public hospitals (with the exception of traditional Chinese medicine decoction pieces) should be procured through a provincial

RISK FACTORS

centralized drug purchase platform. The provincial procurement agency should formulate the procurement plans, collect budgets submitted by hospitals and reasonably compile a drug procurement catalog of the hospitals with its own administration region. Such agency is also responsible for classifying the drugs to be procured through bids, negotiations, direct purchases by hospitals or to be manufactured by appointed manufacturers. This policy is intended to reduce the retail prices of pharmaceutical products by cutting the intermediaries between hospitals and manufacturers. Consolidated procurement and direct settlement between hospitals and manufacturers may increase the bargaining power of hospitals and increase the pricing pressure on our enoxaparin sodium injection products. If PRC government authorities implement other reform on the current tender process for pharmaceutical products or revise other policies affecting pharmaceutical prices, which result in downward adjustments to the retail prices of our enoxaparin sodium injection products, our wholesale prices, our revenue and profitability could be adversely affected.

In addition, it is typical that the prices of pharmaceutical products will decline over the life of the product as a result of, among other things, increased competition from substitute products, the tender process by the hospitals or the government authorities, pricing policies of the relevant government authorities, or voluntary price adjustments by pharmaceutical companies. Any downward adjustments or pricing pressure of our enoxaparin sodium injection products could have a material and adversely effect on our business, financial conditions and results of operations.

Sales of our pharmaceutical products depend on the reimbursement policies of the governmental authorities and health insurers. Failure to obtain or maintain adequate medical insurance coverage and reimbursement for our pharmaceutical products could limit our ability to market those products and decrease our ability to generate revenue.

Sale of our pharmaceutical products depend, in part, on the extent to which third-party payors, including government health programs, commercial health insurers, and managed care organizations, provide coverage and establish adequate reimbursement levels for such products. Furthermore, no uniform policy of coverage and reimbursement for products exists among governmental medical insurance or among private payors and the coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often time consuming and costly that may require us to provide substantial scientific and clinical support for the use of our pharmaceutical products to each payor government or private payor, separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than the EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budget constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Our enoxaparin sodium product has been covered by the national medical insurance of eight EU countries it has been sold to. In the U.S., government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Government authorities

RISK FACTORS

currently impose mandatory discounts for certain patient groups, such as Medicare, Medicaid and Veterans Affairs hospitals, and may seek to increase such discounts at any time. Under the NRDL in the PRC, patients are entitled to full or partial reimbursement of costs for pharmaceutical products listed in the National Medical Insurance Catalog or provincial medical insurance catalogs. A pharmaceutical product’s inclusion in or exclusion from the NRDL or provincial medical insurance catalogs will significantly affect the demand for such product in the PRC. Our enoxaparin sodium injection is currently included in the NRDL and certain provincial medical insurance catalogs.

Private payors are increasingly requesting the drug companies to provide them with predetermined discounts from list prices and are likely to challenge the prices charged for medical products. Therefore, physicians may need to show that patients have superior treatment outcomes with our drug candidates compared to standard of care drugs in order to get reimbursement. Moreover, increasing efforts by governmental and private payors in the EU, the U.S. and China to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our drug candidates. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, there is no assurance that reimbursement will be available for any of our drug candidates when commercialized and, if reimbursement is available, the level of reimbursement will be sufficient. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidates for which we have obtained the marketing approval.

The inclusion of pharmaceutical products by the relevant authorities into a medical insurance catalog is based on a variety of factors, including efficacy, safety and price, which may be outside of our control. Moreover, the relevant government authorities or private payor, such as private health insurers, may also, from time to time, change the scope of reimbursement for the products that are listed in any medical insurance catalog. There can be no assurance that any of our enoxaparin sodium injection products currently listed in these medical insurance catalogs will remain listed, or that changes in the scope of reimbursement will not negatively affect our product sales. If any of our enoxaparin sodium injection products or their indications are removed from any medical insurance catalog, or if the scope of reimbursement is reduced, demand for our enoxaparin sodium injection products may decrease and our revenues and profitability could be adversely affected.

If we are unable to win bids to sell our enoxaparin sodium injection products to hospitals in EU and China through the bidding process, we will lose market share and our revenue and profitability could be adversely affected.

The majority of our enoxaparin sodium injection products we sell to our third party distributors are then sold to hospitals and other medical institutions in EU and China. In EU, we generally collaborate with third party distributors for our sales of enoxaparin sodium injection. Our enoxaparin sodium injection products are sold to the third party distributors at a fixed price according to our negotiation with each third party distributor, on the basis of the bidding price at which the third party distributor resells the products to hospitals and clinics. In China, each public medical institution has historically procured drugs through a provincial centralized drug purchase platform, and made substantially all of its purchases of pharmaceutical products through a centralized tender process. We

RISK FACTORS

submit bids in a centralized tender process to supply our enoxaparin sodium injection products to these institutions at specified prices. Our bids are generally considered on the basis of price relative to substitute products and their clinical effectiveness, as well as the quality of our enoxaparin sodium injection products and services, among other things. If we are successful in winning bids in a centralized tender process, the relevant products will be sold to the public hospitals and other medical institutions at the bid prices, which is the primary determinant of the prices at which we sell our enoxaparin sodium injection products to our distributors. The centralized tender process can create pricing pressure among substitute products or products that are perceived to be substitute products. In November 2018, the national pilot program for drug centralized procurement with minimum procurement quantities was launched in 11 cities in China, which was later expanded to other areas in September 2019. The bid-winning drugs under the regime will be procured by the public hospitals in the covered regions with priority, which will significantly boost their market shares and revenues. The centralized procurement regime requires the generic drugs to pass the QCE in order to participate in the centralized tendering. If we fail to acquire the QCE status, or we are unable to win in the bidding process, our market share, revenues, and profitability may be adversely affected. For details, please refer to “Business—Pricing,” and “Regulatory Environment—The Drug Centralized Procurement in ‘4+7 Cities’ and Wider Areas.”

Our sales volumes and profitability depend on our ability to successfully differentiate our enoxaparin sodium injection products and price our bids in a manner that enables us to succeed in the bidding process at profitable levels. If we are unable to do so, we will lose the revenue associated with the sale of the affected enoxaparin sodium injection products to the relevant hospitals and other medical institutions in EU and China, which may have a material and adverse impact on our market share and results of operations. We may fail to win bids due to various factors, including reduced demand for the relevant product, uncompetitive bidding price, failure to meet certain quality requirements, insufficient service quality to meet tender requirements, the relevant product is perceived to be less clinically effective than competing products or our services or other aspects of our operations are perceived to be less competitive. If our enoxaparin sodium injection products are not selected in the bidding process in one or more regions, we will be unable to sell the relevant products to the hospitals and other medical institutions in those regions, and our market share, revenues and profitability could be adversely affected.

If we fail to commercialize new pharmaceutical products, our business prospects could be adversely affected.

Our long-term competitiveness depends on our ability to enhance our existing products and to commercialize new pharmaceutical products for the PRC and overseas markets. There can be no assurances that we are able to successfully commercialize the new pharmaceutical products we develop. In general, relatively few drug development programs end up producing a commercial product. Since the product development process is lengthy, the competitive landscape for the pharmaceutical products we develop may change significantly over the development period, particularly because the approval process for new pharmaceutical products is increasingly lengthy, and our products may lose the competitive advantages in pricing or efficacy that we had anticipated during their development. In addition, the products we develop may be approved for more limited indications than we had anticipated, which may make the commercialization of the product less successful or profitable. We could also fail to develop and implement an effective marketing strategy with respect to those products we are able to successfully develop. In the event we fail to successfully commercialize new pharmaceutical products, our investment in the innovative drugs could be adversely affected.

RISK FACTORS

If we are unable to conduct effective academic marketing or maintain a qualified sales force, our sales and business prospects could be adversely affected.

Successful sales and marketing are crucial for us to increase the market penetration of our existing products, expand our coverage of hospitals and other medical institutions and promote new products in the future. If we are unable to increase or maintain the effectiveness and efficiency of our sales and marketing activities, our sales and business prospects could be adversely affected.

In particular, our sales and marketing efforts are anchored by academic marketing, through which we promote our enoxaparin sodium injection products to medical professionals and hospitals. Therefore, our sales and marketing force, whether in-house sales representatives or third-party promoters, must possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication skills. If we are unable to effectively train our in-house sales representatives and third-party promoters or monitor and evaluate their academic marketing performances, our sales and marketing may be less successful than desired.

Moreover, our ability to attract, motivate and retain qualified and professional sales force is especially important because we also rely on our in-house sales force to market and sell our pharmaceutical products. Competition for experienced marketing, promotion and sales personnel is intense. If we are unable to attract, motivate and retain a sufficient number of qualified and professional marketing, promotion and sales personnel, sales volumes of our enoxaparin sodium injection products may be adversely affected and we may be unable to expand our hospital coverage or increase our market penetration as contemplated.

If we fail to maintain an effective distribution network for our enoxaparin sodium injection products, our business and sales of the relevant products could be adversely affected.

We primarily rely on our network of distributors to distribute our enoxaparin sodium injection products both in the PRC and in the EU. Our ability to maintain and grow our business in these regions will depend on our ability to maintain and manage a distribution network that timely delivers our enoxaparin sodium injection products to our current and potential markets through our sales and marketing activities. All of our distributors are independent third parties. Therefore, our ability to manage the activities of our distributors is relatively limited. We enter into distribution agreements with substantially all of our distributors and mainly rely on these distribution agreements to govern our relationships with distributors, including their compliance with laws, rules, regulations and our policies. Our distributors may take one or more of the following actions, any of which could have a material adverse effect on our business, prospects and reputation:

- failing to distribute our enoxaparin sodium injection products in the manner we contemplate, impairing the effectiveness of our distribution network;
- breaching our agreements with them, including by selling products that have expired, or by selling products outside their designated territories or to hospitals other than their designated hospitals or engaging sub-distributors;
- failing to maintain the requisite licenses or otherwise failing to comply with applicable regulatory requirements when selling our products; and
- violating anti-corruption, anti-bribery, competition or other relevant laws and regulations.

RISK FACTORS

Any violation or alleged violation by distributors of our distribution agreements or any applicable laws and regulations could result in the erosion of our goodwill, expose us to liabilities, disrupt our distribution network and create an unfavorable public perception about the quality of our products, resulting in a material adverse effect on our business, financial condition, results of operations and prospects. Since not all of our distributors may sell our enoxaparin sodium injection products on an exclusive basis, our enoxaparin sodium injection products may also compete with similar products from our competitors sold by our distributors.

We typically enter into agreements with our distributors for a term of less than five years, which requires us to continually renew distribution agreements across our distribution network to maintain such business relationships. Our distributors might elect not to renew their agreements with us or otherwise terminate their business relationships with us for various reasons. For example, if price controls or other factors substantially reduce the margins they can obtain through the resale of our enoxaparin sodium injection products to hospitals and medical institutions and sub-distributors, they may terminate their agreements with us. If any of our major distributors, or a significant number of our distributors, voluntarily or involuntarily suspend or terminate their relationships with us, or we are otherwise unable to maintain and expand our distribution network effectively, our sales volumes and business prospects could be adversely affected. In particular, for our sales in certain overseas markets, we work with only one distributor in each country. As such, if we fail to maintain our relationship with a distributor in any one country, our sales and performance in the country such distributor is located would be adversely affected as we may not be able to enter into new distribution relationships with other distributors in a timely manner or at all. Many factors can affect our ability to establish or maintain such relationships, including that we may fail to find an appropriate partner for a desired overseas market, the costs of doing so are prohibitively high or legal or administrative procedures are overly complex and time consuming. Consequently, any disruption to our distribution network, including our failure to maintain relationships, form new relationships or renew our existing distribution agreements could negatively affect our ability to effectively sell our products and would materially and adversely affect our business, results of operations, financial condition and prospects. In addition, a decline in our distributors' performance would lead to a decline in the productivity of our distribution network and could have a negative effect on our revenue.

If our distributors or third-party promoters fail to effectively market and promote our enoxaparin sodium injection products, it could adversely affect our sales for the relevant products.

We collaborate with or rely on our distributors or third-party promoters to market and promote our enoxaparin sodium injection products in certain markets. Our ability to continue to generate and increase demand for our enoxaparin sodium injection products depends on our ability to continue to maintain and manage an effective third party promotion network. However, we have limited control over these third parties, which may expose us to a greater risk that such products may not be effectively promoted in the manner contemplated by our sales and marketing strategies than if we conducted the marketing and promotion activity using our internal sales force. The failure of our distributors or third-party promoters to effectively promote our enoxaparin sodium injection products could have an adverse effect on our sales volumes for the relevant products, as well as our brand value. Moreover, we typically enter into agreements with them for a limited term of years. They may elect not to renew their promotion agreements with us or otherwise terminate their business relationships with us for a number of reasons, many of which are outside our control, including to promote competing products. In the event that our distributors or third-party promoters fail to effectively promote our pharmaceutical products or terminate their business relationship with us, we may not be able to enter

RISK FACTORS

into similar relationships with others in time, or at all, which could adversely affect our sales volumes for the relevant products. In addition, if we fail to effectively manage our third party promotion network, we may be unable to extend our coverage and deepen our market penetration in the manner contemplated by our strategies, and such network may not provide us with the benefits of operational flexibility and resource allocation we contemplate.

During the Track Record Period, our five largest customers accounted for a significant portion of our total revenue and any decrease in revenue generated from any of them could materially and adversely affect our business, results of operation and financial condition.

During the Track Record Period, a substantial amount of our revenue is derived from sales to a limited number of customers. For the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, the aggregate amount of revenue generated from our five largest customers accounted for approximately 60.4%, 59.9%, and 49.5% of our total revenue, respectively. Revenue generated from our largest customer for the same periods accounted for approximately 39.8%, 37.6% and 28.6% of our total revenue, respectively. Please refer to the section headed “Business—Customers” for more details. We are not the exclusive supplier for all of these customers, and there is no assurance that our five largest customers will continue to purchase from us at the current levels or at all in the future. If any of our five largest customers significantly reduces its purchase volume or ceases to purchase from us, and we are not able to identify new customers in a timely manner, our business, financial condition and results of operation may be materially and adversely affected. In addition, there is no assurance that our major customers will not negotiate for more favorable terms for them in the future. Under such circumstances, we may have to agree to less favorable terms so as to maintain the ongoing cooperative relationships with our major customers. If we are unable to reduce our production cost accordingly, our profitability, results of operations and financial condition may be materially and adversely affected. Furthermore, our profitability highly correlates with our customers’ business performance. If our customers fail to maintain their existing market share or business, our sales will decrease correspondingly. Therefore, any risks which could have negative impact on our major customers could in turn have negative impact on our business.

We are subject to credit risks of our customers. If we experience delays in collecting or if we are unable to collect payments from customers, our cash flows and operations could be adversely affected.

We generally grant credit terms from one month to three months to our customers, and up to 270 days to certain creditworthy customers. The average turnover days of our trade receivables for the same periods were 75 days, 67 days and 92 days, respectively. As of December 31, 2017, 2018 and September 30, 2019, our trade receivables were RMB710.7 million, RMB1,109.4 million and RMB1,067.3 million, respectively, of which 45.0%, 54.3%, 45.4% were derived from our five largest customers. As a result, we may be exposed to credit risks. We cannot assure you that we can properly assess and respond in a timely manner to changes in their credit profile.

If our customers’ cash flows, working capital, financial condition or results of operations deteriorate, they may be unable, or they may otherwise be unwilling, to pay trade receivables owed to us promptly or at all. Any substantial defaults or delays could materially and adversely affect our cash flows, and we could be required to terminate our relationships with our customers in a manner that may adversely and materially affect our cash flows and operations.

RISK FACTORS

Real or perceived incidents of product contamination, or severe side effects caused by our products could materially and adversely affect our reputation, results of operations and financial conditions, and subject us to regulatory actions and contractual liabilities.

Product safety and quality is critical to our business. Our reputation, results of operations and financial condition could be materially and adversely affected by product contamination and our association with any contamination incidents. In addition, the mere publication of information or speculation asserting that any of our products contains or has contained any contaminants, over which we have no control, could damage our reputation and have a material adverse effect on us, regardless of whether such information or speculation have any factual basis. Our products may also cause undesirable or unintended side effects as a result of a number of factors, many of which are outside our control. These factors include potential side effects not revealed in clinical testing, unusual but severe side effects in isolated cases, defective products not detected by our quality management system or misuse of our products by end-users. Our products may also be perceived to cause severe side effects when a conclusive determination as to the cause of the severe side effects is not obtained or is unobtainable.

Further, our products may be perceived to cause severe side effects if other pharmaceutical companies' products containing the same or similar active pharmaceutical ingredients, raw materials or delivery technologies as our products cause or are perceived to have caused severe side effects, or if one or more regulators, such as the EMA, NMPA or the FDA, or an international institution, such as the WHO, determine that products containing the same or similar pharmaceutical ingredients as our products' could cause or lead to severe side effects. Such incidences may cause negative publicity and have material adverse impact on the industry and therefore affect our business and results of operations. For example, in 2008, FDA received reports of serious acute hypersensitivity reaction caused by OSCS contamination of heparin API. Such contamination was referred to as economically motivated adulteration, where the heparin API manufacturers intentionally contaminated heparin API with OSCS in order to reduce the cost of production. Although the FDA later confirmed our heparin sodium API products did not have such contamination, the incidence of OSCS contamination rendered FDA to strength its regulation and supervision on imported heparin sodium API from China, and enhanced its standard in monitoring the manufacture and supply of heparin.

If our products cause, or are perceived to cause, severe side effects, we may face a number of consequences, including, but not limited to:

- injury or death of patients;
- a severe decrease in the demand for, and sales of, the relevant products;
- recall or withdrawal of the relevant products;
- revocation of regulatory approvals for the relevant products or the relevant production facilities;
- damage to the brand name of our products and the reputation of our Company;
- stricter and more frequent regulatory inspections of our production facilities and products;
- removal of relevant products from any medical insurance catalogs or provincial lists of special medications related to the severe diseases insurance;
- inability to participate in the centralized tender process;

RISK FACTORS

- exposure to lawsuits and regulatory investigation relating to the relevant products that result in liabilities, fines or penalties; and
- breach of contract with our major customers.

As a result of these potential consequences, our revenue and profitability could be adversely affected.

Counterfeits of our products could negatively affect our sales, damage our reputation and the brand names for the relevant products and expose us to liability claims.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as the PRC, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode our sales volume of the relevant products. Moreover, counterfeit products may or may not have the same chemical composition as our products, which may make them less effective than our products, entirely ineffective or even cause severe adverse side effects. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even result in litigation against us. The existence and prevalence of counterfeit pharmaceutical products, products of inferior quality and other unqualified products in the healthcare markets in recent years from time to time may reinforce the negative image in general of all pharmaceutical products manufactured in the PRC or other relevant markets among consumers, and may harm the reputation and brand names of companies like us, particularly in overseas markets. As a result of these factors, the continued proliferation of counterfeit pharmaceutical products in the market could affect our sales, damage our reputation and the brand names for the relevant products and expose us to liability claims.

Drug adverse reactions and negative results from off-label use of our products could materially harm our business reputation, product brand name and financial condition and expose us to liability.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the NMPA, the FDA, EMA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our product is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our products less effective or entirely ineffective and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition, including the Company’s share price. These occurrences may also expose us to liability and subject us to litigation against us and may also ultimately result in failure to obtain regulatory approval for our drug candidates.

RISK FACTORS

The market opportunities for our drug candidates may be smaller than we anticipate, which could render some drug candidates ultimately unprofitable even if commercialized.

We estimate the incidence and prevalence of target patient populations for particular diseases based on various third-party sources, such as scientific literature, surveys of clinics, patient foundations or market research, as well as internally generated analysis, and we use such estimates in making decisions regarding our drug development strategy, including determining on which candidates to focus our resources for preclinical or clinical trials. These estimates may be inaccurate or based on imprecise data. The total addressable market opportunity will depend on, among other things, acceptance of the drug by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or access.

Furthermore, new studies may change the estimated incidence or prevalence of the diseases that our drug candidates target, and the number of addressable patients for our drug candidates in any case may turn out to be lower than expected. In such cases, even if we obtain significant market share for our drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications. Any of the above unfavorable developments could have a material adverse effect on our business, financial condition and results of operations.

We are subject to risks associated with our exports to the EU, the U.S. and other countries.

We export into various overseas regions, such as the EU, the U.S. and other countries, and we are planning to expand our footprint in the overseas markets. Our international sales and operations are subject to various risks related to economic or political uncertainties including among others:

- general economic and political conditions;
- imposition of tariffs, quotas, trade barriers and other trade protection measures imposed by foreign countries;
- import or export licensing and certification requirements imposed by various foreign countries;
- the closing of borders by foreign countries to the import of our products due to, among other things, perceived health or safety issues;
- difficulties and costs associated with complying with, and enforcing remedies under, a wide variety of complex domestic and international laws, treaties and regulations;
- different regulatory structures and unexpected changes in regulatory environments;
- different labor laws and industrial relations arrangements;
- earnings that may be subject to withholding requirements, higher tax rates and incremental taxes upon repatriation; and
- potentially negative consequences from changes in tax laws.

Negative consequences relating to these risks and uncertainties could jeopardize or limit our ability to transact business in one or more of the markets where we operate or in other developing markets and could materially and adversely affect our business, financial condition, results of operations and prospects.

RISK FACTORS

Risks Relating to Manufacture and Supply of Our Products

If our products are not manufactured to the necessary quality standards, it could harm our business and reputation, and our revenue and profitability could be adversely affected.

Our products and manufacturing processes are required to meet certain quality standards. We have established a quality control management system and standard operating procedures to help prevent quality issues in respect of our products. Please refer to “Business—Quality Control” for further details of our quality control management system and standard operating procedures. Despite our quality control system and procedures, we cannot eliminate the risk of errors, defects or failure. We may fail to detect or cure quality defects as a result of a number of factors, many of which are outside our control, including:

- manufacturing errors;
- technical or mechanical malfunctions in the manufacture process;
- human error or malfeasance by our quality control personnel;
- tampering by third parties; and
- quality issues with the raw materials we purchase or produce.

In addition, when we expand our manufacturing capacity in the future, we may not be able to ensure consistent quality between products manufactured in the existing and new facilities, or need to incur substantial costs for doing so. Furthermore, if we acquire other pharmaceutical companies, we may not be able to immediately ensure that their manufacturing facilities and processes will meet our own quality standards.

Failure to detect quality defects in our pharmaceutical products or to prevent such defective products from being delivered to end-users could result in patient injury or death, product recalls or withdrawals, license revocation or regulatory fines, or other problems that could seriously harm our reputation and business, expose us to liability, and adversely affect our revenues and profitability.

Delays in completing and receiving regulatory approvals for our manufacturing facilities could delay our development plans or commercialization efforts.

Our principal manufacturing facilities are located at our headquarters in Shenzhen, China and Wisconsin, the U.S. Our manufacturing facilities and our manufacture process will be subject to ongoing, periodic inspection by the NMPA, FDA, EMA or other comparable regulatory agencies to ensure compliance with CGMP, which is usually the pre-requisite to obtain marketing approval in the respective jurisdictions. Failure to comply with applicable regulations could lead to increased expense and result in sanctions being imposed on us, including fines, injunctions, civil penalties, requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of products or product candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

If we suffer substantial disruption to any of our production sites or encounter problems in manufacturing our products, our business and results of operations could be adversely affected.

During the Track Record Period, we generated a significant portion of our revenue from sales of products produced at three of our production sites, including two sites located in Shenzhen, China

RISK FACTORS

and the SPL facility located in Wisconsin, U.S. The continued operation of our production sites and our production safety may be substantially interrupted and materially and adversely affected due to a number of factors, many of which are outside of our control. These may include fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars, or other natural disasters, as well as loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities or their vicinity and regulatory changes.

If the operation of any of our major production sites is substantially disrupted, we may not be able to replace the equipment or inventories at such facilities, or use different sites or a third party contractor to continue our production in a legal, timely and cost-effective manner or at all. Although we maintain property insurance for our production facilities and material equipment, the amount of our insurance coverage may not be sufficient to cover our losses in the event of a significant disruption to any of our production sites. Problems may also arise during manufacturing for a variety of reasons, including equipment malfunction, failure to follow specific protocols and procedures, problems with raw materials, delays related to the construction of new sites or the expansion of our existing production sites, including changes in production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. As a result of disruption to any of our production sites or any problems in manufacturing our products, we may fail to fulfill contract obligations or meet market demand for our products, and our business, revenues and profitability could be adversely affected.

If we fail to increase our production capacity, our business prospects could be adversely affected.

We manufacture a significantly portion of our products at our production sites located in Shenzhen, China and Wisconsin, the U.S. We plan to expand the production capacity of Pingshan Industrial Park, specifically, our annual production capacity of pre-filled syringes of enoxaparin sodium injection. Our ability to expand our manufacturing capacity is subject to a number of risks and uncertainties, including our ability to obtain the requisite permits, licenses and approvals for the construction and operation of the new production facilities and production lines, the risk of construction delays and delays in equipment procurement, as well as our ability to timely recruit sufficient qualified staff to support the increase in our production capacity. Consequently, there can be no assurance that we will be able to increase our production capacities in the manner we contemplate, or at all. In the event we fail to increase our production capacities, we may not be able to capture the expected growth in demand for our existing pharmaceutical products, or to successfully commercialize additional pharmaceutical products, each of which could adversely affect our business prospects. Moreover, our plans to increase our production capacities require significant capital investment, and the actual costs of our expansion plan may exceed our original estimates, which could adversely affect the return on our expenditure.

If our OEMs do not produce pharmaceutical products meeting our specifications in sufficient volumes at commercially acceptable prices, our sales volumes and margins for the relevant products could be adversely affected.

We currently use OEMs to produce a portion of our key products, enoxaparin sodium injection, and may in the future increase our reliance on the OEMs to meet increased demand for our existing products or our newly introduced products, particularly if we are unable to successfully enhance our production capacity. We have less control over our OEMs’ production process than our own, and the

RISK FACTORS

risks of such products not being produced in the necessary volumes or at the appropriate quality levels are higher than if we manufacture in-house. The OEMs may fail to maintain the necessary licenses, permits and certificates to carry out production of our products, breach their obligations to produce our products on a timely basis, otherwise cease to conduct the OEMs' business or fail to abide by our quality control requirements. Quality issues related to products our OEMs produce for third parties may also be imputed to the products they manufacture for us and adversely affect our reputation.

If the OEMs we appoint do not produce pharmaceutical products meeting our specifications in sufficient volumes at commercially acceptable prices, or we are unable to appoint OEMs to do so, we may have insufficient quantities of our products to meet our customers' demands and our sales volumes and margins for the relevant products could be adversely affected.

We may experience supply interruptions that could harm our ability to manufacture products.

We purchase certain materials and components used in the manufacture of our products from external suppliers, and we purchase certain raw materials and equipment from fixed sources for reasons of quality assurance, cost effectiveness, availability, or constraints resulting from regulatory requirements. We may not be able to obtain these raw materials, medical devices or components for an indeterminate period of time if these third-party suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including regulatory requirements or actions, adverse financial developments of the suppliers, and/or unexpected demand, labor shortages or disputes. A reduction in, or lack of availability of, raw materials or interruptions in the supply chain may also impact our profitability to the extent that we are required to pay higher prices for, or are unable to secure adequate supplies of, the necessary raw materials.

General economic conditions could adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and components used in the manufacture of our products. While we work closely with suppliers to monitor their financial viability, assure continuity of supply, and maintain high quality and reliability, these efforts may not be successful. In addition, regulatory agencies from time to time have limited or banned the use of certain materials used in the manufacture of our products. For example, regulatory agencies may limit the supply of porcine small intestine, if there is an outbreak of swine fever. Trade war, regulatory embargoes and policy changes on importation and exportation between different countries could also result in delays or shortages in the supply of our raw materials.

A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology, and the loss of any existing supply contract could have a material adverse effect on us. Furthermore, we may not be able to identify suitable replacement for these materials, devices and components on reasonable terms or at all if such supply was subsequently found to not be in compliance with our quality standards or resulted in quality failures or product contamination and/or recall when used to manufacture, formulate, fill or finish our products. These events could adversely affect our ability to satisfy demand for our products, which could materially and adversely affect our product sales and operating results.

We rely on supply from limited suppliers, which may severely harm our business and results of operations.

Our principal supplies include packaging materials, crude heparin and porcine small intestines, the majority of which we source from external suppliers, and we expect to continue to rely on our

RISK FACTORS

external suppliers for a substantial percentage of such supplies. Our suppliers are subject to various regulations and are required to obtain and maintain various qualifications, government licenses and approvals. There is a limited number of such suppliers with the requisite qualifications, licenses and approvals. During the Track Record Period, we purchased syringes mainly from two suppliers in China. Any of our suppliers may lose its qualification or eligibility because of its failure to comply with regulatory requirements. In addition, our suppliers may also elect to no longer service us due to the rigorous regulations and requirements of the regulatory authorities regarding the manufacture of our products (including the need for approval of any change in supply arrangements). Furthermore, we may be involved in contract disputes with our suppliers which may cause our suppliers to suspend supply to us. We may not be able to find alternative materials or suppliers and secure approval for their use in a timely manner or at all, which may cause delay in supply of our raw materials and interruption in our manufacturing. If any of these happens, our results of operations may be materially and adversely affected.

Fluctuations in prices of our raw materials may have a material adverse effect on us if we are not able to transfer the cost increase to our customers.

Purchase of raw materials accounted for a significant portion of our total cost of sales during the Track Record Period. In order to manufacture our products, we must obtain sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner. We rely on our suppliers for our business, which exposes us to risks associated with fluctuations in prices of raw materials, and reductions in the availability of raw materials may disrupt our operations.

The prices of our principal raw materials, such as crude heparin and porcine small intestine, may be affected by a number of factors, including market supply and demand, the PRC or international environmental and regulatory requirements, natural disasters such as the outbreak of swine fever, and the global economic conditions. Due to the outbreak of African swine fever in late 2018, the number of breeding stock pigs has decreased constantly since the beginning of 2019, and continued throughout 2019, which led to shortage in supply and price increase of porcine small intestines and therefore the shortage in supply and price increase of crude heparin. Generally, there is one year lag from the price increase of porcine small intestine to that of heparin API. We may have limited capability to transfer the increasing costs of raw materials to our customers in a timely manner. A significant increase in the costs of raw materials may increase our cost of sales and negatively affect our profit margins and, more generally, our business, financial conditions, results of operation and prospects, if we are not able to transfer the cost increase to our customers.

Failure to maintain optimal inventory levels could increase our operating costs or lead to unfulfilled customer orders, either of which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are required to maintain optimal inventory levels in order to successfully meet our customers' demand. However, we are exposed to inventory risk as a result of rapid changing market demands, and fluctuation in the supply market as well as the volatile economic environment globally. There can be no assurance that we can accurately predict these trends and events and avoid over-stocking or under-stocking our products. Further, demand for products could change significantly between the time when the products are ordered and the time when they are ready for delivery. When we begin to sell a new product, it is particularly difficult to forecast product demand accurately. For details, see “Business—Inventory”.

RISK FACTORS

We maintain significant inventory levels for a substantial portion of our products for sales into our distribution network. We may be unable to sell such inventory in sufficient quantities. Inventory levels in excess of demand may result in inventory write-downs, expiration of our products or an increase in inventory holding costs and a potential negative effect on our liquidity. In 2017 and 2018 and the nine months ended September 30, 2019, we incurred write-down of inventories of approximately RMB37.6 million, RMB40.6 million and RMB36.9 million respectively. If we underestimate demand for our products, we may experience inventory shortages which may, in turn, result in unfulfilled customer orders, leading to a negative impact on our customer relationships. There can be no assurance that we will be able to maintain proper inventory levels of our products, and any such failure may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Relating to the Research and Development of Our Product Candidates

If we are unable to successfully complete clinical development, obtain regulatory approval and commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our innovative drug business will depend on the successful development, regulatory approval and commercialization of our drug candidates, all of which are still in preclinical or clinical development, and other drug candidates we may develop. We have invested a significant portion of our efforts and financial resources in the development, licensing and acquisition of our existing drug candidates. The success of our drug candidates will depend on several factors, including:

- successful enrollment of patients in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals;
- establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- the performance by contract research organizations, or CROs, or other third parties to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- successfully launching commercial sales of our drug candidates, if and when approved; and
- obtaining sufficient supplies of any competitor drug products that may be necessary for use in clinical trials for evaluation of our drug candidates.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in our ability or be unable to obtain approval for and/or to successfully commercialize our drug candidates, which would render us fail to achieve our milestones as planned, and materially harm our drug development business. These factors present uncertainty and material

RISK FACTORS

risks to our commercial success and may cause potential [REDACTED] to lose a substantial amount or substantially all of their [REDACTED] investment in our business.

If we encounter difficulties enrolling patients in the clinical trials of our drug candidates, the clinical development activities of such drug candidates could be delayed or otherwise adversely affected.

As of the Latest Practicable Date, we have exclusive development and commercial rights in Greater China for five drug candidates, among which two are in phase III global clinical trials and two are in phase II global trials. We plan to gradually participate in the clinical trial for our drug candidates in China as part of their global trial under the MRCT. We also have one self-developed drug candidate currently at preclinical stage. The timely completion of clinical trials in accordance with their protocols depends, among other things, on the ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in the clinical trials for our drug candidates for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the protocol.

The clinical trials for our drug candidates will likely compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, some of the clinical trials may be conducted at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for the clinical trials for our drug candidates at such clinical trial sites. Even if a sufficient number of patients can be enrolled, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect the development of our drug candidates.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and unsuccessful clinical trials or procedures relating to products under development could have a material adverse effect on our prospects.

Clinical testing is expensive and can take multiple years to complete, and its outcome is inherently uncertain. There can be no assurance that these trials or procedures will be completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication. Failure to successfully complete these trials or procedures in a timely and cost-effective manner could have a material adverse effect on our prospects. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results.

Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In addition, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including differences in physical conditions, and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from

RISK FACTORS

earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. Even if our future clinical trial results show favorable efficacy and impressive durability of antitumor responses, not all patients may benefit.

If clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including but not limited to:

- regulators, institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- manufacturing issues relating to our own facilities or third party CMOs that we engage, including problems with manufacturing, supply quality, compliance with GMP, or obtaining from third parties sufficient quantities of a drug candidate for use in a clinical trial;
- clinical trials of our drug candidates may produce negative or inconclusive results, and additional clinical trials or abandon drug development programs may be required;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- relevant third-party contractors, including clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- clinical trials of our drug candidates may be suspended or terminated for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate; and
- the supply or quality of our drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

For example, in November 2019, Resverlogix, in which we held 38.80% equity interest as of the Latest Practicable Date, announced that the primary endpoint of the phase III trial for RVX-208 was narrowly missed. Resverlogix has been in continuous discussion with the FDA regarding the clinical development approach for RVX-208 based on the phase III trial results, which may cause delay to the timetable of the trial and regulatory approval process as previously contemplated.

RISK FACTORS

If additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate are required to be conducted, if the clinical trials of our drug candidates or other testing cannot be successfully conducted, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may (i) be delayed in obtaining regulatory approval for our drug candidates; (ii) not obtain regulatory approval at all; (iii) obtain approval for indications that are not as broad as intended; (iv) have the drug removed from the market after obtaining regulatory approval; be subject to additional post-marketing testing requirements; (v) be subject to restrictions on how the drug is distributed or used; or (vi) be unable to obtain reimbursement for use of the drug. Significant clinical trial delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may harm our business and results of operations.

If we fail to achieve product development milestones, as disclosed in this document or subsequent public disclosures, it could adversely affect our business prospects.

We disclose in this document our expectations or targets for the timing of certain milestones associated with our drug development programs, including the anticipated regulatory approval for the manufacture and sale of a product. After [REDACTED], as a [REDACTED] company we may continue to make such disclosures of our expectations in this respect. However, the successful implementation of our product development programs is subject to significant business, economic and competitive uncertainties and contingencies, including, product development risk, the availability of funds, competition, grants of relevant approvals and permits and regulation, which we will re-evaluate from time to time based on the regulation, government policies and the continued growth of the pharmaceutical market.

The actual timing for achieving product development milestones could vary significantly from our expectations due to a number of factors, many of which are outside our control. There can be no assurance that our preclinical studies or clinical trials will be completed as planned or at all or that we will make regulatory submissions or receive regulatory approvals as planned or that we will be able to adhere to our current schedule for the launch of any of our products candidates. If we fail to achieve one or more of these milestones as planned, it could adversely affect the price of our Shares and our business prospects.

We invest substantial resources in research and development in order to develop our drug candidates and enhance our technologies, which we may not be able to do successfully.

The global pharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. In 2017, 2018 and the nine months ended September 30, 2019, our R&D expenses amounted to RMB93.8 million, RMB186.5 million and RMB114.9 million, respectively. We expect to continue to invest significant amounts of human and capital resources to develop our drug candidates and enhance our technologies that will allow us to advance our pipeline drugs and enhance the scope and quality of our services. We intend to continue to strengthen our technical capabilities in drug discovery, development, and manufacturing, which are capital and time intensive. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products or obtain the necessary regulatory

RISK FACTORS

approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may render our efforts obsolete, which could significantly reduce demand for our products or services and harm our business and prospects.

We may not be able to successfully license-in new drug candidates, or license-out our existing drug candidates.

From time to time, we may seek to license-in or license-out drug candidates. We license-in promising drug candidates to expand our existing portfolio. As of the Latest Practical Date, we licensed-in two drug candidates in phase III clinical trial, two drug candidates in phase II clinical trial and one drug candidates in phase I clinical trial. We cannot assure you that if we decide to license-in other drug candidates in the future, we will be successful in identifying favorable candidates or that the prospective licensor would agree to license such products to us at favorable commercial terms or at all. Even if we are able to license-in the drug candidates that we target, we cannot assure you that the product will be successfully commercialized. Conversely, we may license-out our existing drug candidates to other drug developers. We cannot assure you that if we decide to license-out our drug candidates in the future, we will successfully be able to do so, or that any such partner will be able to successfully develop or commercialize products licensed from us, which in turn could adversely affect the licensing fees that we may receive from such arrangement.

Even after we successfully license-in or license-out drug candidates, we cannot assure you that our licensors or licensees will not breach the relevant license agreements, whether inadvertently or otherwise. Alternatively, our licensors or licensees might conclude that we have materially breached our license agreements. In either case, the license agreements may be terminated, thereby removing our ability to develop and commercialize the drug products we licensed-in or generate licensing fees and royalties from the drug products we licensed out.

We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.

As we have limited human and financial resources, we must limit our research and development programs to specific drug candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. In addition, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate. Such developments could have a material adverse effect on our business, financial condition and results of operations.

RISK FACTORS

Risks Relating to Our CDMO Business

Our CDMO business is dependent on our customers’ spending on and demand for outsourced biologics discovery, development and manufacturing. A reduction in spending or demand could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

The success of our CDMO business depends primarily on the number and size of service contracts with our customers, primarily pharmaceutical and biotechnology companies. Over the past several years, we have benefitted from an increased demand for our services as a result of the continued growth of the global biologics market, increasing research and development budgets of our customers, and greater degree of outsourcing by our customers. A slowing or reversal of any of these trends could have a significant adverse effect on the demand for our services.

In addition to the forgoing industry trends, our customers’ willingness and ability to utilize our services are also subject to, among other things, their own financial performance, changes in their available resources, their decisions to acquire in-house discovery, development or commercial manufacturing capacity, their spending priorities, their budgetary policies and practices, and their need to develop new biological products, which, in turn, is dependent upon a number of factors, including their competitors’ discovery, development and commercial manufacturing initiatives, and the anticipated market update, clinical and reimbursement scenarios for specific products and therapeutic areas. In addition, consolidation in the industries in which our customers operate may have an impact on such spending as our customers integrate acquired operations, including research and development departments and their budgets. If our customers reduce their spending on our services as a result of any of these or other factors, our business, financial condition, results of operations, cash flows and prospects would be materially and adversely affected.

As our service contracts are typically contingent on successful completion of pre-set steps in the biologics development process, we may bear financial risks related to the success of our customer’s project.

Under most of our project-based contracts or work orders, we recognize revenue upon completion of pre-set steps and delivery and acceptance of the study results and/or other deliverables. For more information, see “Financial Information—Significant Accounting Policies and Estimates”. As a result, if we fail to deliver services in a timely manner in accordance with our contractual requirements, regulatory standards or ethical considerations, we could be subject to significant costs or liability and our reputation could be harmed, which could have an adverse effect on our business, financial condition, results of operations, cash flows and prospects.

Furthermore, if our customers’ biologics fail to pass the requisite steps or proceed through development, regulatory approval or commercialization, our CDMO services would be severely impacted and we would not be able to fully realize the value of our service contracts.

In pricing our contracts, we take into consideration the market positioning of our services, prices of comparable services offered by our competitors, degree of saturation of the current market, market trends, complexities of the services required, costs and expenses of our services and the timeline of the contract. However, our evaluation of these factors may be inaccurate or even incorrect. If we underprice our contracts or overestimate our costs, we would incur losses from our contracts, and our business, financial condition, results of operations, cash flows and prospects would be adversely affected.

RISK FACTORS

In conducting drug discovery and development when providing CDMO services, we may face potential liabilities, in particular, product liability risks.

In providing our CDMO services, we may face a range of potential liabilities. We typically undertake to defend, indemnify and hold our customers harmless from and against any liabilities and damages (including reasonable attorneys’ fees) resulting from any third party claims, demands, suits or proceedings to the extent arising out of or relating to our negligence, willful misconduct, unlawful activities or material breach of the long-term service agreement or project-based service contract or a work order under the long-term service agreement. In particular, we may face product liability risks if the biologics we help to discover, develop or manufacture are subject to product liability claims. Our liability is not always capped under our long-term service agreements or project-based service contracts. We provide services in the discovery, development and commercial manufacturing of biologics that are intended ultimately to be used in humans, either in clinical trials or as marketed products, although we do not commercially market or sell these products to end users. If any of these biologics harms people due to our negligence, willful misconduct, unlawful activities or material breach, we may be subject to litigation and may be required to pay damages. Damages awarded in a product liability action could be substantial and could have a material and adverse impact on our reputation, business, financial condition, results of operations and prospects. Although we currently maintain product liability and professional liability insurance, our insurance coverage may be inadequate or may become unavailable on terms acceptable to us.

Our customer agreements may contain provisions that run counter to our interests or expose us to potential liability.

Our long-term service agreements generally provide that a customer can terminate the agreement or any work order under the agreement without cause by giving prior written notice. Most of our project-based service contracts also allow customers to unilaterally terminate the contract without cause by giving prior written notice. If a customer terminates a work order or project-based service contract without cause, typically we are only entitled to receive service fees earned up to the date of termination, costs already incurred or irrevocably committed and in some cases a limited amount of penalty. For more information, see “Business—Our CDMO Business”. Therefore, cancelation or modification of a large work order or project-based service contract, or proximate cancelation or modification of multiple smaller work orders or project-based service contracts, could materially and adversely affect our business, financial condition, results of operations and prospects. Such restriction typically remains effective for a number of years after the relevant long-term service agreement or project-based service contract is completed, and in some cases is effective for an indefinite period. For some customers, the exclusivity clause covers a broad range of products. Complying with such exclusivity clause restricts our ability to obtain new projects and adversely affects the extent to which other customers or potential customers use our services, and failure to do so could significantly harm our business and reputation, as well as expose us to liability for breach of contract.

We may not be able to continue to serve our customers if we fail to meet our customers’ standards in audits and inspections.

Our customers regularly audit and inspect our facilities, processes and practices to ensure that our services are meeting their standards in the biologics discovery, development and manufacturing

RISK FACTORS

process. However, we cannot assure you that we will be able to pass all the customer audits and inspections. Failure to pass any of these audits or inspections to our customers’ satisfaction could significantly harm our reputation and result in the termination of ongoing biologics projects by our customers, which could materially and adversely affect our business, financial condition, results of operations and prospects.

Our backlog might not be indicative of our future revenue, and we might not realize all of the anticipated future revenue associated with our backlog.

Our backlog represents the total contract value of work that has been contracted for but remains to be completed as of a certain date. The contract value of a project represents the total amount that we expect to receive under the terms of the contract assuming the contract is fully performed in accordance with its terms. Backlog is not a measure defined by generally accepted accounting policies and may not be indicative of our future operating results. Our methodology for determining backlog may not be comparable to the methodology used by other companies in determining their backlogs. As of the Latest Practicable Date, our backlog reached US\$62.1 million, and out of such backlog, service fees of approximately US\$49.6 million and US\$12.5 million are expected to be generated in 2020 and 2021 onwards, respectively. However, these figures are based on the assumption that the relevant contracts will be performed in full in accordance with their respective terms and expected timetables. The actual amount of service fees we expect to receive from such backlog in the relevant periods will be different from the estimated amount of revenue if there is any modification, termination or suspension of the relevant contracts by our customers or any delay in the timetable. We cannot guarantee that the revenue projected in our backlog will be realized or, if realized, will result in profits. Projects may remain in our backlog for an extended period of time beyond what was initially anticipated due to various factors beyond our control. In addition, project cancellations, suspensions or scope adjustments may occur from time to time, which could reduce the dollar amount of our backlog and the revenue and profits we ultimately earn from the contracts. As a result, you should not unduly rely on our backlog information presented in this document as an indicator of our future earnings performance or business prospects.

Risks Relating to Extensive Governmental Regulations

If we or parties on whom we rely fail to comply with the laws and regulations related to, or maintain the necessary licenses for, the development, production, sales and distribution of our products, operation of our businesses and our investments, our ability to conduct our business could be materially impaired.

The pharmaceutical industry is subject to extensive government regulation and supervision. We are governed by various local, regional and national regulatory regimes in various aspects of our operations, including licensing and certification requirements and procedures for manufacturers of pharmaceutical products, operating and safety standards, as well as environmental protection regulations. There can be no assurance that the legal framework, licensing and certification requirements or enforcement trends in our industry will not change in a manner that may result in increased costs of compliance, or that we will be successful in responding to such changes. In addition, we are subject to the risk of adverse changes to favorable policies from which we currently benefit, and the introduction of unfavorable policies. The costs we incurred to comply with these laws and regulations, including those related to environmental protection, may materially increase our total costs and decrease our profit. Any violation of these laws, rules or regulations may result in substantial fines,

RISK FACTORS

criminal sanctions, revocations of operating permits, shutdown of our production facilities and obligations to take corrective measures.

We are also required to obtain, maintain and renew various permits, licenses and certificates to develop, produce, promote and sell our products. Third parties, such as distributors, third-party promoters and third-party manufacturers, on whom we may rely to develop, produce, promote, sell and distribute our products may be subject to similar requirements. We and third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or the parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates.

Many of such permits, licenses and certificates are material to the operation of our business, and if we or parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. We may also fail to comply with other relevant laws and regulations related to our operations including our investments. For example, we did not obtain the approvals from the NDRC for our outbound investments in certain overseas subsidiaries. The competent PRC authority has confirmed that such lack of approval will not adversely affect our future outbound investment activities in these entities and we are not required to reapply the NDRC approval in respect of the above investments. See “Business—Legal Proceedings and Compliance.” However, there is no assurance that the competent PRC authority will not impose any other administrative measures on us in the future. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring us or parties on whom we rely to obtain any additional permits, licenses or certificates that were previously not required to operate our business, there can be no assurance that we or parties on whom we rely will successfully obtain such permits, licenses or certificates.

If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in China, to the satisfaction of the NMPA, that the drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to preclinical and clinical data, the NDA or BLA must include significant information regarding the chemistry, manufacturing and controls for the drug candidate. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA to the NMPA, the NMPA decides whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for filing and review by the NMPA.

Regulatory authorities outside of China, such as the FDA and EMA, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements and approval processes can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one

RISK FACTORS

country does not mean that regulatory approval will be obtained in any other country. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time consuming. The foreign regulatory approval process may include all of the risks associated with obtaining NMPA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all.

The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly both inside and outside the U.S. and China, and approval is never guaranteed. Following any approval for commercial sale of our drug candidates, certain changes to the drug, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA, FDA and EMA and comparable regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of any other drug candidate in the future.

Undesirable adverse events caused by our products and drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Undesirable adverse events caused by our products or drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, FDA or other comparable regulatory authority, or could result in limitations or withdrawal following approvals. If results of our trials reveal a high and unacceptable severity or prevalence of adverse events, our trials could be suspended or terminated and the NMPA, FDA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates.

Adverse events have been reported in our clinical trials which could affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential drug liability claims. Any of these occurrences may harm our reputation, business, financial condition and prospects significantly. In this document and from time to time, we disclose clinical results for our drug candidates, including the occurrence of adverse events and serious adverse events. Each such document speaks only as of the date of the data cutoff used in such document, and we undertake no duty to update such information unless required by applicable law.

Our products and any future products will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products and/or drug candidates.

Our products and any additional drug candidates that are approved by the regulators are and will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China, the U.S., the EU, and/or other countries.

RISK FACTORS

Manufacturers and manufacturers' facilities are required to comply with extensive regulatory requirements from the NMPA, FDA, EMA, and/or other comparable authorities. As such, we are and will be subject to continual review and inspections by the regulators in order to assess our compliance with applicable laws and requirements and adherence to commitments we made in any application materials with the NMPA or other authorities. Accordingly, we must continue to devote time, money and effort in all areas of regulatory compliance.

The regulatory approvals for our products and any approvals that we receive for our drug candidates are and may be subject to limitations on the indicated uses for which our product may be marketed. The approvals we obtain may also be subject to other conditions which may require potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of our products or drug candidates. Such limitations and conditions could adversely affect the commercial potential of our products.

The NMPA or comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval if we fail to maintain compliance with these ongoing regulatory requirements or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our products or drug candidates or with our manufacturing processes may result in revisions to the approved labeling or requirements to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of our products and drug candidates; and/or injunctions or the imposition of civil or criminal penalties.

The NMPA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products placed on the market. Products may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, FDA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the NMPA, FDA, EMA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China or abroad, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are unable to maintain regulatory compliance, we may lose any regulatory approval that we have obtained and we may not achieve or sustain profitability.

RISK FACTORS

Changes in government regulations or in practices relating to the healthcare industry, including healthcare reform and compliance with new regulations may result in additional costs.

The healthcare industry is heavily regulated globally. Changes in government regulations or in practices relating to the healthcare industry, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures which will lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects.

In the U.S., The Patient Protection and Affordable Care Act (PPACA) was enacted by the Congress in March 2010 and established a major expansion of healthcare coverage, financed in part by a number of new rebates, discounts, and taxes that may have a significant effect on our expenses and profitability. We face uncertainties due to federal legislative and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. For example, tax reform legislation enacted at the end of 2017 eliminates the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019. We anticipate continued Congressional interest in modifying provisions of the PPACA. Any future replacement, modification or repeal of the PPACA may adversely affect our business and financial results, particularly if the legislation reduces incentives for employer-sponsored insurance coverage and we cannot predict how other future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval and commercialize our drug candidates and affect the prices we may fix. In China, the U.S. and some other jurisdictions, a number of legislative and regulatory changes and proposed changes regarding healthcare could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our products and any drug candidates for which we obtain regulatory approval. In recent years, there have been and will likely continue to be efforts to enact administrative or legislative changes to healthcare laws and policies, including measures which may result in more rigorous coverage criteria and downward pressure on the price that we fix for any approved product. Any reduction in reimbursement from government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

We are subject to environmental regulations; if we fail to comply with such regulations or such regulations change, it may impair our ability to conduct our business and we may be exposed to liability and potential costs for environmental compliance.

We are subject to laws, rules and regulations concerning environmental protection, including the discharge of effluent water and solid waste as well as the disposal of hazardous substance during our manufacturing processes, primarily in the PRC and U.S., where we conduct manufacturing activities and may become subject to similar laws, rules and regulations in other jurisdictions in the future. In addition, we are required to obtain clearances and authorizations from government authorities for the treatment and disposal of such discharge. The costs we incurred for environmental protection may materially increase our total costs and decrease our profit. There can be no assurances that we will be able to comply fully at all times with applicable environmental laws, rules and

RISK FACTORS

regulations. Any violation of these laws, rules or regulations may result in substantial fines, criminal sanctions, revocations of operating permits, shutdown of our production facilities and obligations to take corrective measures.

Furthermore, relevant government authorities may take steps towards the adoption of more stringent environmental regulations. Due to the possibility of unanticipated regulatory or other developments, the amount and timing of future environmental expenditures may vary substantially from those currently anticipated. If there is any change in the environmental regulations, we may need to incur substantial capital expenditures to install, replace, upgrade or supplement our pollution control equipment, take additional protective and other measures against potential contamination or injury caused by hazardous materials, or make operational changes to limit any adverse impact or potential adverse impact on the environment. If these costs become prohibitively expensive, we may be forced to curtail or cease certain of our pharmaceutical manufacturing business. In addition, if we become subject to any significant environmental-related liabilities, it could adversely affect our financial condition and results of operations.

We are subject to extensive governmental approvals and compliance requirements for our land and properties.

For our production facilities and other premises, we must obtain various permits, certificates and other approvals from the relevant administrative authorities at various stages of property development, including, for example, planning permits, construction permits, land use rights certificates, certificates for passing environmental assessments, certificates for passing fire control assessments, certificates for passing construction completion inspections and ownership certificates. We are also subject to other compliance requirements. For example, we are required to complete construction within a specific period since we obtained the land from the PRC government. We have encountered, and may in the future encounter, problems with fulfilling the conditions precedent to the receipt of certain of those permits, certificates and approvals, and we may not always be able to obtain them in a timely manner, or at all. For example, we failed to timely complete the construction of certain buildings at our Pingshan Industrial Park. According to the relevant PRC laws and regulations, in respect of failure to complete construction in time other than due to the reasons related to the government authorities, the relevant PRC authorities may impose liquidated damages on the company since the required completion date. If the delay is within two years since the required completion date, the company may be imposed a liquidated damage of up to 1.5% of the land premium every three months since the required completion date. If a company fails to complete construction for more than two years since the required completion date, the company may be imposed a liquidated damage of up to 20% of the land premium and the land may be subject to forfeiture to the PRC government. As of the Latest Practicable Date, we paid liquidated damages of RMB2.42 million imposed by the relevant PRC authorities. Although Pingshan Administrative Bureau has confirmed that the land with respect to the Pingshan Industrial Park is not regarded as idle land and the delay is not due to the reason of the company therefore such land and the construction built on it are not subject to forfeiture, there is no assurance that the relevant PRC authorities will not impose forfeiture and other penalties on us in the future. Please refer to “Business—Legal Proceedings and Compliance” for more information. In addition, one of our lessors does not have the certificate of ownership for the business property we leased. In accordance with the relevant regulations in China, if the lessor fails to obtain the certificate of ownership for the leased property, the agreement between the lessor and the lessee may become invalid. Please refer to “Business—Properties and Facilities” for more information.

RISK FACTORS

Risks Relating to Our Intellectual Property Rights

We may not be able to protect our intellectual property rights.

As of the Latest Practicable Date, we owned 76 patents and patent applications, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the same.

If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to products, which could make it difficult for us in those jurisdictions to defend the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

If we are unable to obtain and maintain patent protection for our products and drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete directly against us.

Our success depends in large part on our ability to protect our proprietary technology, products and drug candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the technology, products and drug candidates that we consider commercially important by filing patent applications in the PRC, the U.S. and other countries, relying on trade secrets or medical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our R&D output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior deficiencies in the patent application or the lack of novelty of the underlying invention or technology. We may also fail to identify patentable aspects of our R&D output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements or include such provisions in our relevant agreements with parties who have access to confidential or patentable aspects of our R&D output, such as our employees, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a

RISK FACTORS

patent application is filed, jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries. Patent applications in China and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all.

Under the Patent Law of the PRC (中華人民共和國專利法) promulgated by the Standing Committee of the NPC, as amended, patent applications are maintained in confidence until their publication at the end of 18 months from the filing date. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made and the date on which patent applications were filed. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions.

Furthermore, the PRC and, recently, the U.S. have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, even after reasonable investigation we may be unable to determine with certainty whether any of our products, processes, technologies, inventions, improvement and other related matters have infringed upon the intellectual property rights of others, because such third party may have filed a patent application while we are still developing that product, and the term of patent protection starts from the date the patent was filed, instead of the date it was issued. Therefore, the validity of issued patents, patentability of pending patent applications and applicability of any of them to our programs may be lower in priority than third-party patents issued on a later date if the application for such patents was filed prior to ours and the technologies underlying such patents are the same or substantially similar to ours. In addition, under PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the CNIPA, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future are to be issued as patents, they may not be issued in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the PRC, the U.S. and other countries. We may be subject to a third-party preissuance submission of prior art to the CNIPA, USPTO or other related intellectual property offices, or become involved in post-grant proceedings such as opposition, derivation, revocation and re-examination, or *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or drug candidates and compete directly with us without payment to us. Moreover, we may have to participate in interference proceedings declared by the CNIPA, USPTO or other related intellectual property offices to determine priority of invention or in post-grant challenge

RISK FACTORS

proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technologies, products or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords is limited. We may face competition for any approved drug candidates even if we successfully obtain patent protection once the patent life has expired for the product. The issued patents and pending patent applications, if issued, for our products and drug candidates are expected to expire on various dates as described in “Business—Intellectual Property Rights” of this Document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may not be successful in protecting our customers’ intellectual property.

With respect to our CDMO business, we typically have access to a significant amount of intellectual property owned by our customers. Our customers typically retain ownership of all intellectual property associated with their projects, including the intellectual property provided to us and the intellectual property arising from the services we provide, except for intellectual property created or developed in connection with the provision of our services that is derivative of our own intellectual property or that relates to manufacturing processes developed at our expense.

Despite the measures we take to protect our customers’ or our own intellectual property, unauthorized parties may attempt to obtain and use them. Failure to protect our customers’ intellectual property may subject us to liability for breach of contract, as well as significantly damage our reputation, which is fundamental to our business. Failure to protect our own intellectual property may severely disrupt our business operation of CDMO service, and reduce or eliminate any competitive

RISK FACTORS

advantage we have developed. Either could materially harm our business, financial condition, results of operations and prospects, and any remediation may significantly divert management’s attention and resources from other activities.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our products and drug candidates could be found invalid or unenforceable if being challenged in court or before the CNIPA or courts or related intellectual property agencies in other jurisdictions.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patents, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

Defendant counterclaims alleging invalidity or unenforceability are commonplace, a third party can assert invalidity or unenforceability of a patent on numerous grounds. Third parties may also raise similar claims before administrative bodies in China or abroad, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our products or drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we, our patent counsel, and the patent examiner could be unaware of invalidating prior art during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as we expect.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our drug candidates. We may also be unaware of third-party patents or patent applications, and given the

RISK FACTORS

dynamic area in which we operate, additional patents are likely to be issued that relate to aspects of our business. There are a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the pharmaceutical industry generally. As the pharmaceutical industry expands and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would substantially divert diversion of employee resources from our business. In the event of a successful claim against us of infringement or misappropriation, or a settlement by us of any such claims, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, pay royalties or redesign our infringing drug candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. Any such license might not be available on reasonable terms or at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the market price of our Shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the CNIPA, USPTO and other patent agencies in several stages over the lifetime of the patent. The CNIPA, USPTO and various

RISK FACTORS

governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process.

Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates.

Depending on decisions by the NPC and the CNIPA, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. On December 5, 2018, the State Council submitted the draft of the fourth amendment to the Patent Law of the PRC to the NPC. The potential influence on our existing patent rights and future patent applications remains uncertain. There could be similar changes in the laws of other jurisdictions that may impact the value of our patent rights or our other intellectual property rights. The U.S. has enacted and is currently implementing wide-ranging patent reform legislation. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our products and drug candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements or include such undertakings in the agreement with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into employment agreement or consulting agreement with our employees and consultants that includes undertakings regarding assignment of inventions and discoveries. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, certain of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Some of these employees executed

RISK FACTORS

proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any material threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Our in-licensed patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings. If we or our licensors are unsuccessful in any of these proceedings, we may be required to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the development, manufacture, and commercialization of one or more of the drug candidates we may develop, which could have a material adverse impact on our business.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents or other intellectual property. If we or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes (including any patent oppositions) to which we or they are subject, we may lose valuable intellectual property rights through the loss of one or more patents owned or licensed or our owned or licensed patent claims may be narrowed, invalidated, or held unenforceable. In addition, if we or our licensors are unsuccessful in any inventorship disputes to which we or they are subject, we may lose valuable intellectual property rights, such as exclusive ownership of, or the exclusive right to use, our owned or in-licensed patents. If we or our licensors are unsuccessful in any interference proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of our drug candidates. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical drug products. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations, or prospects. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

RISK FACTORS

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

We have entered into license agreements with third parties providing us with rights to various third-party intellectual property, including rights in patents and patent applications. For details, see “Business—Intellectual Property.” These license agreements impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our business. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may need to obtain additional licenses from our existing licensors and others to advance our research or allow commercialization of drug candidates we may develop. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our drug candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Certain of our license agreements also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products. Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe, misappropriate or violate intellectual property of the licensor that is not subject to the license agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow

RISK FACTORS

what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

Risks Relating to Our Financial Positions and Need for Additional Capital

If we do not have access to sufficient funding for the implementation of our strategies and other aspects of our business, our business prospects could be affected.

The implementation of many aspects of our strategies will require significant funding, including:

- the expenses associated with expanding our sales and distribution network;
- the costs of drug development programs for the expansion and diversification of our portfolio;
- the funding required to consummate acquisitions and integrate acquired businesses;
- the costs and expenditures required to grow our business internationally through drug development programs for overseas markets; and
- the capital expenditure required to increase our production capacity and to upgrade and enhance our facilities.

In addition, many aspects of our general business operations have on-going funding requirements that may increase over time.

We expect that the implementation of our strategies and business plans will require us to rely in part on external financing sources. However, our ability to obtain external financing on commercially reasonable terms will depend on a number of factors, many of which are outside of our control, including our financial condition, results of operations and cash flows, the global economic conditions, industry and competitive conditions, interest rates, prevailing conditions in the credit markets and government policies on lending. If we cannot obtain sufficient external financing on commercially acceptable terms to implement our strategies and business plans as currently contemplated, we could be required to revise our strategies and business plans, which could adversely affect our business prospects.

Goodwill comprises a substantial portion of our total assets; if we determine our goodwill to be impaired, it would adversely affect our financial position.

As of September 30, 2019, RMB2,387.6 million, or 15.7%, of our total assets consisted of goodwill relating to our historical acquisitions. Our acquired goodwill primarily consisted of goodwill relating to two acquisitions, acquisition of SPL and the acquisition of Cytovance. In order to determine whether our goodwill is impaired, we are required to estimate, among other things, the expected future cash flows that we will derive from the relevant group of assets, which includes an estimation of the expected growth rate in sales of the relevant products, as well as their future gross margins and related operating expenses. In the event that our estimate of our future cash flows from any of these groups of

RISK FACTORS

assets decreases from our estimate in prior periods, we could be required to recognize an impairment loss in our consolidated statement of comprehensive income for the relevant period in an amount equal to our estimate of the reduction in value of the relevant group of assets. Please refer to “Financial Information – Significant Accounting Policies and Estimates” for further details of our accounting policies for goodwill and goodwill impairment, the estimations assumptions involved therein, and the components of our acquired goodwill during the Track Record Period.

We did not recognize impairment losses in respect of goodwill during the Track Record Period. However, our estimates of the future cash flows from the relevant assets may be susceptible to downward revision as result of factors adversely affecting the global pharmaceutical industry generally, including general decreases in growth rates and margins, as well as factors specific to our business’ growth rates, margins and operating expenses. Moreover, since each of the primary acquisitions for which we are carrying goodwill as of September 30, 2019 related primarily to a single or limited number of key products, we are particularly susceptible to goodwill impairment resulting from adverse changes affecting each of these key products, including changes adversely affecting their respective growth rates, sales or margins. Such adverse changes could require us to record an impairment loss for all or a substantial portion of the goodwill we are carrying in respect of the group of assets relating to each of these key products. If we record an impairment loss as a result of these or other factors, it would adversely affect our financial position for the relevant period.

Changes in market interest rates may have a significant impact on our financial condition.

Our interest income generated from bank borrowings as well as the interest we pay on our indebtedness are affected by market interest rates. High volatility in market interest rates will directly affect our net interest margin, and in turn affect our profitability and financial condition. Fluctuations in market interest rates are subject to various factors beyond our control, such as the regulatory framework of the banking and financial sectors in the PRC and the domestic and international economic and political environments.

A significant amount of our bank borrowings and interest-bearing liabilities are denominated in RMB, therefore we are affected by the fluctuations in the RMB interest rate. Historically, the PBOC has adjusted its benchmark interest rates for many times. For example, the PBOC reduced its benchmark rate five times in 2015, resulting in a decrease in the one-year benchmark lending rate from 5.60% on January 1, 2015 to 4.35% on December 31, 2015. Adjustments to the benchmark interest rates could affect the average yield of our interest-earning assets and the average cost of our interest-bearing liabilities to different extents. Any such adjustments or changes in market interest rates may cause our interest expenses to increase at a faster rate than our interest income, and thus reducing our net interest spread and net interest margin, which, in turn, could adversely affect our financial condition and results of operations. During the Track Record Period, we hedged part of our interest rate risk through interest rate swaps. However, there is no assurance that these interest rate swaps or other hedging measures we use for mitigating the interest rate risk will always be effective.

Fluctuation of the fair value of our investments may adversely affect our financial position

We have strategically invested in a number of biotech companies which focus on research and development of innovative drugs with significant growth potential or cutting edge technologies that we believe will advance the healthcare industry. If the fair value of our investments were to fluctuate, our results of operations may be materially and adversely affected. Such fluctuations are primarily

RISK FACTORS

reflected by changes in our equity investment designed at fair value through other comprehensive income, our financial assets at fair value through profit or loss and our derivative financial instruments. As of December 31, 2017, 2018 and September 30, 2019, our equity investments designed at fair value through other comprehensive income amounted to RMB550.4 million, RMB608.8 million and RMB649.8 million, respectively. As of December 31, 2017, 2018 and September 30, 2019, our financial assets at fair value through profit or loss were RMB1,255.0 million, RMB1,197.7 million and RMB1,603.8 million, respectively. As of December 31, 2017, 2018 and September 30, 2019, our derivative financial instruments amounted to RMB43.2 million, RMB77.2 million and RMB6.8 million, respectively.

Risks Relating to Our General Operations

We operate in a highly competitive environment, and we may not be able to compete effectively against current and future competitors.

We operate in a highly competitive environment. For the reasons discussed in this section below and other possible reasons, we may not be able to compete effectively against current and future competitors. Our inability to compete effectively could result in decrease of sales, reduction of price and loss of market share, any of which could have a material adverse effect on our results of operations and profit margins.

Our finished doses products compete with other similar products or treatments for which our products may be indicated. Our pharmaceutical products compete with a dozen other similar products in the EU and U.S. markets, including products marketed by both multinational and domestic companies. Some of these competing products have experienced rapid growth in recent years, particularly in lower-tier markets. While many of our products are the top seller worldwide, other companies may enter this market and exert competitive pressure.

The global heparin sodium API market is highly concentrated with the major suppliers based in China. The top five players in total accounted for 89.0% of the market share in 2018 with our sales in 2018 accounting for the largest market share. Sales of the second largest supplier accounted for 21.3% of the total market share. Notwithstanding our leading market share position, faced with the increasing costs of production and limitations in supply of porcine small intestines as a result of the African swine flu fever, in order for us to continue maintaining our leading position, we must continue to control our production costs, strengthen our quality control efforts, further consolidate our control over traceable heparin raw materials as well as expand our efforts in sourcing heparin raw materials. If we fail to do so, we may lose our bargaining power and our competitors will be in a position to obtain a larger market share than us. If we are unable to maintain our leading market position, our business, financial condition, results of operations and prospects may be materially and adversely affected.

The biotechnology and pharmaceutical industries are characterized by rapid changes in technology, constant enhancement of industrial know-how and frequent emergence of new products. Future technological improvements and continual product developments in the pharmaceutical market may render our existing products obsolete or decrease our viability and competitiveness. Therefore, our future success will largely depend on our ability to improve our existing products and develop new and competitively priced products which meet the requirements of the constantly changing market. If we fail to introduce new or improved products, or if our new or improved products do not achieve adequate market acceptance, our business prospects may be materially and adversely affected.

RISK FACTORS

Many of our competitors, including foreign pharmaceutical companies and large state-owned pharmaceutical companies, may have substantially greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we have. Certain of our competitors may be actively engaged in research and development in areas where we have products or where we are developing drug candidates or new indications for our existing products. Other companies may discover, develop, acquire or commercialize products more quickly or more successfully than we do. There may also be significant consolidation in the pharmaceutical industry among our competitors, or alliances developed among competitors that may rapidly acquire significant market share. If we fail to effectively compete with our competitors or adjust to structural changes in the biotechnology and pharmaceutical industries, our operations and profitability may be materially and adversely affected.

Our success depends on our key senior management members and our ability to attract, train, motivate and retain highly skilled scientists and other technical personnel

We are dependent on our senior management to manage our business and operations, and on our key research and development personnel to develop new products, technologies and applications and to enhance our existing products. In particular, we rely substantially on our founders including our chairman of the Board, general manager and deputy general manager who are seasoned biochemists with solid scientific background as well as strategic insight to manage our operations. Our success also depends on our team of scientists and other technical personnel and their ability to keep pace with cutting-edge technologies and developments in pharmaceutical industry and develop new products.

We compete for qualified personnel with other pharmaceutical and biotechnology companies, universities and research institutions. The pool of suitable candidates is limited, and we may face challenges in attracting and retaining skilled scientists and other technical personnel. We may not be able to hire and retain enough skilled and experienced scientists or other technical personnel at the current level of wages. To compete effectively, we may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. In addition, we may not be successful in training our professionals to keep pace with changes in customer needs and technological and regulatory standards. Any inability to attract, motivate, train or retain qualified scientists or other technical personnel may have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects. In addition, we do not have key man life insurance on any of our senior management or key personnel. The loss of any one of them would have a material adverse effect on our business and operations.

We may be subject to product liability claims, which could expose us to costs and liabilities and adversely affect our reputation, revenue and profitability.

The development and commercialization of pharmaceutical products entail inherent risks of harm to patients and we are therefore exposed to risks associated with product liability claims as a result of developing, producing, marketing, promoting and selling pharmaceutical products in the jurisdictions in which our pharmaceutical products are marketed and sold. Such claims may arise if any of our products are deemed or proven to be unsafe, ineffective, defective or contaminated or if we are alleged to have engaged in practices such as improper, insufficient or improper labeling of products or providing inadequate warnings or insufficient or misleading disclosures of side effects. Although we are currently not aware of any existing or anticipated product liability claims with respect to our products, there can be no assurances that we will not become subject to product liabilities claims or that we will be able to successfully defend ourselves against any such claims.

RISK FACTORS

If a product liability claim is brought against us, it may, regardless of merit or outcome, result in damage to our reputation, breach of contract with our customers, decreased demand for our products, costly litigation, product recalls, loss of revenue and the inability to commercialize our products. If we are unable to defend ourselves against such claims, among other things, we may be subject to civil liability for physical injury, death or other losses caused by our products and to criminal liability and the revocation of our business licenses if our pharmaceutical products are found to be defective. In addition, we may be required to recall the relevant pharmaceutical products, suspend sales or cease sales. Other jurisdictions in which our products are, or may in the future be, sold, in particular in more developed markets including the EU and the U.S., may have similar or more onerous product liability and pharmaceutical product regulatory regimes, as well as more litigious environments that may further expose us to the risk of product liability claims. We maintain product liability insurance to cover damages that may arise from product liability claims. However, we may not be able to claim reimbursement under the product liability insurance, or our insurance coverage may not be sufficient to reimburse us, for any expenses or losses we may suffer. Even if we are able to successfully defend ourselves against any such product liability claims, doing so may require significant financial resources and the time and attention of our management. Moreover, even the allegation that our pharmaceutical products are harmful, whether or not ultimately proven, may adversely affect our reputation and sales volumes.

Any product liability insurance may be prohibitively expensive, or may not fully cover our potential liabilities. Any business disruption, litigation or natural disaster might result in substantial costs and diversion of resources. Any product liability insurance for clinical trials, when obtained, may be prohibitively expensive, or may not fully cover our potential liabilities. The inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could have a material and adverse effect on our business and results of operations.

If we become a party or are subject to litigation, legal disputes, claims, administrative proceedings or other administrative measures, such involvement may divert our management’s attention and result in costs and liabilities.

We may from time to time become a party to various litigation, legal disputes, claims, administrative proceedings or other administrative measures arising in the ordinary course of our business. On-going litigation, legal disputes, claims, administrative proceedings or other administrative measures may divert our management’s attention and consume their time and our other resources. Furthermore, any litigation, legal disputes, claims, administrative proceedings or other administrative measures which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. Negative publicity arising from litigation, legal disputes, claims, administrative proceedings or other administrative measures may damage our reputation and adversely affect the image of our brands and products. In addition, if any verdict or award is rendered against us or we are imposed any fines or penalties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business ventures or projects. Consequently, our business, financial condition and results of operations may be materially and adversely affected. On December 19, 2019, the Shenzhen Securities Regulatory Bureau of the CSRC issued a letter of caution (“**Caution Letter**”) to us which identified three issues of concern, being (i) irregular accounting treatment of our equity investment in Resverlogix; (ii) internal approval process discrepancies with respect to certain related party transactions and other related pricing policy disclosure discrepancies; and (iii) inadequate registration of insiders (the “**Concerned**

RISK FACTORS

Matters”). According to our PRC legal adviser, the Concerned Matters may give rise to certain breaches of the Administrative Measures for the Disclosure of Information of Listed Companies and the Provisions for Establishing a Registration and Administration System for Persons with Inside Information published by the CSRC. No fine or penalty has been imposed on us in respect of the above issues but we cannot guarantee that fine or penalty will not be imposed upon us in the future. Please refer to “Business—Legal Proceedings and Compliance” for more information.

If we, our employees, distributors, agents, suppliers or affiliates engage, or are perceived to engage, in misconduct or breaches, including corrupt practices or leakage of confidential information, our business or reputation could be harmed and we could be exposed to regulatory investigations, costs and liabilities.

We are subject to risks in relation to actions taken by us, our employees, distributors, agents, suppliers or affiliates that constitute violations of anti-corruption and other related laws in jurisdictions where we conduct business. There have been several instances of corrupt practices in the pharmaceutical industry recently, including, among other things, receipt of kickbacks, bribes or other illegal gains or benefits by pharmacies hospitals and medical practitioners from manufacturers, distributors, third-party promoters and retail pharmacies in connection with the prescription of pharmaceutical products. Any allegations of such behavior against us, our employees, distributors, agents or affiliates or the pharmaceutical industry in general could generate negative publicity and materially and adversely affect our reputation and business prospects.

We do not and cannot fully control the conduct of our employees, agents, distributors or suppliers or affiliates. Our employees, agents or distributors may, in their interactions with hospitals, medical institutions and medical professionals, attempt to increase the sales volume of our products through means that constitute violations of applicable anti-corruption and other related laws. If our employees, agents, or distributors engage in corrupt or other improper conduct that result in violation of applicable anti-corruption laws in respective jurisdictions, our reputation could be harmed. While we have implemented specific measures against corruption and bribery, there can be no assurance that we were or are able to entirely prevent our employees or distributors from engaging in such activities in the past or in the future. We may be held liable for actions taken by our employees or distributors, which could expose us to regulatory investigations and penalties. Actions taken by relevant regulatory authorities or courts that provide an interpretation of laws and regulations that differs from our interpretation or that adopt additional anti-bribery, anti-corruption laws and regulations could also require us to make changes to our operations. Our reputation, corporate image, and business operations may be materially and adversely affected if we, our employees, distributors or suppliers fail to comply with these measures or become the target of any negative publicity as a result of actions taken by us, our employees, distributors or affiliates, which may in turn have a material adverse effect on our results of operations and prospects.

For example, pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Purchase and Sales of Medicines (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》), which was promulgated by the NHFPC and came into effect on March 1, 2014, if we are involved in criminal, investigational or administrative procedures for commercial bribery, we will be listed in the adverse records of commercial briberies by the relevant government authorities, as a result of which our products cannot be purchased by public medical institutions or medical and health institutions receiving financial subsidies within a specific territorial scope for two years; and if we are listed in the adverse records of commercial briberies twice within five years, our products cannot be

RISK FACTORS

purchased by public medical institutions or medical and health institutions receiving financial subsidies throughout China for two years. Please refer to “Regulatory Environment” for further details of relevant PRC regulations on commercial bribes.

A small amount of our revenue was derived from countries that are targets of sanctions imposed by the United States, the European Union, Australia and other government authorities during the Track Record Period.

The U.S. and other jurisdictions or organizations, including the European Union, the Australia and United Nations, have, through executive order, passing of legislation or other governmental means, implemented measures that impose economic sanctions against such countries or against targeted industry sectors, groups of companies or persons, and/or organizations within such countries. For example, the U.S. government, through the U.S. Department of the Treasury’s Office of Foreign Assets Control (the “**OFAC**”) and the U.S. Department of State, administers and enforces economic and trade sanctions against a number of foreign countries and territories (the “**Sanctioned Countries**”), entities and individuals based on U.S. foreign policy and national security goals. The E.U. and its member states, as well as other countries, also administer and enforce sanctions. In addition, the U.S. Department of Commerce administers and enforces U.S. export controls that prohibit entities and individuals globally from exporting, reexporting or transferring export-controlled U.S. origin goods to Sanctioned Countries and/or persons without a license or authorization.

During the Track Record Period, we had sales of our products to end-user customers which were located in the Balkans (Bosnia, Croatia and Serbia), Belarus, Egypt, Iran, Tunisia and Ukraine (the “**Relevant Countries**”), each of which countries or regions is subject to or otherwise implicates certain sanctions administered by government agencies or organizations in the U.S., EU or Australia, or by the United Nations (“**International Sanctions**”). The payment obligations related to such sales were remitted through certain banks who are designated as Specifically Designated Nationals (the “**SDN Lists**”) by OFAC. During the same period, we also had deliveries of our products to destinations which included the Relevant Countries upon instructions from our customers not located in the Relevant Countries. For the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, revenue generated from sales and/or deliveries to the Relevant Countries accounted for approximately 1.05%, 0.89% and 1.95% of our total revenue, respectively. We have not been notified that any International Sanctions will be imposed on us for our sales and/or deliveries to the countries subject to International Sanctions during the Track Record Period. See “Business—Risk Management and Internal Control.”

However, we are unable to predict the interpretation or implementation of the International Sanctions with respect to any past activities by us in the Relevant Countries. There is no assurance that the U.S., EU, Australia or other relevant government agencies or organizations would not determine that we engage or have engaged in sanctionable activities targeted by the International Sanctions. If any government agencies or organizations were to determine that we engaged in sanctionable activities, we could be imposed certain sanctions, which could range from restrictions on our access to exports or bank financing to blocking of our property within the relevant jurisdictions, or other penalties and our reputation and future business prospects could be adversely affected. In addition, because sanctions programs are constantly evolving, new requirements or restrictions could come into effect, or relevant regulatory authorities may interpret current sanctions in such a manner, that might increase scrutiny on our business or result in one or more of our business activities being deemed to have violated sanctions or being sanctionable.

RISK FACTORS

We may pursue collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships, or other strategic initiatives or arrangements, which may fail to produce anticipated benefits and adversely affect our business.

As part of our business strategy, we continually pursue opportunities of collaboration, in-licensing, joint ventures, strategic alliances, or partnerships that we believe would be complementary to or promote our existing business. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, or other strategic arrangements may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology, or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all.

Furthermore, partners, collaborators or other parties to such transactions or arrangements may fail to fully perform their obligations or meet our expectations or cooperate with us satisfactorily for various reasons, including risks or uncertainties related to their business and operations. There may be conflicts or other collaboration failures and inefficiencies between us and the other parties.

Such transactions or arrangements may also require or stand in need of actions, consents, approvals, waivers, participation or involvement of various degrees from third parties, such as regulators, government authorities, creditors, licensors or licensees, related individuals, suppliers, distributors, shareholders, or other stakeholders or interested parties. We may not obtain such required or desired actions, consent, approval, waiver, participation or involvement on a timely basis, on acceptable terms, or at all.

These collaboration, investments and transactions may also present financial, managerial and operational challenges, including:

- diversion of management attention from managing our existing business;
- difficulty with integrating businesses, operations, personnel, financial and other systems;
- lack of experience in operating in the geographical or product markets of the acquired business;
- increased levels of debt potentially leading to associated reduction in ratings of our debt securities and adversely impact our various financial ratios; and
- the requirement that we periodically review the value at which we carry our investments and, in the event we determine that the value at which we carry an investment has been impaired, the requirement to record a non-cash impairment charge, which charge could substantially affect our reported earnings in the period of such charge, would negatively impact our financial ratios and could limit our ability to obtain financing in the future.

We intend to grow our business in part through acquisitions; if we fail to successfully complete acquisitions or enhance post-acquisition performances in the future, it could have an adverse effect on our business prospects.

Our acquisition strategy has significantly contributed to our historical growth and expansion into new therapeutic areas. For instance, we acquired SPL in 2014 and Cytovance in 2015 to strengthen our leading position in the global heparin market and expanded our business to CDMO service industry. We also acquired Topknow in 2018 to enhance our vertical integration on the heparin

RISK FACTORS

industry value chain. We intend to continue to accelerate our business growth through selective acquisitions of suitable pharmaceutical companies. However, our ability to consummate acquisitions is subject to a number of risks and uncertainties, including that:

- we are unable to identify suitable acquisition targets and reach agreement on acceptable terms;
- we do not have access to financing for acquisitions on acceptable terms;
- we fail to obtain the governmental approvals and third party consents necessary to consummate any proposed acquisition; and
- increasingly intense competition for attractive acquisition targets makes the consummation of acquisitions on commercially acceptable terms increasingly difficult.

Even if we are able to consummate acquisitions, our ability to successfully grow our business through such acquisitions remains subject to further risks and uncertainties, including that:

- the acquired businesses do not provide us with the intellectual property rights, technology, R&D capability, production capacity or sales and marketing infrastructure we had anticipated;
- the acquired businesses are subject to unforeseen liabilities;
- we are unable to successfully integrate the acquired businesses in order to achieve the expected synergies with our own business or to increase the efficiencies of the acquired businesses in the manner we contemplated;
- we are unable to effectively manage our enlarged business operations, or manage acquired businesses that may operate in new therapeutic areas, markets, regulatory environments or geographic regions; and
- the acquired businesses do not generate the revenue and profitability we had anticipated.

To the extent we are unable to consummate acquisitions and successfully grow our business through such acquisitions, our ability to achieve future growth of our business consistent with our historical growth rate will more heavily depend on the organic growth of our business, including new product development through internal R&D and in-licensing of products, than it has in the past, and there can be no assurances we will be able to achieve similar growth rates organically. Consequently, if we fail to successfully complete acquisitions in the future, it could have an adverse effect on our business prospects.

Moreover, the process of seeking and consummating acquisitions and integrating and managing acquired businesses, whether or not they are successful, may divert our resources and management attention from our existing businesses and impair our ability to successfully manage and grow our business organically.

We may not be successful in obtaining or maintaining necessary rights for our development pipeline through acquisitions and in-licenses.

Because our programs may involve additional drug candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to

RISK FACTORS

acquire or in-license any compositions, methods of use, or other intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or drug candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects for growth.

We may not be able to realize our anticipated investment returns from our investments.

From time to time, we may make strategic investments in (a) investment targets that fit into and support our existing value chain and (b) cutting edge technologies that we believe will advance the healthcare industry, both of which would allow us to further access a wider variety of participants in the healthcare ecosystem while maintaining our position at the forefront of science.

Our investees are primarily growth companies still in the development stages, such as HighTide and Kymab. The performance of our invested companies, including but not limited to the commercial success of their drug candidates, will affect our cash flow and results of operation. Given that they are growth companies still in the development stages, such companies may have a higher failure rate. These companies may have relatively short operating histories and are in need of a significant amount of capital to grow their business as well as to gain traction. They may not be able to successfully complete clinical development, obtain regulatory approval or commercialize their drug candidate, or experience delays in doing so. Moreover, they may not have sufficient financial resources to meet their financial obligations, particularly during economic slowdowns. Our investments at this stage of a company’s development are therefore speculative and entail a number of risks. Accordingly, we may fail to realize our anticipated returns on investments in such investees, and may even experience a total loss on such investments. Furthermore, the due diligence process that we undertake in connection with an investment and may not guarantee that our investments would be successful. Please refer to “History, Development and Corporate Structure” for more information.

We also have limited influence over the management and operations of our investees when we acquire minority interest in such companies. We are subject to the risk that the majority shareholders or the management of our investees may act in a manner that does not serve our interests. The general operational risks, such as inadequate or failed internal control of our investees may also expose our investments to risks. Furthermore, our investees may fail to abide by their agreements with us, for which we may have limited or no recourse. If any of the foregoing were to occur, our business, reputation, financial condition and results of operations could be materially and adversely affected.

In addition, our investments in our investees are generally illiquid. Our ability to realize our anticipated investment returns will depend on the investee’s ability to complete a domestic or overseas initial public offering or trade sale, which in turn relies, among other things, the business and financial performance of our investees. If any of our investees were to go bankrupt, such investees’ debts would

RISK FACTORS

first be paid off to its creditors and any remaining assets would be divided among the shareholders. We cannot assure you that there would be any remaining assets for the shareholders after the repayment of debts and we could lose all the resources and expenses we contributed to such entity. Any such event could materially and adversely affect our business, financial condition and results of operations.

We plan to expand our international business. If we are unsuccessful in our plans, it could have an adverse effect on our business prospects.

We sell finished dose pharmaceutical products and APIs to certain overseas markets including the EU and the U.S. and plan to further expand our international business. For further information, see “Business – Sales and Marketing”. However, further expansion in overseas markets may expose us to risks and uncertainties, including but not limited to:

- risks associated with dealing with regulatory regimes, regulatory bodies and government policies with which we might be unfamiliar, in order to obtain overseas permits, licenses and approvals necessary to manufacture or import, market and sell products in or to overseas jurisdictions;
- risks associated with commercializing our products in new markets where we have limited experience with the local market dynamics and no existing or developed sales, distribution and marketing infrastructure;
- risks associated with local unions and employment disputes;
- risks associated with higher costs for new product development and relying on potential overseas partners and/or their distribution network for the development, commercialization, marketing and distribution of our products;
- increased risk of product liability litigation and regulatory scrutiny arising from the marketing and sale of pharmaceutical products in overseas markets and the costs incurred dealing with such procedures, as well as our ability to obtain insurance to adequately protect us from any resulting liabilities; and
- risks associated with compliance with local tax laws and regulations including but not limited to timely filing of tax returns and tax payment, and disputes or disagreements with local tax authorities with respect to matters including but not limited to calculation of tax liabilities and preferential tax treatments.

Specifically, to expand our sales of enoxaparin sodium injection into the U.S. market, we have established sales arrangement with one customer, and thus our sales in the U.S. will largely depend on its success in the commercialization of its enoxaparin sodium injection. If our customer fails to successfully market and sell its enoxaparin sodium injection products in the U.S., our sales volumes and results of operations could be adversely affected.

Our plans may require significant investment but may fail to generate the level of returns we expected. If we are unable to expand our international business effectively or at all, our business prospects may be adversely affected.

If we fail to effectively manage our anticipated growth or execute on our growth strategies, our business, financial condition, results of operations and prospects could suffer.

Our growth strategies include but not limited to increasing our penetration into the global market, maximize the commercial value for our new drugs in China, expanding our drug discovery,

RISK FACTORS

development and manufacturing capacity for our CDMO business and pursuing strategic acquisitions. For more information, see “Business—Our Strategies”. Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing our growth strategies will require, among other things, our ability to continue to innovate and develop advanced technology in the highly competitive global pharmaceutical market, effective coordination and integration of our facilities and teams across different sites, successful hiring and training of personnel, effective cost control, sufficient liquidity, effective and efficient financial and management control, increased marketing and customer support activities, effective quality control, and management of our suppliers to leverage our purchasing power. Any failure to execute our growth strategies or realize our anticipated growth could adversely affect our business, financial condition, results of operations and prospects.

Increased labor costs could negatively affect our ability to operate efficiently and have a material and adverse impact on our revenues and profitability.

The cost of labor in the PRC has been steadily increasing over the past years as a result of inflation, government-mandated wage increases and other changes in PRC labor laws, as well as competition for talents and qualified employees among pharmaceutical companies. Unless we are able to pass on these increased labor costs to our customers by increasing the prices of our products and services, our financial condition and results of operations may be adversely affected. Many aspects of our strategies and business growth may require us to have additional employees. We may also have additional employees as a result of acquisitions or organic growth of our business. If we implement such strategies but fail to realize the benefits and efficiencies we anticipate, we may be unable to offset the corresponding increases in our staff costs, which adversely affect our revenues and profitability.

We may fail to sufficiently and promptly respond to rapid scientific and technological changes, clinical demand and market changes in the healthcare industry.

The global healthcare industry is characterized by rapid advances in science and technology and the continuous emergence of new treatment options. Our future success partially depends on our ability to launch new products or services that meet evolving market demands, in particular, new drugs, that are effective in treating new diseases and illnesses and CDMO services. We cannot assure you that we will be able to respond to emerging or evolving trends by improving our product portfolio and services in a timely manner, or at all.

In addition, clinical demand for healthcare products may change rapidly. Our success depends on our ability to anticipate product offering lead-time and demand, identify customer preferences and adapt our products and services to these preferences. We may need to adjust our research and development plan, production scale and schedule, product portfolio, and inventory levels based on customer demand, sales trends and other market conditions. There can be no assurance that we will be able to sufficiently and promptly respond to changes in clinical demand and purchasing patterns in the future, and such failure may have a material and adverse effect on our business, financial condition, results of operations and profitability.

RISK FACTORS

If an improved version of an originator product is developed by the originator company or if the market acceptance for the treatment regimen involving the originator product significantly declines, sales or potential sales of our biosimilar products may suffer.

Originator companies may develop improved versions of an originator product as part of a life cycle extension strategy and may obtain regulatory approval of the improved version under a new or supplemental application filed with the applicable regulatory authority. Should the originator company succeed in obtaining an approval of an improved biological product, it may capture a significant share of the originator product market in the applicable jurisdiction and thereby significantly reduce the market for our potential biosimilar drugs and drug candidates.

Moreover, originator products face competition as technological advances are made, or as new products are introduced, that may offer patients a more convenient form of administration or increased efficacy. As new products are approved that compete with the originator products, sales of the originator products and in turn, our biosimilars to such originators, may be significantly and adversely impacted. Any of the above developments could have a material adverse effect on our business, financial condition and results of operations.

If our internal risk management and control system is not adequate or effective, and if it fails to detect potential risks in our business as intended, our business, financial condition and results of operations could be materially and adversely affected.

As of the Latest Practicable Date, we have an internal control system in place to monitor and control potential risk areas relevant to our business operations. In connection with the [REDACTED], we have examined our internal control system and made certain enhancements where appropriate, in order to satisfy our internal control requirements after the completion of the [REDACTED]. However, due to the inherent limitations in the design and implementation of our internal control system, our internal control system may not be sufficiently effective in identifying, managing and preventing all risks if external circumstances change substantially or extraordinary events take place.

Further, integration of various business operations from potential future acquisitions may give rise to additional internal control risks that are currently unknown to us, despite our efforts to anticipate such issues. If our internal control system fails to detect potential risks in our business as intended, or is otherwise exposed to weaknesses and deficiencies, our business, financial condition and results of operations could be materially and adversely affected.

Our risk management and internal controls also depend on effective implementation by our employees. There can be no assurance that such implementation by our employees will always function as intended, or such implementation will not be subject to human errors, mistakes or intentional misconduct. If we fail to implement our policies and procedures in a timely manner, or fail to identify risks that affect our business with sufficient time to plan for contingencies for such events, our business, financial condition and results of operations could be materially and adversely affected, particularly with respect to the maintenance of our relevant approvals and licenses granted by the relevant authorities.

If our brands fail to maintain a positive reputation, many aspects of our business and our business prospects could be adversely affected.

We believe that market awareness and recognition of our brands, particularly Hepalink, have contributed significantly to the success of our business. We also believe that maintaining and

RISK FACTORS

enhancing these brands is critical to maintaining our competitive advantage. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. In addition, we may expand our network of distributors and third-party promoters to increase our marketing efforts. It may be difficult to effectively manage our brand reputation as we have relatively limited control over these third parties. If we are unable to maintain or enhance our brand recognition and increase awareness of our products, or if we incur excessive marketing and promotion expenses to do so, our business and results of operations may be materially and adversely affected.

If we suffer failure or disruption in our information systems, our ability to effectively manage our business operations could be adversely affected.

We make use of information systems to obtain, process, analyze and manage data. We use these systems to, among other things, monitor the daily operations of our business, maintain operating and financial data, manage our customer documentation as well as manage our production operations and quality monitoring systems. Any system damage or failure that interrupts data input, retrieval or transmission or increases service time could disrupt our normal operations. There can be no assurance that we will be able to effectively handle a failure of our information systems, or that we will be able to restore our operational capacity in a timely manner to avoid disruption to our business. The occurrence of any of these events could adversely affect our ability to effectively manage our business operations. In addition, if the capacity of our information systems fails to meet the increasing needs of our expanding operations, our ability to expand may be constrained.

We could be exposed to risks related to our management of medical data.

Clinical trials for our drug candidates routinely collect and maintain medical data treatment records and other personal details of enrolled subjects. Laws and regulations of the various jurisdictions in which we conduct our clinical trials generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. Such institutions and personnel will be liable for damage caused by divulging the subjects’ private or medical records without consent. We take measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials, including encrypting such information in our information technology system so that it cannot be viewed without proper authorization, and setting internal rules requiring our employees to maintain the confidentiality of our subjects’ medical records. However, these measures may not be always effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, the clinical trials frequently also involve professionals from third party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure to protect the confidentiality of subjects’ medical records and personal data, or any restriction on or liability as a result of, our use of medical data, could have a material adverse effect on our business, financial condition and results of operations.

We may be restricted from transferring our scientific data abroad or using human genetic resources collected in China.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “**Scientific Data Measures**”), which

RISK FACTORS

provide a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term state secret is not clearly defined, if and to the extent our R&D of medical drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China). In addition, on July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) (“**Service Guide**”), which became effective on October 1, 2015. According to the Service Guide, the sampling, collection or research activities of human genetic resources through clinical trials shall be required to be filled with the China Human Genetic Resources Management Office through the online system. On May 28, 2019 the State Council promulgated the Regulations of PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) which became effective on July 1, 2019 (the “**Human Genetic Resources Regulation**”). The Human Genetic Resources Regulation stipulates that collecting human genetic resources of China’s important genetic families and specific regions, or collecting those human genetic resources in such categories and quantities as prescribed by the administrative department for science and technology under the State Council, preserving China’s human genetic resources and providing the basic platform for scientific research, utilisation of China’s human genetic resources for international cooperation in scientific research, as well as transporting China’s materials of human genetic resources abroad shall be subject to the approval of the administrative department for science and technology under the State Council. If we are unable to obtain necessary approvals or comply with the regulatory requirements in a timely manner, or at all, our R&D of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If the relevant government authorities consider the transmission of our scientific data or collection and usage of human genetic resources to be in violation of the requirements under the applicable PRC laws and regulations, we may be subject to fines and other administrative penalties imposed by those government authorities.

Our business benefits from certain preferential tax and financial incentives, the expiration of or changes to which could adversely affect our profitability.

We currently benefit from certain preferential tax treatments, as well as tax concessions in relation to our research and development costs. In particular, Our Company and Shenzhen Techdow have benefited from a preferential PRC income tax rate of 15%, compared with the 25% income tax rate generally applicable to PRC tax resident enterprises under the EIT Law. Our Company and Shenzhen Techdow’s qualification as a High and New Technology Enterprise will expire in November 2021 and October 2020, respectively. We plan to renew our and Shenzhen Techdow’s qualification in due course.

The current or future preferential tax treatments, tax concessions, tax allowances and financial incentives applicable to our Company or our subsidiaries may be changed, terminated, or otherwise become unavailable due to many factors, including changes in government policy or administrative

RISK FACTORS

decisions by relevant government authorities. For example, on November 27, 2014, the State Council issued the Notice on Cleaning Up and Regulating Taxation and Other Preferential Policies (《國務院關於清理規範稅收等優惠政策的通知》) (the “**Preferential Policies Notice**”), which required local governments and government agencies to review and clean up the preferential policies they have promulgated, and to abolish preferential policies that are in violation of state laws and regulations. On May 10, 2015, the State Council issued a notice suspending the clean-up of preferential policies set out in the Preferential Policies Notice until further notice. In 2017, 2018 and the nine months ended September 30, 2019, we recognized income from government grants in the amounts of RMB42.5 million, RMB33.8 million and RMB28.0 million, respectively. Due to the Preferential Policies Notice and further potential changes in government policies, we cannot be certain of the level of government grants we will receive in the future. Our post-tax profitability and cash flows may be adversely affected as a result of one or more of these or other factors.

We may be subject to additional tax liabilities in connection with our transfer pricing arrangements, which could have adverse impacts on our financial condition.

During the Track Record Period, we carried out certain intra-group transactions, mainly intra-group sales of finished goods. Our profit allocation and income tax positions in the jurisdictions in connection with such transfer pricing arrangements are subject to the interpretations by relevant tax authorities of applicable tax law as well as applicable rules and regulations with respect to transfer pricing in these jurisdictions. Significant judgment and the use of estimates are required in determining our profit allocation and income tax positions in terms of our transfer pricing arrangements. If a competent tax authority of a relevant jurisdiction determines that the transfer prices and the transaction terms that we have adopted as well as our historical income tax provisions and accruals are not appropriate, such authority may require the relevant subsidiaries to re-assess the transfer prices and re-allocate the income or adjust the taxable income. If we are considered not to be in compliance with the applicable transfer pricing rules and regulations, the relevant tax authority may also have the power to order us to pay all outstanding tax and statutory interest or fines.

Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may affect our reputation and, as a result, our business, financial condition and results of operations may be negatively affected.

We, our Shareholders, Directors, officers, employees and business partners may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our employees and business partners were not-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity, and may not be able to diffuse them to the satisfaction of our investors and customers.

Changes in international trade policies and barriers to trade or the emergence of a trade war may have an adverse effect on our business and expansion plans.

International market conditions and the international regulatory environment have historically been affected by competition among countries and geopolitical frictions. Changes to trade policies, treaties and tariffs of the jurisdictions in which we operate, or the perception that these changes could occur, could adversely affect the financial and economic conditions of the jurisdictions in which we

RISK FACTORS

operate, as well as our overseas expansion, our financial condition and results of operations. The U.S. administration under President Donald J. Trump has advocated more stringent restrictions and policies on international trade and significantly increased tariffs on certain goods imported into the U.S., particularly from China. Despite that the U.S. and China reached a partial trade deal in December 2019, under which the U.S. agreed to cancel some new tariffs and reduce rates for other duties in exchange for China to purchase more U.S. agricultural products and to make changes regarding intellectual property and technology, the trade tension between China and the U.S. may be reinstated. Any escalation in trade tensions or a trade war, or the perception that such escalation or trade war could occur, may have tremendous negative impact on the economies of not merely the two countries concerned, but the global economy as a whole.

We face risks related to natural disasters, health epidemics and other outbreaks of contagious diseases.

Our business could be adversely affected by natural disasters or outbreaks of epidemics. These natural disasters, outbreaks of contagious diseases, and other adverse public health developments in China or any other market in which we operate and conduct business could severely disrupt our business operations by damaging our network infrastructure or information technology system or impacting the productivity of our workforce. The outbreak of any severe epidemic disease, such as avian flu, H1N1 flu, SARS or coronavirus, may disrepute our production process, which could negatively affect our financial condition, operational results and future prospects.

RISKS RELATED TO CONDUCTING BUSINESS IN CHINA

Adverse changes in political, economic and other policies of the Chinese government could have a material adverse effect on the overall economic growth of China, which could reduce the demand for our products; and could otherwise materially and adversely affect our business, operations or competitive position.

We are a China-based pharmaceutical company. Accordingly, our business, financial condition, results of operations and prospects are significantly affected by economic, political and legal developments in China.

The Chinese economy differs from the economies of most developed countries in many respects, including, but not limited to:

- the extent of government involvement;
- the level of development;
- the growth rate;
- the control of foreign exchange;
- the allocation of resources;
- an evolving regulatory system; and
- the level of transparency in the regulatory process.

Although China has experienced rapid economic growth over the past decades, its continued growth has slowed since the second half of 2008. There is no assurance that future growth will be sustained at similar rates or at all.

RISK FACTORS

The Chinese government implements various measures intended to encourage economic growth and guide the allocation of resources. These measures may include differential policies towards specific groups of pharmaceutical companies, such as promotion of traditional medicines or state-owned companies, or investments in biopharmaceutical companies competing with us, which may have an adverse effect on us. Our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are applicable to us. Further, any adverse change in the economic conditions or government policies in China could have a material adverse effect on overall economic growth and the level of healthcare investments and expenditures in China, which in turn could lead to a reduction in demand for our products and consequently have a material adverse effect on our business.

The Chinese economy has been transitioning from a planned economy to a more market-oriented economy. Although the Chinese government has implemented reform measures allowing for an increasingly market-based economy, reduced state ownership of productive assets and established sound corporate governance practices in business enterprises, a substantial portion of the productive assets in China is owned by the Chinese government. The continued control of these assets and other aspects of the national economy by the Chinese government could materially and adversely affect our business. The Chinese government also exercises significant control over Chinese economic growth through the allocation of resources, controlling payment of foreign currency-denominated obligations, setting monetary policy and providing preferential treatment to particular industries or companies.

Changes and developments in China’s economic, political and social conditions could adversely affect our financial condition and results of operations. For example, the pharmaceutical market may grow at a slower pace than expected, which could adversely affect our business, financial condition or results of operations.

There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.

A significant portion of our operations are conducted in China, and are governed by PRC laws, rules and regulations. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In 1979, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past three decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the non-binding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

RISK FACTORS

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

You may experience difficulties in effecting service of legal process and enforcing judgments against us and our management.

We are incorporated under the laws of the PRC. A majority of our Directors, Supervisors and senior management personnel also reside in the PRC, and substantially all of their assets are located in the PRC. As a result, it may not be possible to effect service of process within the U.S. or elsewhere outside the PRC upon our Directors, Supervisors and senior management personnel, including with respect to matters arising under the U.S. federal securities laws or applicable state securities laws.

On July 14, 2006, the Supreme People’s Court of the PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned* (關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排) (the “Arrangement”). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a PRC court is expressly selected as the court having sole jurisdiction for the dispute. Therefore, it is not possible to enforce a judgment rendered by a Hong Kong court in the PRC if the parties in dispute have not agreed to enter into a choice of court agreement in writing. Although the Arrangement became effective on August 1, 2008, the outcome and effectiveness of any action brought under the Arrangement remain uncertain. In addition, the PRC has not entered into a treaty for the reciprocal recognition and enforcement of court judgments with the U.S., the United Kingdom, Japan and most other western countries, and Hong Kong has no arrangement for the reciprocal enforcement of judgments with the U.S.. As a result, recognition and enforcement in the PRC or Hong Kong of judgment of a court in the U.S. or any other jurisdictions mentioned above in relation to any matter that is not subject to a binding arbitration provision may be difficult or impossible.

We are a PRC enterprise and we are subject to PRC tax on our global income, and any dividends paid to [REDACTED] and gains on the sale of our Shares by our [REDACTED] are subject to PRC tax. Under the EIT Law of the PRC, our offshore subsidiaries may therefore be subject to PRC income tax on their worldwide taxable income.

As a PRC-incorporated company, under applicable PRC tax laws, we are subject to a tax of 25% on our global income. Under applicable PRC tax laws, regulations and statutory documents, non-PRC resident individuals and enterprises are subject to different tax obligations with respect to dividends received from us or gains realized upon the sale or other disposition of our Shares.

RISK FACTORS

Non-PRC individuals are generally subject to PRC individual income tax under the Individual Income Tax Law of the PRC (中華人民共和國個人所得稅法) with respect to PRC source income or gains at a rate of 20% unless specifically exempted by the tax authority of the State Council or reduced or eliminated by an applicable tax treaty. We are required to withhold related tax from dividend payments. Pursuant to applicable regulations, domestic non-foreign-invested enterprises issuing shares in Hong Kong may generally, when distributing dividends, withhold individual income tax at the rate of 10%. However, withholding tax on distributions paid by us to non-PRC individuals may be imposed at other rates pursuant to applicable tax treaties (and up to 20% if no tax treaty is applicable) if the identity of the individual holder of H shares and the tax rate applicable thereto are known to us. There is uncertainty as to whether gains realized upon disposition of H shares by non-PRC individuals are subject to PRC individual income tax.

Non-PRC resident enterprises that do not have establishments or premises in the PRC, or that have establishments or premises in the PRC but their income is not related to such establishments or premises are subject to PRC EIT at the rate of 10% on dividends received from PRC companies and gains realized upon disposition of equity interests in the PRC companies pursuant to the EIT Law and other applicable PRC tax regulations and statutory documents, which may be reduced or eliminated under special arrangements or applicable treaties between the PRC and the jurisdiction where the non-resident enterprise resides. Pursuant to applicable regulations, we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our Shares (including HKSCC Nominees). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, payment of any such refund will be subject to the PRC tax authorities’ verification. As of the Latest Practicable Date, there were no specific rules on how to levy tax on gains realized by non-resident enterprise holders of H shares through the sale or transfer by other means of H shares.

There remains significant uncertainty as to the interpretation and application of the relevant PRC tax laws by the PRC tax authorities, including whether and how individual income tax or EIT on gains derived by holders of our Shares from their disposition of our Shares may be collected. If any such tax is collected, the value of our Shares may be materially and adversely affected.

Under the EIT Law, an enterprise established outside the PRC with “de facto management bodies” within China is considered a “resident enterprise,” meaning that it is treated in a manner similar to a Chinese enterprise for PRC EIT purposes. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties” of the enterprise. In addition, the Notice Regarding the Determination of Chinese- Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal, and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights. State Administration of Taxation of the PRC, or SAT, has subsequently provided further guidance on the implementation of Circular 82.

RISK FACTORS

As substantially all of the operational management of our Company is currently based in the PRC, our offshore subsidiaries may be deemed to be “PRC resident enterprises” for the purpose of the EIT Law. If our offshore subsidiaries are deemed PRC resident enterprises, they could be subject to the EIT at 25% on our global income, except that the dividends they receive from our PRC subsidiaries may be exempt from the EIT to the extent such dividend income constitutes “dividends received by a PRC resident enterprise from its directly invested entity that is also a PRC resident enterprise.” It is, however, unclear what type of enterprise would be deemed a “PRC resident enterprise” for such purposes. The EIT on our subsidiaries’ global income could significantly increase our tax burden and adversely affect our cash flows and profitability.

Payment of dividends is subject to restrictions under PRC law and regulations.

Under PRC law and regulations, we may only pay dividends out of distributable profits. Distributable profits are our after-tax profits as determined under PRC GAAP or IFRS, whichever is lower, less any recovery of accumulated losses and appropriations to statutory and other reserves that we are required to make. As a result, we may not have sufficient or any distributable profit to enable us to make dividend distributions to our Shareholders, including in periods for which our financial statements indicate we are profitable. Any distributable profit not distributed in a given year is retained and available for distribution in subsequent years.

Moreover, our operating subsidiaries and joint ventures in the PRC may not have distributable profit as determined under PRC GAAP. Accordingly, we may not receive sufficient distributions from our subsidiaries and joint ventures for us to pay dividends. Failure by our operating subsidiaries and joint ventures to pay us dividends could adversely impact our ability to make dividend distributions to our Shareholders and our cash flow, including periods in which we are profitable.

Future changes in laws, regulations or enforcement policies in China could adversely affect our business.

Laws, regulations or enforcement policies in China, including those regulating healthcare and the pharmaceutical industry, are evolving and subject to frequent changes. Currently, the PRC pharmaceutical industry is heavily regulated and many aspects of our business depend on the receipt of the relevant government authorities’ approvals and permits. Further, regulatory agencies in China may periodically, and sometimes abruptly, change their enforcement practices. Therefore, prior enforcement activity, or lack of enforcement activity, is not necessarily predictive of future actions. Any enforcement actions against us could have a material adverse effect on us. Any litigation or governmental investigation or enforcement proceedings in China may be protracted and may result in substantial costs and diversion of resources and management attention, negative publicity, and damage to reputation. In addition, such changes may be applied retroactively and thus subject our business and operations to increased uncertainties and risks.

For example, on November 11, 2015, the NMPA issued Certain Policies in relation to the Review and Approval of Drug Applications (關於藥品註冊審評審批若干政策的公告) (the “NMPA Notice No. 230 (2015)”), which set out ten key points to be applied in the process of reviewing and approving drug applications and clinical trials, with an emphasis on the accuracy of clinical trials data, effectiveness of the drug and consistency between the original innovative version and the generic version of a product as demonstrated in comparability studies. Our future drug applications are now subject to stricter approving standard.

RISK FACTORS

Since late 2015, the PRC regulatory authority has promulgated a series of regulations setting forth the requirements of consistency evaluation for generic drugs, including the Opinion of the General Office of the State Council on Conducting the Consistency Evaluation of the Quality and Efficacy of Generic Drugs (《國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見》), the Announcement on Relevant Matters Concerning the Consistency Evaluation for Quality and Efficacy of Generic Drugs (No. 100 (2017)) (《國家食品藥品監督管理總局關於仿製藥質量和療效一致性評價工作有關事項的公告》) and the Announcement on the Relevant Matters Concerning the Quality and Efficacy Consistency Evaluation of Generic Drugs (No. 102 (2018)) (《國家藥品監督管理局關於仿製藥質量和療效一致性評價有關事項的公告》), which set forth timelines for completion of consistency evaluation and consequences for failure to timely complete the evaluation. For more information, see “Regulatory Environment”.

Any failure to comply with the PRC Social Insurance Law and the Regulation on the Administration of Housing Provident Funds may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

According to the Social Insurance Law and the Regulation on the Administration of Housing Provident Funds and other applicable PRC regulations, any employer operating in China must open social insurance registration accounts and housing provident fund registration accounts, and contribute social insurance premium and housing provident fund for its employees. Any failure to make timely and adequate contribution of social insurance premium and housing provident fund for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such unpaid social insurance premium and housing provident fund within a specified period of time, and the competent authority may further impose fines or penalties. As of September 30, 2019, the total payable amount of social insurance premium and housing provident fund was approximately RMB36.9 million. As of the Latest Practicable Date, we have not received any order of correction or any fines or penalties from the competent authority and also have not received any complaint or labor arbitration application from any of our employees, in each case as a result of any such failure. However, the competent authority could require us to rectify any non-compliance by making contribution of unpaid social insurance premium and housing provident fund or impose fine or penalty related thereto. Please refer to “Business—Legal Proceedings and Compliance” for more information.

Fluctuations in exchange rates may result in foreign currency exchange losses and may have a material adverse effect on your [REDACTED].

The change in the value of the RMB against the Hong Kong dollar and other currencies may fluctuate and is affected by, among other things, changes in China’s political and economic conditions. For instance, in the PRC from 1995 until July 2005, the conversion of the RMB into foreign currencies, including the Hong Kong dollar and U.S. dollar, has been based on fixed rates set by the PBOC. The PRC government, however, has, with effect from July 21, 2005, reformed the exchange rate regime by moving into a managed floating exchange regime based on market supply and demand with reference to a basket of currencies. On July 21, 2005, this revaluation resulted in the RMB appreciating against the U.S. dollar and the Hong Kong dollar by approximately 2% on that date. On September 23, 2005, the PRC government widened the daily trading band for the RMB against non-U.S. dollar currencies from 1.5% to 3.0% to improve the flexibility of the new foreign exchange system. As a consequence, RMB has fluctuated sharply since July 2008 against other freely traded currencies, in tandem with the U.S. dollar. On June 19, 2010, the PBOC announced that it intended to further reform the RMB

RISK FACTORS

exchange rate regime by enhancing the flexibility of the RMB exchange rate. On March 17, 2014, the PBOC enlarged the previous floating band of the trading prices of the RMB against the U.S. dollar in the inter-bank spot foreign exchange market from 1% to 2% in order to further improve the managed floating RMB exchange rate regime based on market supply and demand with reference to a basket of currencies. However, it remains unclear how this flexibility might be implemented. The RMB was added to its group of global reserve currencies by The International Monetary Fund on November 30, 2015, which makes RMB to some extent more susceptible to market forces as the PRC government loosens some of its currency controls. As a China-based company, any significant change in the exchange rates of the Hong Kong dollar against RMB may materially adversely affect any dividends payable on, our Shares in Hong Kong dollars.

Furthermore, as a result of our international operations, we are exposed to exchange rate risks related to other currency that can affect our revenue, costs, margins and profits. Our reporting currency is RMB. A significant portion of raw materials procurement and manufacturing costs of our API and enoxaparin sodium injection products are incurred in China and settled in RMB whilst a majority of the revenues we derive are in US dollars or Euros. A decrease in the value of the US dollar or Euros against the RMB can result in our incurring other comprehensive losses and there can be no assurance that such decreases will not occur in the future.

Inflation in the PRC could negatively affect our profitability and growth.

Economic growth in the PRC has been accompanied by periods of high inflation in the past, and the PRC government has implemented various policies from time to time to control inflation. For example, the PRC government introduced measures in certain sectors to avoid overheating of the economy, including tighter bank lending policies and increases in bank interest rates. The effects of the stimulus measures implemented by the PRC government since the global economic crisis that unfolded in 2008 may have contributed to the occurrence of, and continuing increase, in inflation in China. If such inflation is allowed to proceed without mitigating measures by the PRC government, our cost of sales would likely increase, and our profitability would be materially reduced, as there is no assurance that we would be able to pass any cost increases onto our customers. If the PRC government implements new measures to control inflation, these measures may also slow economic activities and reduce demand for our products and services and severely hamper our growth.

Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations.

In the past, local governments in China granted certain financial incentives from time to time to us and our PRC subsidiaries as part of our efforts to encourage the development of local businesses. We recognized RMB42.5 million, RMB33.8 million and RMB28.0 million of government grant income for the years ended December 31, 2017 and 2018 and for the nine months ended September 30, 2019, respectively. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot

RISK FACTORS

guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

The political relationships between China and other countries may affect our business operations.

During the Track Record Period, we relied on certain overseas suppliers to obtain raw materials for our products, and we have relied on the services from and collaboration with entities in foreign countries and regions, in particular the U.S. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in those foreign countries and regions. Tensions and political concerns between China and the relevant foreign countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects.

China’s political relationships with those foreign countries and regions may affect the prospects of our relationship with third parties. There can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions.

Furthermore, in the event that China and/or the U.S. impose import tariffs, trade restrictions or other trade barriers affecting the importation of raw materials, we may not be able to obtain a steady supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected.

RISKS RELATING TO THE [REDACTED]

The characteristics of the A share and H share markets may differ.

Our A Shares were listed on the Shenzhen Stock Exchange in 2010. Following the [REDACTED], our A Shares will continue to be traded on the Shenzhen Stock Exchange and our H Shares will be traded on the Hong Kong Stock Exchange. Under current PRC laws and regulations, without approval from the relevant regulatory authorities, our H Shares and A Shares are neither interchangeable nor fungible, and there is no trading or settlement between the H share and A share market. With different trading characteristics, the H share and A share market have divergent trading volumes, liquidity and investor bases, as well as different levels of retail and institutional investor participation. As a result, the trading performance of our H Shares and A Shares may not be comparable. Nonetheless, fluctuations in the price of our A Shares may adversely affect the price of our H Shares, and *vice versa*. Due to the different characteristics of the H share and A share market, the historical prices of our A Shares may not be indicative of the performance of our H Shares. You should therefore not place undue reliance on the prior trading history of our A Shares when evaluating an investment in our H Shares.

There has been no prior public market for our H Shares and an active trading market for our H Shares may not develop or sustain.

Prior to the [REDACTED], there has been no public market for our H Shares. The initial issue [REDACTED] for our H Shares was the result of negotiations among our Company and the [REDACTED]

RISK FACTORS

[REDACTED] (for themselves and on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the market price for our H Shares following the [REDACTED]. We have applied for [REDACTED] of, and permission to deal in, the H Shares (including any H Shares which may be issued pursuant to the exercise of the [REDACTED]) on the Hong Kong Stock Exchange. A [REDACTED] on the Hong Kong Stock Exchange, however, does not guarantee that an active and liquid trading market for our H Shares will develop, or if it does develop, will be sustained following the [REDACTED] or that the market price of our H Shares will not decline following the [REDACTED]. The price and trading volume of our H Shares may be volatile, which could lead to substantial losses to [REDACTED]. The price and trading volume of our H Shares may be highly volatile as a result of various factors. Some of these factors are beyond our control, including but not limited to:

- actual or anticipated fluctuations in our revenue and operating results;
- news regarding recruitment or loss of key personnel by us or our competitors;
- announcements of competitive developments, acquisitions or strategic alliances in our industry;
- changes in earnings estimates or recommendations by financial analysts;
- potential litigation or regulatory investigations;
- general market conditions or other developments affecting us or our industry;
- changes in any relevant government policies or regulations;
- the operating and stock price performance of other companies, other industries and other events or factors beyond our control; and
- the release of lock-up or other transfer restrictions on our outstanding H Shares or sales or perceived sales of additional H Shares by the Controlling Shareholders or other shareholders.

Moreover, the securities market has from time to time experienced significant price and volume fluctuations that were unrelated or not directly related to the operating performance of the underlying companies. These broad market and industry fluctuations may have a material and adverse effect on the market price and trading volume of our H Shares.

You will incur immediate and significant dilution and may experience further dilution if we issue additional Shares in the future.

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per H Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] consolidated net tangible asset value to HK\$[REDACTED] per Share, based on the low end of the [REDACTED] of HK\$[REDACTED] per H Share. There can be no assurances that if we were to immediately liquidate after the [REDACTED], any assets will be distributed to Shareholders after the creditors' claims. In order to expand our business, we may consider [REDACTED] and issuing additional Shares in the future. Purchasers of the [REDACTED] may experience dilution in the net tangible asset value per H Share of their H Shares if we issue additional Shares in the future at a price which is lower than the net tangible asset value per Share at that time.

RISK FACTORS

Your right to participate in any future rights [REDACTED] may be limited, which may cause dilution to your holdings.

We may from time to time distribute rights to our Shareholders, including rights to acquire our securities. However, we cannot make such rights available to persons in the U.S. unless we register both the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective and we may not be able to establish a necessary exemption from registration under the U.S. Securities Act. Accordingly, you may be unable to participate in our rights [REDACTED] in the future and may experience dilution in your holdings.

Future sales or perceived sales of substantial amounts of our Shares in the public market could have a material and adverse effect on the prevailing market price of our H Shares and our ability to raise additional capital in the future.

The market price of our H Shares could decline as a result of substantial future sales of our H Shares or other securities relating to our Shares in the public market. Such a decline could also occur with the issuance of new Shares or other securities relating to our Shares, or the perception that such sales or issuances may occur. Future sales, or perceived sales, of substantial amounts of our Shares could materially and adversely affect the prevailing market price of our H Shares and our ability to raise additional capital in the future. Our Shareholders would experience a dilution in their holdings upon the issuance of additional Shares by the Company.

There will be a gap of several days between pricing and trading of our H Shares, and the price of our H Shares when trading begins could be lower than the [REDACTED].

The initial price to the public of our H Shares [REDACTED] in the [REDACTED] is expected to be determined on the [REDACTED]. However, the H Shares will not commence trading on the Hong Kong Stock Exchange until they are delivered, which is expected to be not more than five Business Days after the [REDACTED]. As a result, [REDACTED] may not be able to sell or otherwise deal in the H Shares during that period. Accordingly, holders of our H Shares are subject to the risk that the price of the H Shares when trading begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time of sale and the time trading begins.

There can be no assurances that we will declare and distribute any amount of dividends in the future.

Under PRC law and the constitutional documents of our company, dividends may be paid only out of distributable profits, which refers to after tax profits as determined under PRC GAAP less any recovery of accumulated losses and required allocations to statutory capital reserve funds. Any distributable profits that are not distributed in a given year are retained and become available for distribution in subsequent years. The calculation of our distributable profits under PRC GAAP differs in many aspects from the calculation under IFRS. As a result, our company may not be able to pay a dividend in a given year if they do not have distributable profits as determined under PRC GAAP even if they have profits as determined under IFRS. Please refer to “Financial Information—Dividend Policy” for further details of our dividend policy.

RISK FACTORS

There can be no assurances that future dividends will be declared or paid. The declaration, payment and amount of any future dividends are subject to the discretion of our Directors depending on, among other considerations, our operations, earnings, financial condition, cash requirements and availability, our constitutional documents and applicable law.

Our Controlling Shareholders have significant influence over the Company and their interests may not be aligned with the interests of the other Shareholders

Immediately following the completion of the [REDACTED], assuming the [REDACTED] is not exercised, our Controlling Shareholders will collectively control approximately [REDACTED]% of the voting power at general meetings of our Company. Our Controlling Shareholders will, through their voting power at the Shareholders meetings and their delegates on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments, and our management. Our Controlling Shareholders may not act in the best interests of our minority Shareholders. In addition, without the consent of our Controlling shareholders, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a sale of our Company and may significantly reduce the price of our Shares.

You should not place any reliance on any information released by us in connection with the [REDACTED] of our A Shares on the Shenzhen Stock Exchange.

Following the listing of our A Shares on the Shenzhen Stock Exchange, we have been subject to periodic reporting and other information disclosure requirements in the PRC. As a result, from time to time we publicly release information, including financial statements and financial data, relating to us on the Shenzhen Stock Exchange or other media outlets designated by the Shenzhen Stock Exchange or the CSRC or other regulatory bodies. However, the information announced by us in connection with our A Shares is based on regulatory requirements of the securities authorities and market practices in the PRC which are different from those applicable to the [REDACTED]. Such information does not and will not form a part of this document. As a result, prospective [REDACTED] in our H Shares are reminded that, in making their [REDACTED] decisions as to whether to purchase our H Shares, they should rely only on the financial, operating and other information included in this document and the [REDACTED]. By applying to purchase our H Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong with respect to the [REDACTED].

Facts, forecasts and statistics in this document relating to the PRC economy and pharmaceutical industry may not be fully reliable.

Facts, forecasts and statistics in this document relating to the PRC, the PRC economy and pharmaceutical industry in China are obtained from various sources including official government publications that we believe are reliable. However, we cannot guarantee the quality or reliability of these sources. Neither we or the [REDACTED] nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic

RISK FACTORS

assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and market practice and other problems, the statistics in this document relating to the PRC economy and the pharmaceutical industry in China may be inaccurate or may not be comparable to statistics produced for other economies and should not be unduly relied upon. As such, no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources is made. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon. Further, there can be no assurances that they are stated or compiled on the same basis or with the same degree of accuracy, as may be the case in other countries.

You should read the entire document carefully and we strongly caution you not to place any reliance on any information contained in press articles or other media coverage regarding us, our business, our Shareholders and management team, our industries, our Shares and the [REDACTED].

There has been, prior to the publication of this document, and there may be, subsequent to the date of this document but prior to the completion of the [REDACTED], press and media regarding us, our business, our Shareholders and management team, our industry, our Shares and the [REDACTED].

None of us, the Joint Sponsors, or any other person involved in the [REDACTED] have authorized the disclosure of any such information in the press or media and none of these parties accept any responsibility for the accuracy or completeness of the information contained in such press articles and/or other media or the fairness or appropriateness of any forecasts, views or opinions expressed by the press and/or other media regarding our Shares, the [REDACTED], our business, our industries or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information, forecasts, views or opinions expressed or any such publications. To the extent that such statements, forecasts, views or opinions are inconsistent or conflict with the information contained in this document, we disclaim responsibility for them. Accordingly, prospective [REDACTED] are cautioned to make their [REDACTED] decisions on the basis of the information contained in this document only and should not rely on any other information.

WAIVERS AND CONSENTS FROM STRICT COMPLIANCE WITH THE HONG KONG LISTING RULES

In preparation for the [REDACTED], the Company has applied for the waivers and consents from strict compliance with the relevant provisions of the Listing Rules.

WAIVER IN RELATION TO MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rules 8.12 and 19A.15 of the Listing Rules, we must have sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong.

Since most of the business operations of our Company and our subsidiaries are managed and conducted in the PRC, U.S. or EU, and all of our executive Directors ordinarily reside in the PRC, we do not and, for the foreseeable future, will not contemplate that we will have sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rules 8.12 and 19A.15 of the Listing Rules.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with the requirements under Rules 8.12 and 19A.15 of the Listing Rules, subject to the following conditions. In order to maintain effective communication with the Stock Exchange, we will put in place the following measures between us and the Stock Exchange:

1. We have appointed Mr. Bu and Ms. Chan Sze Ting as our authorized representatives (the “**Authorized Representatives**”) pursuant to Rules 3.05 and 19A.07 of the Listing Rules. The Authorized Representatives will act as our Company’s principal channel of communication with the Stock Exchange. The Authorized Representatives will be readily contactable by phone, facsimile and email to promptly deal with enquiries from the Stock Exchange, and will also be available to meet with the Stock Exchange to discuss any matter within a reasonable period of time upon request of the Stock Exchange;
2. When the Stock Exchange wishes to contact the Directors on any matter, each of the Authorized Representatives will have all necessary means to contact all of our Directors (including our independent non-executive Directors) and senior management team promptly at all times. Our Company will also inform the Stock Exchange promptly in respect of any changes in the Authorized Representatives. We have provided the Stock Exchange with the contact details (i.e. mobile phone number, office phone number, fax number and email address) of all Directors to facilitate communication with the Stock Exchange;
3. All Directors who do not ordinarily reside in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and can meet with the Stock Exchange within a reasonable period;
4. We have appointed Somerley Capital Limited as our compliance advisor (the “**Compliance Advisor**”) upon [REDACTED] pursuant to Rule 3A.19 of the Listing Rules for a period commencing on the [REDACTED] and ending on the date on which we comply with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [REDACTED]. The Compliance Advisor will have access at all times to our Authorized Representatives, the Directors and other senior management and act as the additional channel of communication with the Stock Exchange when the Authorized Representatives are not available; and

WAIVERS AND CONSENTS FROM STRICT COMPLIANCE WITH THE HONG KONG LISTING RULES

5. We have provided the Stock Exchange with the names, mobile phone numbers, office phone numbers, fax numbers and email addresses of at least two of the Compliance Advisor’s officers who will act as the Compliance Advisor’s contact persons between the Stock Exchange and the Company pursuant to Rule 19A.06(4) of the Listing Rules.

Pursuant to Rule 19A.05(2) of the Listing Rules, we shall ensure that the Compliance Advisor will have access at all times to our Authorized Representatives, our Directors and other officers. We shall also ensure that such persons will timely provide such information and assistance as the Compliance Advisor may need or may reasonably request in connection with the performance of the Compliance Advisor’s duties as set forth in Chapter 3A and Rule 19A.06 of the Listing Rules. We shall ensure that there are adequate and efficient means of communication among our Company, our Authorized Representative, our Directors, and other officers and the Compliance Advisor, and will keep the Compliance Advisor fully informed of all communications and dealings between us and the Stock Exchange.

WAIVER IN RESPECT OF APPOINTMENT OF JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, we must appoint a company secretary who, by virtue of his/her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of the company secretary. Note 1 to Rule 3.28 of the Listing Rules further provides that the Stock Exchange considers the following academic or professional qualifications to be acceptable:

- (a) a member of The Hong Kong Institute of Chartered Secretaries;
- (b) a solicitor or barrister as defined in the Legal Practitioners Ordinance (Chapter 159 of the Laws of Hong Kong); and
- (c) a certified public accountant as defined in the Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong).

In assessing the “relevant experience,” the Stock Exchange will consider the individual’s:

- (i) length of employment with the issuer and other issuers and the roles he/she played;
- (ii) familiarity with the Listing Rules and other relevant laws and regulations including the SFO, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;
- (iii) relevant training taken and/or to be taken in addition to the minimum requirement under Rule 3.29 of the Listing Rules; and
- (iv) professional qualifications in other jurisdictions.

Our Company has appointed Mr. Bu as one of the joint company secretaries. He has extensive experience in board and corporate management matters but presently does not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules, and may not be able to solely fulfill the requirements of the Listing Rules. Therefore, we have appointed Ms. Chan Sze Ting (“**Ms. Chan**”), an Associate of The Hong Kong Institute of Chartered Secretaries, who fully meets the requirements stipulated under Rules 3.28 and 8.17 of the Listing Rules to act as the other joint company secretary

WAIVERS AND CONSENTS FROM STRICT COMPLIANCE WITH THE HONG KONG LISTING RULES

and to provide assistance to Mr. Bu for an initial period of three years from the [REDACTED] to enable Mr. Bu to acquire the “relevant experience” under Note 2 to Rule 3.28 of the Listing Rules so as to fully comply with the requirements set forth under Rules 3.28 and 8.17 of the Listing Rules.

Ms. Chan will work closely with Mr. Bu to jointly discharge the duties and responsibilities as company secretary and assist Mr. Bu to acquire the relevant experience as required under Rules 3.28 and 8.17 of the Listing Rules. Mr. Bu will also be assisted by (a) the Compliance Advisor of the Company for the first full financial year from the [REDACTED], particularly in relation to Hong Kong corporate governance practices and compliance issues; and (b) the Hong Kong legal advisors of the Company, on matters concerning the Company’s ongoing compliance with the Listing Rules and the applicable laws and regulations. In addition, Mr. Bu will endeavor to attend relevant trainings and familiarize himself with the Listing Rules and duties required for a company secretary of a PRC issuer [REDACTED] on the Stock Exchange.

We have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with the requirements of Rules 3.28 and 8.17 of the Listing Rules. The waiver is valid for an initial period of three years from the [REDACTED], and is granted on the condition that we engage Ms. Chan, who possesses all the requisite qualifications required under Rule 3.28 of the Listing Rules, to assist Mr. Bu in discharging his duties as a joint company secretary and in gaining the “relevant experience” as required under Note 2 to Rule 3.28 of the Listing Rules.

Upon the expiration of the initial three-year period, the qualifications of Mr. Bu will be re-evaluated to determine whether the requirements as stipulated in Rules 3.28 and 8.17 of the Listing Rules can be satisfied and whether the need for ongoing assistance will continue. In the event Mr. Bu fulfills all the requirements stipulated at the end of the initial three-year period, the above joint company secretary arrangement would no longer be necessary for our Company.

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

**WAIVERS AND CONSENTS FROM STRICT COMPLIANCE WITH THE
HONG KONG LISTING RULES**

[REDACTED]

WAIVERS AND CONSENTS FROM STRICT COMPLIANCE WITH THE HONG KONG LISTING RULES

[REDACTED]

WAIVER FROM STRICT COMPLIANCE WITH RULE 4.05A OF THE LISTING RULES

In February, 2018, we entered into an equity transfer agreement with the shareholders of Topknow to acquire Topknow’s entire equity interests for a cash consideration of RMB2,400,000,000 (the “**Acquisition**”). The Acquisition constitutes an acquisition of a material subsidiary during the Track Record Period for which disclosure of pre-acquisition financial information of Topknow for the period from the commencement of the Track Record Period to the day immediately before the completion date of the Acquisition (the “**Pre-acquisition Period**”) is required under Rule 4.05A of the Listing Rules. Pursuant to Rule 4.05A of the Listing Rules, financial information of Topknow for the Pre-acquisition Period must normally be drawn up in conformity with accounting policies adopted by our Company and be disclosed in the form of a note to the accountants’ report or in a separate accountants’ report.

We have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with Rule 4.05A of the Listing Rules, that instead of disclosing financial information of Topknow for the Pre-acquisition Period in the form of a note to the accountants’ report or in a separate accountants’ report, we will present the consolidated financial information of the Group and Topknow (the “**Enlarged Group**”) throughout the Track Record Period in this document on the following grounds:

- (a) **In Compliance with the Accounting Standards:** Mr. Li and Ms. Li have, as a couple, collectively held over 70% equity interest in both our Company and Topknow, for a significant period of time prior to the Acquisition, and have continued to control the two entities after the Acquisition. Accordingly, the Acquisition constituted a business combination under common control, which is outside the scope of IFRS 3. Instead, the pooling of interests method is applied, which involves incorporating the financial statement items of entities that underwent business combination under common control as if they had been combined from the date when the entities first came under the control of the controlling party. As such, the consolidated financial statements of our Company have been prepared as if Topknow had been combined throughout the Track Record Period.
- (b) **Consolidated financial statements would enable [REDACTED] to have a fuller picture of the overall financial performance of our Group:** By presenting the consolidated financial statements of the Enlarged Group throughout the Track Record Period, the intra-group transactions between the Group and Topknow would be eliminated to reflect the true financial performance of the Enlarged Group. If we were to present the separate financial statements of Topknow and the Group for the Pre-acquisition Period and present the consolidated financials of the Enlarged Group after the Acquisition, the financial statements of the Group for the Pre-acquisition Period would not be comparable to the consolidated financial statement of the Enlarged Group after the Acquisition. Presenting the consolidated financials of the Enlarged Group throughout the Track Record Period would enable the [REDACTED] to have a fuller picture of the overall performance of the Enlarged Group and the management discussion and analysis on year-to-year change in

WAIVERS AND CONSENTS FROM STRICT COMPLIANCE WITH THE HONG KONG LISTING RULES

the financial data would be more meaningful for the [REDACTED] to assess the performance of the Enlarged Group throughout the Track Record Period.

- (c) **Effectively demonstrates the track record of our Controlling Shareholders during the Track Record Period:** In addition to a significant overlap between our Controlling Shareholders and the controllers of Topknow as illustrated above, there have been overlapping roles between the board of our Company and Topknow. Mr. Li, Ms. Li and Mr. Shan are the founders of Topknow and have been board members of Topknow for over 10 years prior to the Acquisition. Given the significant overlap in our Controlling Shareholders and management and that of Topknow, consolidated financial statements of the Enlarged Group throughout the Track Record Period would effectively demonstrate the financial performance of the Enlarged Group resulting from the control and management of our Controlling Shareholders and management team.
- (d) **Consistent with the financial information disclosed in the annual report published on the Shenzhen Stock Exchange:** The financial statements disclosed in our Company’s 2018 annual report published on the Shenzhen Stock Exchange treated the Acquisition as a combination of businesses under the same control and disclosed financial information for the year ended December 31, 2018 and restated financials for the year ended December 31, 2017 of the Enlarged Group on a consolidated basis. As such, inclusion of the financial information of the Enlarged Group on a consolidated basis throughout the Track Record Period in this document would allow for consistency with the financial information disclosed to our [REDACTED] on the Shenzhen Stock Exchange and avoid confusion which may be caused if a different approach is taken for the purpose of the financial statements to be disclosed in this document.

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
Executive Directors		
Mr. Li Li (李鋌) <i>Chairman</i>	9C, Building A, Huifangyuan, Nanguang Road, Nanshan District Shenzhen, China	Chinese
Ms. Li Tan (李坦)	9C, Building A, Huifangyuan, Nanguang Road, Nanshan District Shenzhen, China	Chinese
Mr. Shan Yu (單宇)	9C, Building A, Huifangyuan, Nanshan District Shenzhen, China	Chinese
Mr. Bu Haihua (步海華) <i>Secretary to the Board</i>	13C, 5th Building, Haijingjie Homeland Phase I, 1012 Houhai Avenue, Nanshan District, Shenzhen, China	Chinese
Independent non-executive Directors		
Dr. Lu Chuan (呂川)	Room 406, 4/F, Block J, Kornhill 31-33 Hong Yue Street Hong Kong	Hong Kong
Mr. Chen Junfa (陳俊發)	22B, Tianjian Century Garden Fuzhong 1st Road, Futian District Shenzhen, China	Chinese
Mr. Wang Zhaohui (王肇輝)	No. 704, Building 1, South District 2 Shuangyuan, Chaoyang District Beijing, China	Chinese
SUPERVISORS		
Mr. Zheng Zehui (鄭澤輝) <i>Chairman</i>	Room 102, Unit 3, Building 3, No. 24 Cuizhu Road, Xiangshan District, Guilin, China	Chinese
Ms. Tang Haijun (唐海均)	17C, Building 8, Phase 3 Xinghai Mingcheng, Nanshan District Shenzhen, China	Chinese
Ms. Su Jilan (蘇紀蘭) <i>Employee supervisor</i>	No. 8 Langshan Road, Fifth Industrial Zone, Nanshan District, Shenzhen, China	Chinese

Further information is disclosed in the section headed “Directors, Supervisors and Senior Management” in this document.

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

Goldman Sachs (Asia) L.L.C.

68/F, Cheung Kong Center
2 Queen’s Road Central
Hong Kong

Morgan Stanley Asia Limited

Level 46, International Commerce Center
1 Austin Road West
Kowloon
Hong Kong

[REDACTED]

Legal Advisers to our Company

As to Hong Kong and United States laws

Davis Polk & Wardwell

18/F, The Hong Kong Club Building
3A Chater Road
Hong Kong

As to PRC law

Tian Yuan Law Firm

10/F, China Pacific Insurance Plaza
28 Fengsheng Hutong, Xicheng District
Beijing, China

As to International Sanctions law

Hogan Lovells

11th Floor, One Pacific Place
88 Queensway
Hong Kong

**Legal Advisers to the Joint
Sponsors and [REDACTED]**

As to Hong Kong and United States laws

Sullivan & Cromwell (Hong Kong) LLP

28th Floor, Nine Queen’s Road Central
Hong Kong

As to PRC law

Commerce & Finance Law Offices

6/F, NCI Tower
A12 Jianguomenwai Avenue
Chaoyang District
Beijing, China

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Reporting Accountants

Ernst & Young
22/F, CITIC Tower
1 Tim Mei Avenue
Central
Hong Kong

Compliance Adviser

Somerley Capital Limited
20/F, China Building
29 Queen's Road Central
Hong Kong

[REDACTED]

CORPORATE INFORMATION

Registered office	No.21, Langshan Road Nanshan District, Shenzhen People’s Republic of China
Headquarters and Principal Place of Business in the PRC	No.21, Langshan Road Nanshan District, Shenzhen People’s Republic of China
Principal Place of Business in Hong Kong	Level 54, Hopewell Centre 183 Queen’s Road East Hong Kong
Company’s website	www.hepalink.com <i>(information contained in this website does not form part of this document)</i>
Joint company secretaries	Mr. Bu Haihua (步海華) No.21, Langshan Road Nanshan District, Shenzhen People’s Republic of China Ms. Chan Sze Ting (陳詩婷) (ACS, ACIS) Level 54, Hopewell Centre 183 Queen’s Road East Hong Kong
Authorized representatives	Mr. Bu Haihua (步海華) No.21, Langshan Road Nanshan District, Shenzhen People’s Republic of China Ms. Chan Sze Ting (陳詩婷) Level 54, Hopewell Center 183 Queen’s Road East Hong Kong
Strategy Development Committee	Mr. Li Li (Chairman) Ms. Li Tan Dr. Lu Chuan
Remuneration and Evaluation Committee	Mr. Wang Zhaohui (Chairman) Mr. Chen Junfa Mr. Li Li
Audit Committee	Mr. Chen Junfa (Chairman) Dr. Lu Chuan Mr. Wang Zhaohui ⁽¹⁾

Note:

(1) Mr. Wang Zhaohui will serve as a member of the Audit Committee with effect from the [REDACTED].

CORPORATE INFORMATION

Nomination Committee

Dr. Lu Chuan (*Chairman*)
Mr. Li Li
Mr. Chen Junfa

[REDACTED]

Principal Banks

China Merchants Bank, Shenzhen Branch
China Merchants Bank Tower
No.7088 Shennan Boulevard
Shenzhen, China

Bank of China Limited, Shenzhen Fuhua Sub-Branch
D/District
Northern Side, Coco Park
Fuhua Road, Futian District
Shenzhen, China

The Hongkong and Shanghai Banking Corporation Limited
1 Queen’s Road Central
Hong Kong

INDUSTRY OVERVIEW

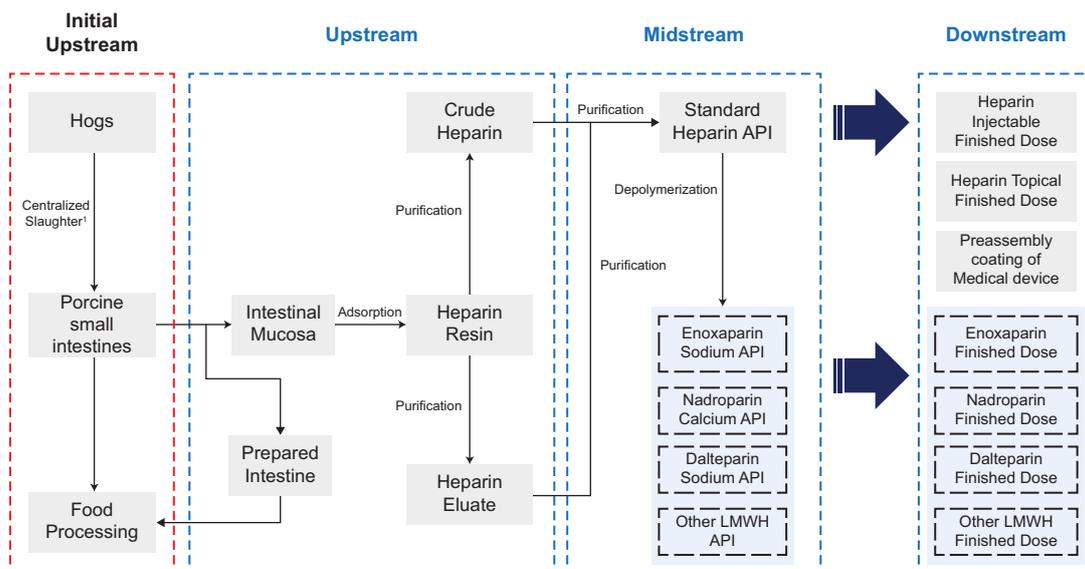
The information and statistics set out in this section and other sections of this document were extracted from different official government publications, available sources from public market research and other sources from independent suppliers. In addition, we engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the [REDACTED]. We believe that the sources of the information in this section and other sections of this document are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading in any material respect or that any fact has been omitted that would render such information false or misleading in any material respect. The information from official and non-official sources has not been independently verified by us, the [REDACTED], Joint Sponsors, [REDACTED], [REDACTED], any of the [REDACTED], any of their respective directors and advisers, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy. Accordingly, the information from official and non-official sources contained herein may not be accurate and should not be unduly relied upon. We confirm that, after making reasonable enquiries, there is no adverse change in the market information since the date of the Frost & Sullivan Report that would qualify, contradict or have an impact on the information in this section in any material respect.

ENOXAPARIN FINISHED DOSE MARKET

Overview

Heparin Industry Value Chain

Heparin is a type of anticoagulant drug and heparin industry consists of the initial upstream procurement of porcine small intestines, the upstream purification of crude heparin, the midstream manufacture of heparin APIs and downstream manufacture and supply of heparin finished doses. The following flowchart illustrates the heparin industry value chain. The Group has an integrated business model covering the full heparin value chain.



¹ Compared with US and EU, the centralization of slaughter in China is low.

Source: Frost & Sullivan Report

INDUSTRY OVERVIEW

Characteristics

Enoxaparin is the gold standard treatment for various indications, including venous thromboembolism and pulmonary embolism, which generates huge market demands and demonstrates significant market potential. Since it was first approved in 1987, enoxaparin finished dose has been marketed in over 100 countries, with millions of patients worldwide and billions of doses consumed, which enables it to become the largest LMWH player in the world. Enoxaparin is the authorized generic that is identical to Lovenox, a top selling drug in Sanofi’s established drug portfolio.

Advantages

Compared with other major LMWH finished doses in the market such as dalteparin sodium and nadroparin calcium, enoxaparin sodium has superior pharmacological and chemical properties, including a longer elimination half-life, superior bioavailability and a higher anti Xa/IIa activity ratio. In addition, enoxaparin sodium is manufactured via β -elimination and therefore does not bear the risk of nitrite impurity that can be carcinogenic and genetically toxic, while the manufacture process of dalteparin sodium and nadroparin calcium applies nitrous acid degradation that may result in nitrite impurity. Enoxaparin sodium also has a wider range of approved indications, as shown in the following table, more comprehensive delivery routes and better clinical performance. Therefore, enoxaparin finished dose is expected to replace other LMWH finished doses at a global scale.

<u>LMWHs indications in China</u>	<u>Enoxaparin Sodium</u>	<u>Dalteparin Sodium</u>	<u>Nadroparin calcium</u>
Prophylaxis of Deep Vein Thrombosis Following Abdominal Surgery			
Surgery	✓	✓	✓
Internal Medicine	✓	✗	✗
Treatment of Deep Vein Thrombosis with or without Pulmonary Embolism	✓	✓	✓
Treatment of Ischemic Complications in Unstable Angina and Non-Q-Wave Myocardial Infarction	✓	✓	✓
Extracorporeal circulation in blood dialysis to prevent thrombosis	✓	✓	✓
Treatment of Acute ST-Segment Elevation Myocardial Infarction	✓	✗	✗

Source: Frost & Sullivan Report

Regulatory and Prescription Pathways

EU

In most of the EU countries, since enoxaparin is regarded as a biosimilar drug, prescription of enoxaparin is based on brands, patients generally can only be given the same brand of enoxaparin finished doses as prescribed and different brands cannot be used interchangeably. In the UK, NHS guidelines do not allow automatic substitution of biosimilars at the pharmacy level. MHRA highly recommends that biologics, including biosimilars, shall be prescribed with their brand names. Such recommendation aims to ensure that these pharmaceutical products are not able to be substituted automatically at the pharmacy level. In Germany, products that are manufactured by the same supplier with the same production line are considered bio-identical regardless of the brand names. Only bio-identical biosimilars can be used interchangeably at the pharmacy level. Therefore, even belonging to the same active ingredient group, the originators and their biosimilars may not be considered interchangeable. To promote their products in the EU, enoxaparin suppliers need to proactively market

INDUSTRY OVERVIEW

their brand names to enhance their brand and product awareness among physicians in order for the physicians to prescribe more enoxaparin drugs of their brands.

China

In China, enoxaparin has historically been regarded as a generic drug and prescription of enoxaparin is based on brands. However, due to the Opinions issued by the State Council in April 2018, patients can be given enoxaparin finished doses with the same compound under different brands subject to patients' affordability and choices. On April 3, 2018, the State Council issued Opinions of the General Office of the State Council on the Reform and Improvement of Policies on the Supply, Security and Use of Generic Drugs (《國務院辦公廳關於改革完善仿製藥供應保障及使用政策的意見》) to promote the substitution of generic drugs. According to the Opinions, generic drugs sharing the same quality and efficacy as to the original drugs will be included in a list of drugs that can be used interchangeably with the original drugs. Except for special circumstances specified by the relevant authorities in China, prescription of enoxaparin shall be based on compounds. China is in the process of implementing the approval regime for generic drugs based on Quality Consistency Evaluation (QCE), which is expected to enhance the quality control of generic drug market in China and promote the generic drugs with high quality. If a generic drug passes QCE, it means the generic drug has demonstrated bioequivalence as to the originator drug which indicates the high quality of such generic drug. Doctors are generally more willing to prescribe the generic drug with the QCE qualification due to its proven quality consistency, which will drive up the sales volume of such generic drug. Therefore, to promote enoxaparin finished doses in China in the future, enoxaparin suppliers need to pass the QCE as the generic drugs without the QCE approval are expected to be gradually phased out in the future.

On March 29, 2019, CDE issued the 21st Catalog of Reference Finished Doses for Chemical Generics (《化學仿製藥參比製劑目錄(第二十一批)》), which for the first time covered enoxaparin finished doses under the Catalog of Reference Finished Doses for Chemical Generics (《化學仿製藥參比製劑目錄》). This sets the foundation for enoxaparin finished doses to be approved based on QCE as only generic drugs covered by such catalog can be qualified for QCE approval. On October 15, 2019, NMPA issued the Technical Requirements for Evaluation of Quality and Efficacy Consistency of Chemical Generic Injections (Draft for comments) (《化學藥品注射劑仿製藥質量和療效一致性評價技術要求(徵求意見稿)》), indicating the commencement of establishing QCE approval regime for injectable generic drugs in China.

QCE approved generic drugs will also benefit from the Centralized Drug Procurement (CDP) scheme recently implemented in China. QCE approval is one of the requirements for generic drugs to participate in the CDP. CDP is a governmental nationwide pilot scheme, by which public health institutions are required to pre-set their drug procurement quantity and their procurement cycle, and purchase the drug at the price determined by open bidding. The bidding company with the lowest price offer for a specific drug will generally win the bid. Because of the intended quantity commitment for each bid-winning drug, the public healthcare institutions will procure the bid-winning drugs with priority and doctors will prescribe the drugs to meet the quantity commitment, which will significantly increase the sales volume of such drug and reduce the sales and marketing expenses of the pharmaceutical companies supplying such drugs. In December 2019, National Organization of Centralized Procurement and Use of Drugs Joint Procurement Office issued Documents on National Centralized Drug Procurement (GY-YD2019-2) (《全國藥品集中採購文件(GY-YD2019-2)》), indicating the official start of the CDP in all the 31 provinces. As of the latest Practicable Date, 33

INDUSTRY OVERVIEW

drugs were included in the CDP scheme, and most of them were generic drugs. In certain provinces and cities in China, a generic drug with QCE qualification can directly join the CDP network without waiting for a new round of bidding cycle, which simplifies the participation and bidding process of CDP. For the generic drugs that have passed the QCE, they will enjoy the same treatment as the originator drugs during the CDP process, and are able to bid at the same price level as the originator drugs that is generally higher. In some province, such as Shanxi, generic drugs that passed QCE will be included in the list of drugs that can be substituted for the original drugs, and will be purchased preferentially for clinical use.

U.S.

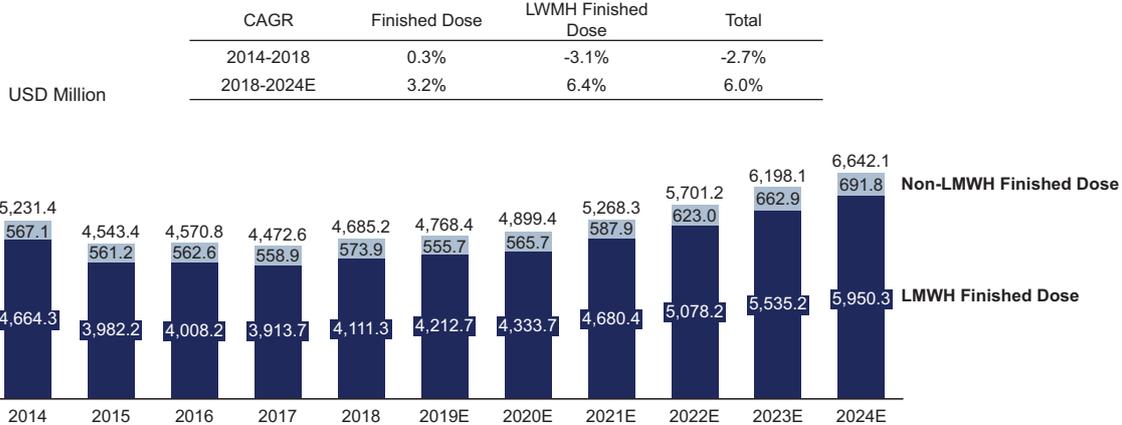
In the U.S., relying on the ANDA pathway, enoxaparin is regarded as a generic drug, and therefore prescription of enoxaparin is based on compounds, where enoxaparin finished doses with the same compound can be used interchangeably among different generic brands. In order to enhance their market shares, enoxaparin suppliers need to ensure their drugs are included in the purchase list of the Group Purchase Organizations (GPOs) in the U.S. as the GPOs currently dominate the distribution channel of generic drugs to the hospital market in the U.S. GPOs refer to the companies that help negotiate the prices of pharmaceutical products and services on behalf of healthcare providers, such as hospitals. GPOs represent some of the largest networks of hospitals and health care providers in the U.S. In 2018, more than 95% of hospitals in the U.S. belonged to a GPO, and about 73% of hospital purchases were via the GPO network. GPOs offer benefits to pharmaceutical manufacturers, as the GPOs can lower their sales and marketing costs and help them avoid duplicating those costs to promote their products among individual hospitals.

Market Size

The global heparin market comprises of heparin and low molecular weight heparin (“LMWH”) finished doses. Enoxaparin is one type of LMWH. Primarily attributable to currency fluctuations and price drops as a result of the introduction of the generic drugs, global heparin market historically decreased from US\$5,231.4 million in 2014 to US\$4,685.2 million in 2018, representing a CAGR of -2.7%, but due to wide clinical use, the global heparin market is expected to grow at a CAGR of 6.0% to US\$6,642.1 million by 2024. As clinical use of LMWH finished doses is generally safer with wider applications than that of heparin finished doses, LMWH finished doses have become the mainstream of heparin finished doses, accounting for more than 80% of the global heparin finished dose market by revenue in 2018, as shown in the following chart:

INDUSTRY OVERVIEW

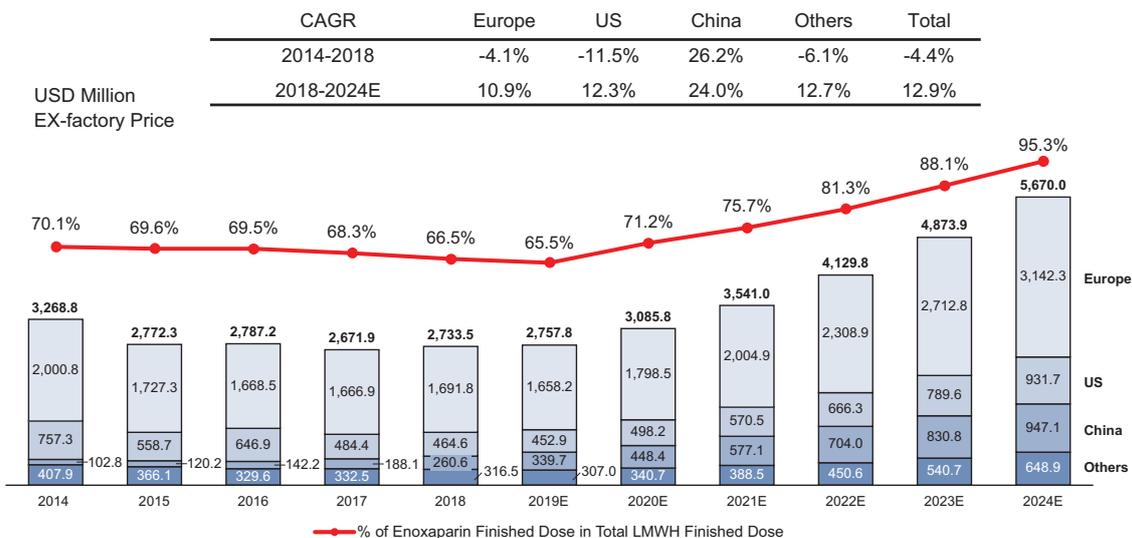
**Global Market of Heparin Finished Dose by Sales Revenue
(Ex-factory Price), 2014-2024E**



Source: Frost & Sullivan Report

Among the LMWH finished doses, enoxaparin finished dose has the largest proportion of the LMWH finished dose market, accounting for 66.5% of the LMWH finished dose market by revenue in 2018. Historically, due to market competition brought by generic drugs, revenue of global enoxaparin finished doses decreased from US\$3,268.8 million in 2014 to US\$2,733.4 million in 2018, representing a CAGR of -4.4%. Enoxaparin finished dose has significant potential to replace other LMWH finished doses due to its wider indications and superior clinical effects, which will significantly stimulate the growth of global enoxaparin finished dose market. The global usage of enoxaparin finished doses exceeded 701.5 million syringe/vial in 2014, which is expected to reach 1,444.3 million syringe/vial in 2024. In particular, usage of enoxaparin in China is expected to increase at a CAGR of 47.5% from 41.9 million syringe/vial in 2018 to 431.7 million syringe/vial in 2024. Driven by the rapid expansion in China and the increasing price levels of the enoxaparin finished doses in the EU and the U.S., global market of enoxaparin finished dose is expected to grow at a CAGR of 12.9% and reach US\$5,670.0 million in 2024. The charts below illustrate the global enoxaparin finished dose market size by region in terms of sales revenue:

Breakdown of Global Enoxaparin Finished Dose Market by Region in Terms of Sales, 2014-2024E



Source: Frost & Sullivan Report

INDUSTRY OVERVIEW

Europe

Europe is the largest market of enoxaparin finished doses worldwide. Primarily due to market competition brought by generic drugs, the sales of enoxaparin finished doses in Europe historically declined from US\$2,000.8 million in 2014 to US\$1,691.8 million in 2018. However, driven by the price increase, European market is expected to reach US\$3,142.3 million by 2024, representing a CAGR of 10.9% from 2018.

The Group is the leading enoxaparin finished dose manufacturer in the EU, accounting for 18.0% of market share by sales volume in 2019. The Group has the largest market shares in the UK and Poland, accounting for 70.9% and 52.5% of the UK and Poland markets in 2019, respectively. It also has leading market positions in Italy and Austria, with a market share of 33.1% and 19.1%, respectively in 2019. The Group also sells its enoxaparin finished doses into the top seven enoxaparin finished dose markets in the EU including Italy, Germany, France, Spain, Poland, the UK and Austria. The following chart illustrates the market shares of the Group in the top seven EU enoxaparin finished dose markets, in total accounting for 18.0% of the market share in the EU by sales volume:

Country	2019 Enoxaparin Finished Doses Market Sales Volume (Million prefilled syringes) ²	2019 Enoxaparin Finished Doses Sales Volume of the Company (Million prefilled syringes) ²	Market Share of the Company by Sales Volume
Italy	79.0 (16.6%) ¹	26.2	33.1%
Germany	69.3 (14.6%) ¹	6.6	9.5%
France	54.9 (11.6%) ¹	3.1	5.6%
Spain	53.1 (11.2%) ¹	4.1	7.8%
Poland	45.0 (9.5%) ¹	23.6	52.5%
UK	27.0 (5.7%) ¹	19.2	70.9%
Austria	14.8 (3.1%) ¹	2.8	19.1%
Others	132.2 (27.7%) ¹	—	—
Total EU	475.3 (100.0%)¹	85.5	18.0%

1. % of total European Union market

2. Vial is not included

Source: Frost & Sullivan Report

In Europe, the pharmacy channel is generally more stable than the hospital channel, as the pharmacy price is in general fluctuated less. For the enoxaparin finished dose, the pharmacy price is around 35%-55% higher than the hospital price, whereas the sales revenue from the pharmacy channel accounted for 55% of the total European market in 2018. Therefore, more pharmaceutical companies are expected to directly sell their drugs through the pharmacy channel.

China

The enoxaparin finished doses market in China has grown rapidly in the recent years, increasing from US\$102.8 million in 2014 to US\$260.6 million in 2018 at a CAGR of 26.2%. The China market has significant growth potential. Compared with Europe and the U.S., in which the penetration rate of enoxaparin finished dose is relatively high, the usage per capita of enoxaparin finished dose in emerging market, such as China, is quite lower. Whereas the per capita use of enoxaparin in the EU was 0.95 dose in 2018, the per capita use remained relatively low in China, reaching 0.03 dose in 2018. Primarily driven by increasing clinical demand, the per capita use of enoxaparin in China is projected to grow to 0.29 dose in 2024. As more biosimilar enoxaparin finished

INDUSTRY OVERVIEW

dose products are marketed, and the awareness of the importance of anticoagulation in patients and doctors is increasing, the penetration rate of enoxaparin finished dose will keep increasing in emerging market, especially in China. Usage of enoxaparin in China was 41.9 million syringe/vial in 2018, which is expected to increase at a CAGR of 47.5% to 431.7 million syringe/vial in 2024. Total sales of enoxaparin in China reached US\$260.6 million in 2018, representing a CAGR of 26.2% from 2014 to 2018, and is projected to reach US\$947.1 million by 2024.

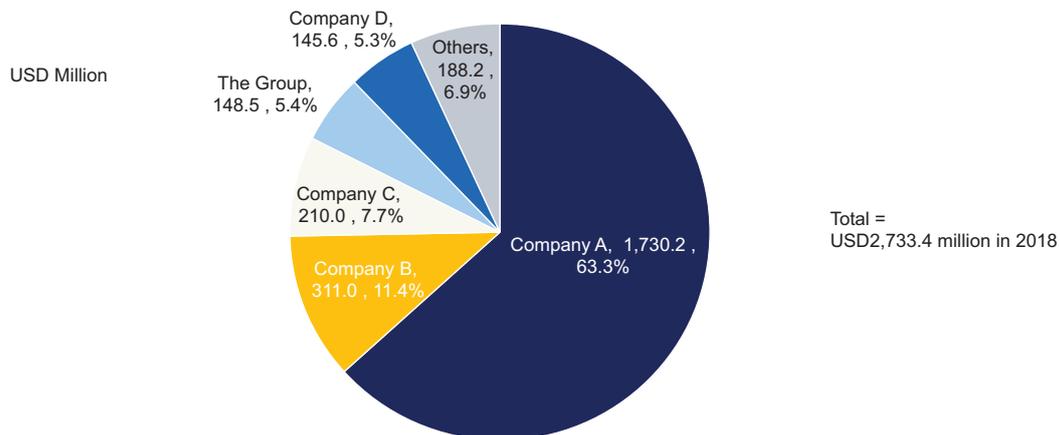
U.S.

In the U.S., primarily due to the introduction of generic drugs and Sandoz’s suspension on the enoxaparin finished doses supply in July 2018, the sales of enoxaparin finished doses decreased from US\$757.3 million in 2014 to US\$464.6 million in 2018. However, the U.S. market is expected to recover and reach US\$931.7 million in 2024 at a CAGR of 12.3% from 2018. In the U.S., the pharmacy price for the enoxaparin finished dose is about 30%-35% higher than the hospital price. The sales revenue from pharmacy channel and hospital channel accounted for 35% and 65% of the market share, respectively, in 2018. Companies who can supply their products through the pharmacy channel are able to acquire a higher profit margin.

Competitive Landscape

Global Competitive Landscape

The Group is the fourth largest supplier of enoxaparin finished dose globally, accounting for 5.4% of the global market by revenue in 2018. The following pie chart illustrates the global competitive landscape of enoxaparin finished dose suppliers in terms of market shares by revenue:

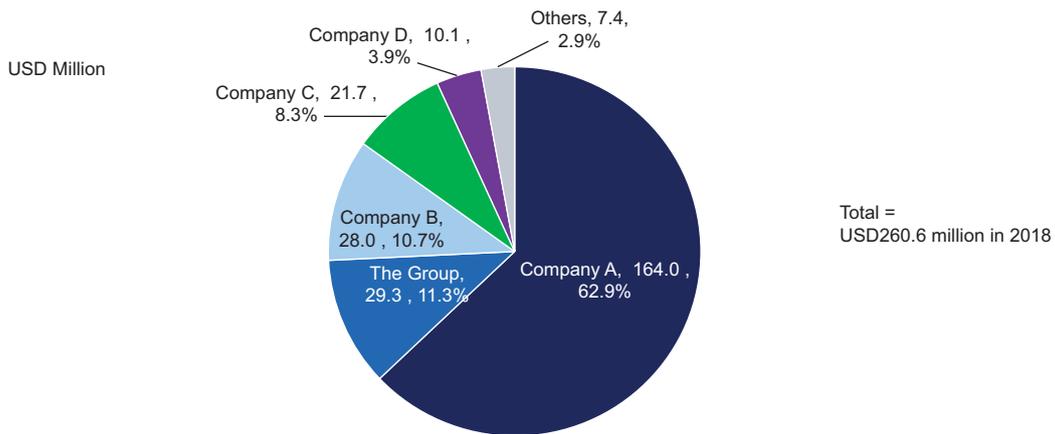


Source: Frost & Sullivan Report

Competitive Landscape in China

The Group is the first company that obtained NMPA approval to market enoxaparin generic drugs in China and the second largest supplier of enoxaparin in China with 11.3% market share by revenue in 2018. The following chart shows the competitive landscape in China in terms of market shares by revenue:

INDUSTRY OVERVIEW



Source: Frost & Sullivan Report

Even though the generic drugs of enoxaparin in total account for 37.1% of enoxaparin sales in China, none of them has been approved based on QCE. To further regulate the enoxaparin market and strengthen quality control in China, the NMPA is expected to implement approval regime of injectable pharmaceuticals based on QCE in 2020. It is expected once the QCE-based approval regime becomes effective, enoxaparin products that pass the QCE will gradually replace the low quality LMWH products due to the proven high quality of QCE-approved enoxaparin.

Before filing the application for QCE-approval with the NMPA for their enoxaparin products, pharmaceutical companies are required to first complete the bioequivalence test (“**BE test**”). As of the Latest Practicable Date, among the eight applicant holders of enoxaparin finished dose, three have already accomplished BE tests and filed for QCE-approval with NMPA, and the Group was the first company among the three. It is estimated that at least three market players will obtain the QCE approval in the upcoming two years.

Entry Barriers

Global Operation Capability

While Europe is the largest market of enoxaparin finished dose, raw materials are mainly sourced from China and enoxaparin API manufacturers for supplying to third parties are primarily based in China. Market players are, therefore, required to be able to operate at a global scale and engage in global sourcing, logistics and distribution arrangements. Companies with integrated business model covering multiple stages of the heparin value chain have competitive advantages in building business relationships with multinational pharmaceutical companies. Lack of such global operation capability or integrated business model may become an entry barrier for new entrants.

Strict Quality Control

Since the Baxter Incident in 2008 and the outbreak of African swine fever in 2018, regulators have increasingly tightened the quality control requirements on heparin products. In order to accommodate such requirements, market players need to continually enhance their compliance with CGMP standards. It may be costly, time-consuming and challenging for new entrants to compete with established market players and meet such strict quality control requirements.

INDUSTRY OVERVIEW

Limited Upstream Supply

Manufacturing of enoxaparin API is concentrated in China and therefore demand for heparin raw materials is high. Many enoxaparin manufacturers are expanding to upstream heparin value chain, such as processing of pig small intestines and manufacturing of crude heparin. The limited upstream supply has led to a stable competitive landscape for enoxaparin finished dose, where a few market players have established long-term exclusive cooperative relationships with the upstream suppliers. New entrants may find it difficult to secure sufficient raw material supply at reasonable price.

Growth Drivers and Future Trends

Growth Drivers

- *Increasing clinical demand*—Growth in aging population will result in a significant increase in the prevalence of chronic and cardiovascular diseases. It is estimated that the population over age 65 will increase at a CAGR of 2.6% from 665.7 million in 2018 to 774.9 million in 2024 globally, and such increase will drive the clinical demand for anticoagulants, especially enoxaparin finished dose products.
- *Growth of emerging markets*—With more marketing activities for enoxaparin finished dose products, the awareness of the importance of anticoagulation in patients and doctors will increase. The penetration rate of enoxaparin finished dose in emerging markets, especially, China, will continually increase, which will stimulate the further growth of global enoxaparin finished dose market.
- *Increase in pricing*—It is expected that the price of heparin APIs will increase significantly by 2020 and stay at the high level till 2024 due to the impact of the African swine fever in China. As the largest heparin APIs export country, the fluctuation in supply and price of heparin APIs in the China market will have a significant impact on the global market. The price increase of heparin APIs will ultimately be transferred to the price of downstream enoxaparin finished doses, which will promote the growth of the global enoxaparin finished dose market.

Future Trends

- *Indication and application expansion*—The clinical applications of enoxaparin finished dose are continually expanding. Studies have shown that enoxaparin finished dose is able to treat various diseases in the areas of cardiology, nephrology and neurology. Compared to novel oral anticoagulants (NOACs), enoxaparin finished dose has wider applications and can be used for treatments in which the use of NOACs has not been approved. For example, enoxaparin finished dose can be used to treat acute ST-segment elevation myocardial infarction and prevent thrombosis in blood dialysis, and for prophylaxis of ischemic complications in unstable angina and non-Q-wave myocardial infarction. The wide application and continuous expansion of the indications of enoxaparin finished dose demonstrate significant growth potential of the global enoxaparin market.
- *Product upgrades*—There are a large number of unclassified LMWH finished doses in China with different manufacturing processes, low quality and lack of clinical data support for efficacy and safety. As an effort by the NMPA to tighten the drug quality control requirements, NMPA is expected to implement the QCE approval regime for injection doses in 2020. Chinese Pharmacopoeia Commission (CPC) is also refining the Chinese

INDUSTRY OVERVIEW

Pharmacopeia standards to regulate the market. With these initiatives by both NMPA and CPC, it is anticipated that an increasing number of unclassified low-quality LMWH finished dose products will be replaced by enoxaparin finished dose products due to the superior clinical effects and outstanding safety profile. Enoxaparin finished dose products are also expected to supplant heparin products in the EU, primarily resulted from their superior efficacy and stable anticoagulant effect.

- *Scaled purchases*—As the second largest pharmaceutical market globally, China’s pharmaceutical market has significant growth potential. In addition to the expanding clinical applications of enoxaparin finished dose and its superior therapeutic effects on certain high-mortality diseases, the recent reforms in China’s pharmaceutical policies, such as Centralized Drug Procurement, will also contribute to a growing enoxaparin finished dose market in China. Under the mechanism of Centralized Drug Procurement, enoxaparin finished dose may be purchased in large quantity, which enables the manufacturers to gain a significant market share with lower marketing expenses.

HEPARIN API MARKET

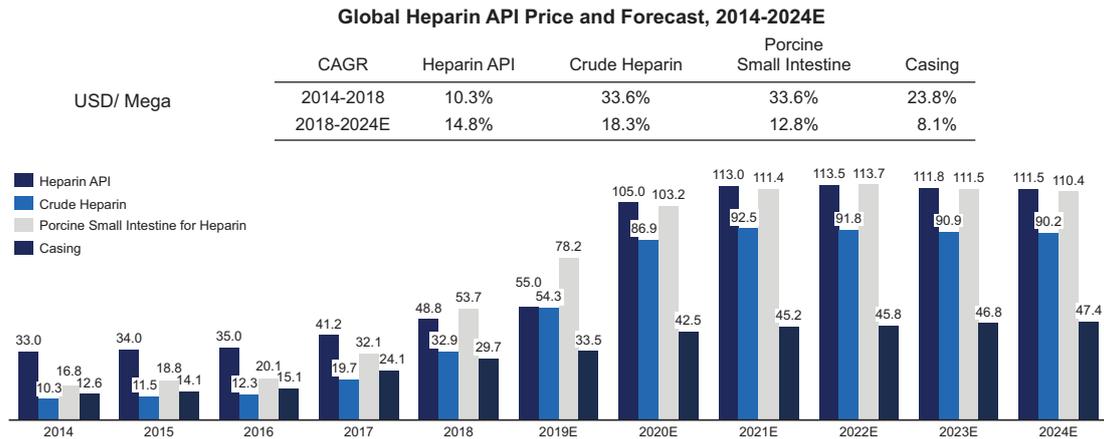
Overview

Heparin API is the active pharmaceutical ingredient and the raw material for manufacturing enoxaparin API and other LMWH APIs, which will be used for manufacturing enoxaparin finished doses and other LMWH finished doses. It is expected that pricing of heparin API will increase significantly in the future due to factors from both demand and supply sides. The global heparin API price is US\$48.8 per mega in 2018, representing a CAGR of 10.3% during 2014 to 2018, and is expected to reach US\$111.5 per mega in 2024 with a CAGR of 14.8%. Downstream of the heparin value chain, i.e. heparin finished dose and LMWH finished dose, are expected to continually expand due to clinical needs, which will generate additional demands for the heparin APIs, and push up both the sales volume and the price of the heparin API. Meanwhile, the upstream market, i.e. crude heparin, is heavily influenced by the supply of breeding stock pigs. The shortage of breeding stock pigs will result in a decreasing supply of porcine small intestines, one of the major raw materials for crude heparin. Such decrease in the quantity of the porcine small intestines will lead to an increase in the price of porcine small intestines, which will be transferred downstream to the price of crude heparin, and further increase the price of heparin API.

In China, three main factors have intensified the shortage of breeding stock pig supplies: (1) the cyclicity of hog price; (2) tightened environmental requirements; and (3) outbreak of African swine fever. First, breeding stock hogs generally have an industry price cycle of four to five years. The hog price uptrend generally lasts for about one to two years, whereas the hog price downtrend lasts for about two to three years. The hog price uptrend of the current cycle started in late 2018. It is expected that the hog price will reach the peak by 2020. Second, since 2017, the Chinese government has increasingly tightened the requirements on the environmental protection of pig breeding and many farms in China have been closed or relocated. Most importantly, the existing farms need to be equipped with pollution control facilities, which significantly increases the cost of pig breeding. Such cost increase is ultimately transferred to the prices of porcine small intestine and crude heparin, the effect of which is expected to continue in the long term. Third, due to the outbreak of African swine fever in late 2018, the number of breeding stock pigs had decreased constantly since the beginning of 2019, and continued throughout 2019, which led to the shortage in supply and a price increase in porcine small intestines, and therefore the shortage in supply and a price increase in crude heparin. As

INDUSTRY OVERVIEW

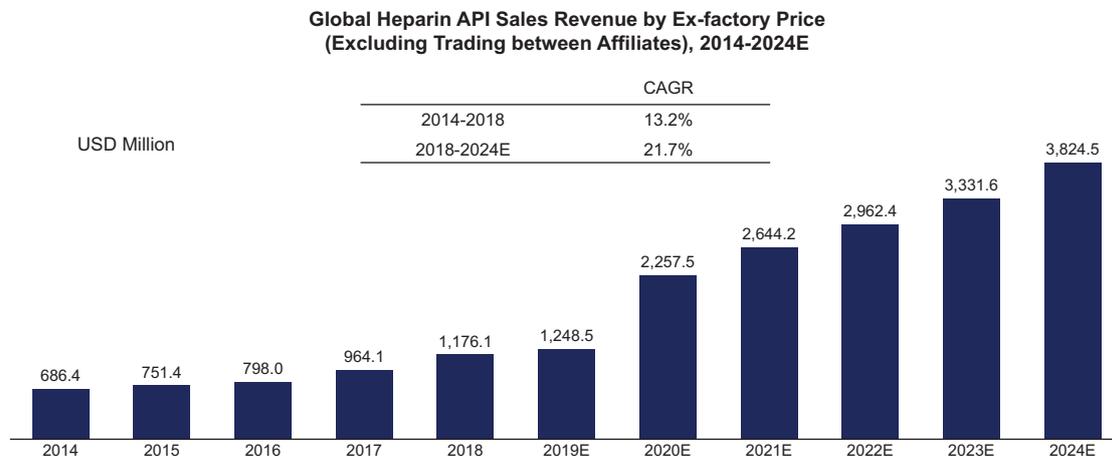
China has the largest heparin API output in the world, and the global demand for heparin API remains inelastic in 2019, such shortage in supply and increased price in crude heparin have resulted in a decrease in the sales quantity of heparin API and an increase in the price of heparin API. The porcine small intestine price increased by 45.6% from 2018 to 2019. Generally, there is one year lag from the price increase of porcine small intestine to that of heparin API. It is estimated that heparin API price will increase by 90.9% from 2019 to 2020. The following chart illustrates the price transmission from porcine small intestines to heparin API:



Source: Frost & Sullivan Report

Market Size

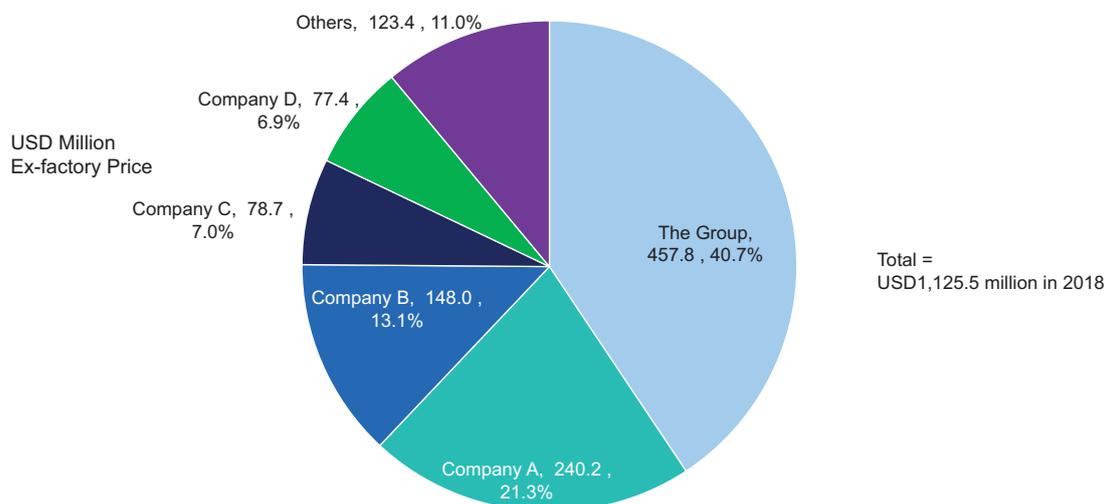
The global sales of heparin API increased steadily from US\$686.4 million in 2014 to US\$1,176.1 million in 2018, representing a CAGR of 13.2%. The situation changed in 2019 as a result of the significant drop in the number of breeding stock pigs in China in 2019 due to the outbreak of African swine fever in late 2018, which caused the shortage and price increase of crude heparin. As a result, heparin API price is expected to increase significantly from 2019 to 2020 and stay at high level till 2024, which will drive the growth of global heparin API market. The global sales of heparin API is projected to reach US\$3,824.5 million in 2024, representing a CAGR of 21.7%, as shown in the following chart:



Source: Frost & Sullivan Report

INDUSTRY OVERVIEW

The global heparin API supply market is highly concentrated with the major suppliers based in China. The top five market players in total accounted for 89.0% of the market share in 2018, and four of them are based in China. The Group is the largest heparin API supplier globally with US\$457.8 million sales accounting for 40.7% of the market share in 2018. The following chart illustrates the market size by sales revenue per market player in 2018:



Source: Frost & Sullivan Report

Future Trends

Increasing price level of crude heparin

The manufacture of heparin APIs heavily relies on the supply of porcine small intestine and is sensitive to environmental protection pressure. The impact of African swine fever in China is expected to last 3 to 5 years, and considering the growth cycle of hogs, it may take 4-6 years for the overall supply of hogs to recover. Therefore, the supply of crude heparin will be continuously limited. The supply of slaughtered hogs in China accounted for 53.4% of the global supply in 2018. Thus the price level of crude heparin will remain high in the short to medium term.

Industrial integration

Along with the strengthened quality control of heparin API and the tight supply of traceable heparin crude as raw materials, heparin API manufacturers are expected to ramp up their efforts in vertical industry value chain integration, in particular integration with the upstream supply of heparin raw material in order to ensure quality and quantity of raw materials and control production costs. As the utilization rate of porcine small intestines is becoming saturated in China, heparin API manufacturers will seek raw material resources from other countries. Therefore, market players with integrated business model covering upstream crude heparin supply and strong global sourcing capacities are expected to enjoy significant competitive advantages to meet the growing market demand.

Steady growth of downstream LMWH finished doses

Due to the expanding indications and lower per capita usage, in particular in China, there are growing clinical demands and significant market potential for LMWH finished doses. Primarily driven

INDUSTRY OVERVIEW

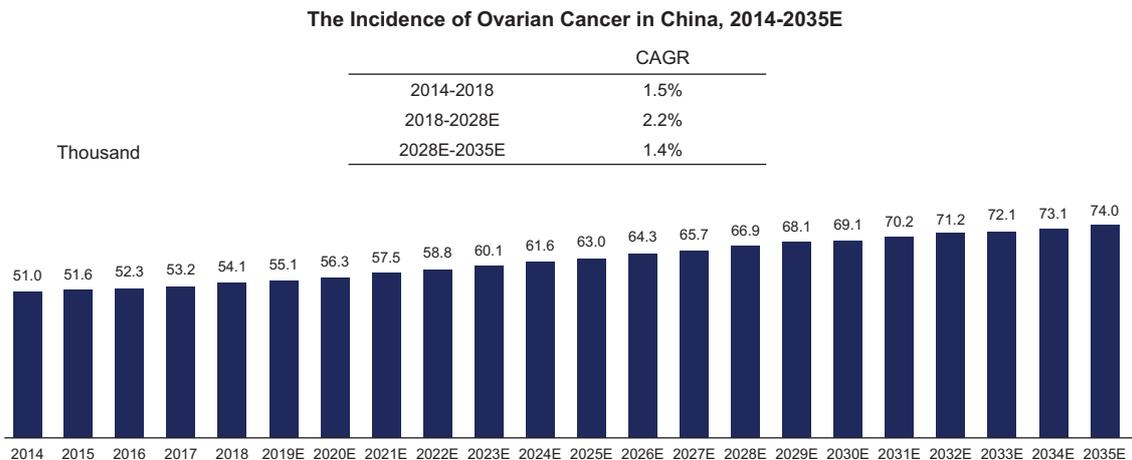
by the increasing incidence of VTE and PE caused by the aging population, demands for LMWH finished doses will continually increase, which will result in a higher demand for heparin APIs.

INNOVATIVE DRUG MARKET

Oncology, anti-infectives, anti-inflammatory, diabetes and cardiovascular are among the therapeutic areas with the significant unmet medical needs worldwide due to its high mortality, high morbidity, or lack of effective treatments. Conventional therapies for these diseases are proven to be limited and many of the first-line treatments remained undeveloped for many years, and thus an increasing number of pharmaceutical companies, from multinational pharmaceutical giants to mid- to small-sized companies, have aggrandized their presence in the innovative drug market, and focused on the development of innovative treatment options, such as targeted therapies.

Ovarian Cancer

Ovarian cancer is a type of cancer that forms in or on ovaries, the female reproductive glands that produce eggs during a woman’s reproductive years. Ovarian cancer may evolve from initial symptoms such as abdominal bloating, changes in appetite, pressure and pain in lower back and menstrual changes to ovarian cysts, masses or tumors. The following chart illustrates the historical trend and forecast of the incidence of ovarian cancer in China from 2014 to 2035:



Source: Frost & Sullivan Report

Ovarian cancer has large unmet medical needs due to poor prognosis and high mortality rate, lack of new first-line treatment and effective later line treatments. Ovarian cancer is the second most common gynecologic malignancy with a high mortality rate. The five-year survival rate of ovarian cancer is 39.1% in China and 47.6% in the U.S. Conventional methods of treating ovarian cancer generally comprise a combination of chemotherapy and surgery. The first-line treatment for primary ovarian cancer is chemotherapy with carboplatin, docetaxel or paclitaxel, which has not been changed for more 10 years. Many women affected by advanced ovarian cancer respond to chemotherapy, but the effects typically are not long-lasting. The clinical course of ovarian cancer patients is marked by periods of remission and relapse of sequentially shortening duration until chemotherapy resistance develops. More than 80% of ovarian cancer patients experience recurrent disease, and more than 50% of these patients die from the disease in less than five years post-diagnosis. Bevacizumab in combination with chemotherapy has been approved for first-line therapy, resulting in a few months’

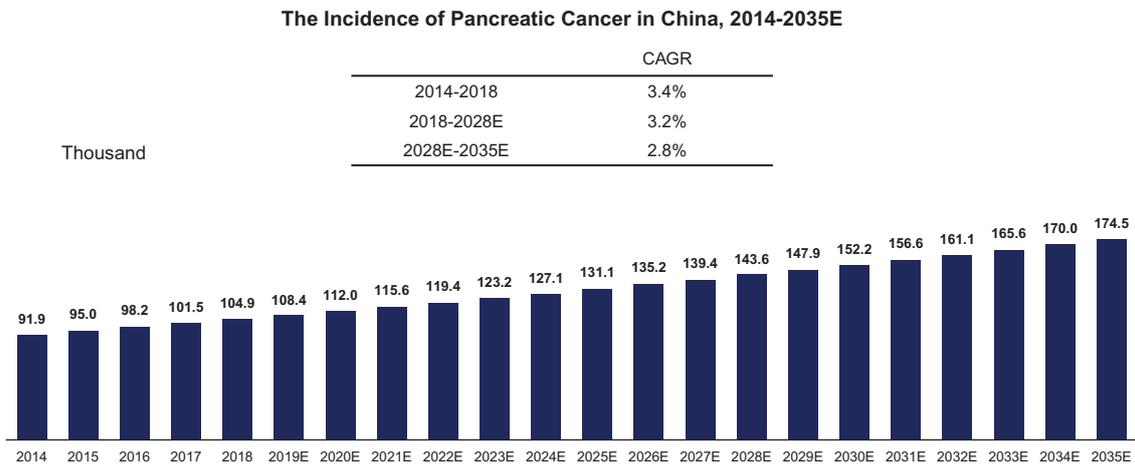
INDUSTRY OVERVIEW

delay in disease progression. The treatment however does not prolong the patients’ life and may cause severe side effects.

PARP inhibitor (olaparib) is approved as first-line maintenance therapy for patients with deleterious BRCA mutations after showing response to first-line chemotherapy. Around 10-15% patients had BRCA mutations, leaving the rest of patients in need of new first-line treatment. Advances in checkpoint inhibitor therapy have gained speed in cancer care; however, ovarian cancer has yet to see any approved indications for immunotherapy agents.

Pancreatic Cancer

Pancreatic cancer is caused by the abnormal and uncontrolled growth of cells in the pancreas, a large gland of the digestive system. Its symptoms include jaundice, sudden weight loss and digestive problems as early warning signs, and severe upper abdomen or back pain, extreme fatigue and diagnosed diabetes as advanced warning signs. The following chart illustrates the historical trend and forecast of the incidence of pancreatic cancer in China from 2014 to 2035:



Source: Frost & Sullivan Report

Pancreatic cancer has large unmet medical needs due to poor survival rate, and drug resistance developed after chemotherapy. Pancreatic cancer is one of the most lethal cancers worldwide. The five-year survival rate is only about 6% globally and 7.2% in China. It is difficult for the doctors to detect and prognose the development of pancreatic cancer at an early stage.

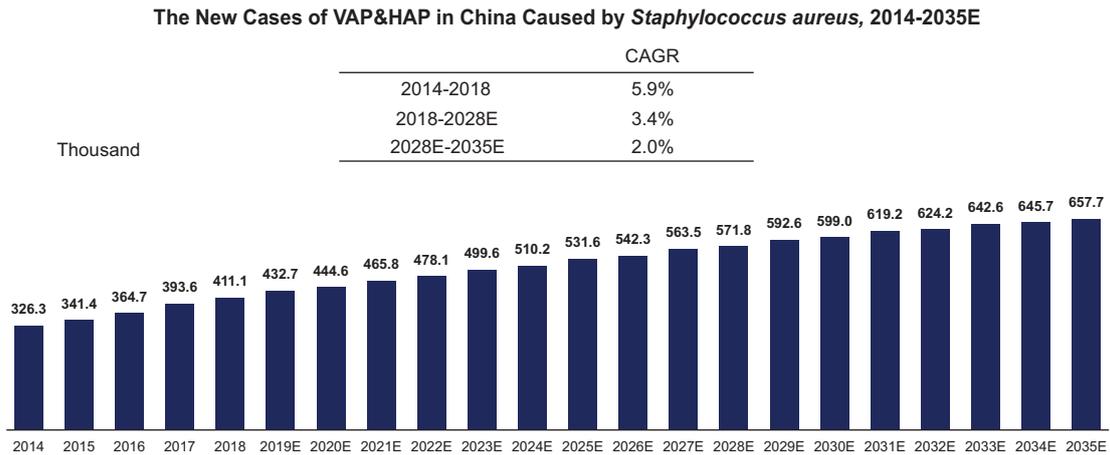
Main treatment methods for pancreatic cancer consist of surgery, radiotherapy, chemotherapy and interventional therapy. However, only around 10% to 15% of the patients are eligible for tumor resection, approximately 28% of the patients have chemotherapy as part of their primary cancer treatment. The options of targeted therapies are limited, most of which have not demonstrated expected efficacy.

In addition, most of the patients taking certain first-line drugs, such as gemcitabine, have been found to develop drug resistance. Recently, PARP inhibitor olaparib was approved in the U.S. as a first-line maintenance treatment of germline BRCA-mutated metastatic pancreatic cancer. However, only about 5%-8% of patients with BRCA mutation were benefited from such new treatment with a limited increase in progression-free survival.

INDUSTRY OVERVIEW

VAP and HAP Caused by *Staphylococcus Aureus*

Ventilator-associated Pneumonia (VAP) is a type of lung infection that usually occurs 48 hours or more after the initiation of mechanical ventilation such as endotracheal intubation or tracheotomy. Hospital-acquired pneumonia (HAP) refers to any pneumonia occurring 48 hours or more after hospital admission. Both VAP and HAP can be caused by bacterium infection, such as infection from *Staphylococcus aureus* (*S. aureus*). The following chart illustrates the historical trend and forecast of the new cases of VAP and HAP caused by *S. aureus* in China from 2014 to 2035:



Source: Frost & Sullivan Report

Anti-infection therapy of VAP and HAP evolves from initial empiric antibiotic therapy, including antibiotics monotherapy and combined antibiotics therapy, to pathogen-specific antibiotic therapy. Methicillin-resistant *Staphylococcus aureus* (MRSA) is one of the most common drug-tolerated pathogens for VAP and HAP, and glycopeptides and linezolid are two types of antibiotics that are commonly used for MRSA-specific therapies.

VAP is a high-mortality disease with the 30-day mortality rate reaching 28.4%. Intubation and ventilator support bypass the normal host defense mechanism, which increases the patients' risks of bacterial infection. Long term and repetitive use of the conventional therapeutic options, anti-microbial therapy may cause patients to develop drug resistance. HAP also has a high death rate with the 30-day mortality rate reaching 23.9%. It is difficult to conduct clinical trials for patients with HAP because the enrolled patients have to undergo empiric antibacterial therapy at the same time, which may obscure the clinical results of the anti-bacterial drugs under study. In addition, anti-microbial resistance in major pathogens of HAP and VAP may ultimately result in treatment failure. Inappropriate anti-microbial therapy in both inpatient and outpatient settings, has increasingly been recognized as a major cause of anti-microbial resistance that may contribute to VAP and HAP's high death rate. Anti-infective mAbs is a new class of anti-infective drugs that has the potential to become the standard of care, respectively, for active adjunctive treatment and prophylactic treatment of VAP and HAP due to its superior safety profile, a remarkably long plasma half-life period of approximately 25 days, and a low possibility of drug resistance.

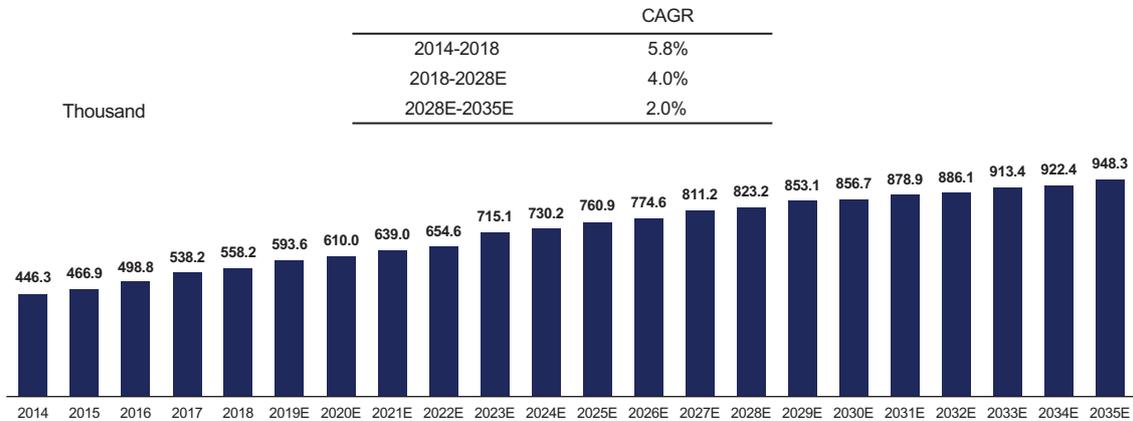
VAP and HAP caused by *Pseudomonas aeruginosa*

Pseudomonas aeruginosa (*P. aeruginosa*) is a common pathogenic bacteria of VAP and HAP, which can be treated by specific antibiotics such as cephalosporin, carbapenem, β -lactamase inhibitors,

INDUSTRY OVERVIEW

aminoglycosides and polymyxin. The following chart illustrates the historical trend and forecast of the new cases of HAP and VAP caused by *P. aeruginosa* in China from 2014 to 2035:

The New Cases of HAP&VAP in China Caused by *Pseudomonas aeruginosa*, 2014-2035E



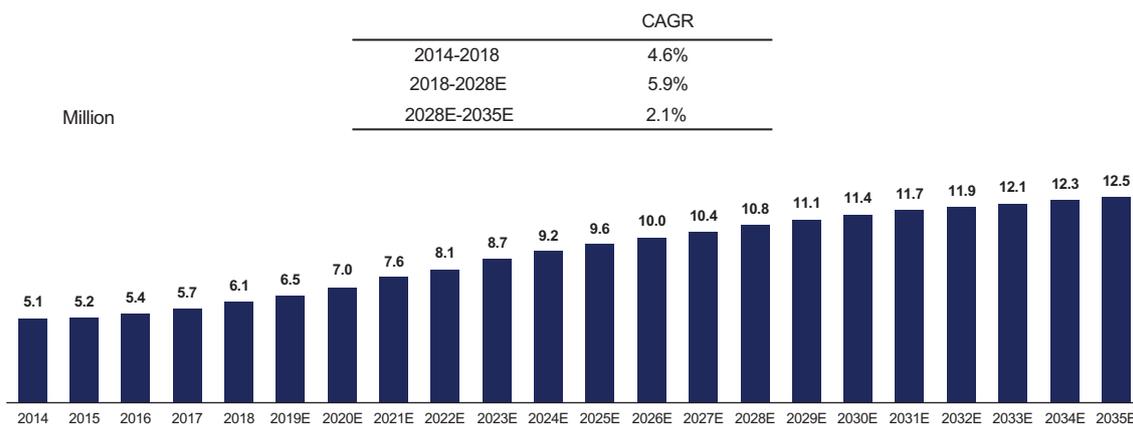
Source: Frost & Sullivan Report

Anti-infective mAbs is a new class of anti-infective drugs that has the potential to become the standard of care, respectively, for active adjunctive treatment and prophylactic treatment of VAP and HAP due to its superior safety profile, a remarkably long plasma half-life period of approximately 25 days, and a low possibility of drug resistance.

Type 2 Diabetes with CHD

Coronary heart disease (CHD) involves the reduction of blood flow to the heart muscle, resulting from build-up of plaque in the arteries of the heart. The most common symptoms of CHD are angina and chest pain. The following chart illustrates the historical trend and forecast of diagnosed patients of type 2 diabetes with CHD in China from 2014 to 2035:

The Diagnosed Patients of Type 2 Diabetes with CHD in China, 2014-2035E



Source: Frost & Sullivan Report

Due to the high correlation between diabetes and cardiovascular diseases, an assessment and control of cardiovascular risk factors, such as hyperglycemia, hypertension and dyslipidemia, combined with an antiplatelet therapy, is necessary for the prevention and treatment of type 2 diabetes with CHD. Treatment options of cardiovascular disease includes many therapeutic agents, such as lipid

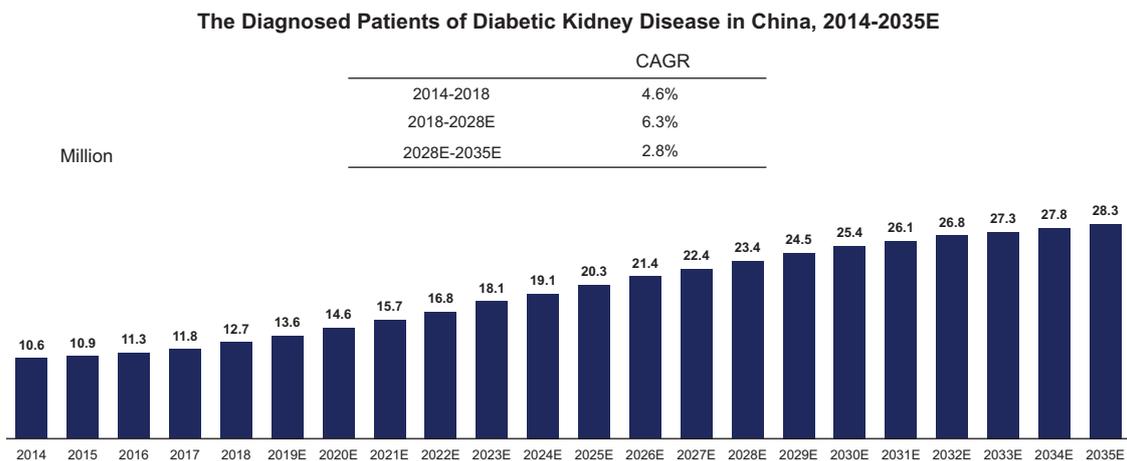
INDUSTRY OVERVIEW

lowering drugs, heart rate lowering agents and blood pressure lowering drugs. However, there still remains a large residual risk of major adverse cardiovascular events (MACE) for patients taking the current therapies.

Despite of the high prevalence of type 2 diabetes with CHD in China, there was few cardiac prevention or rehabilitation program established in China. Even though the coronary death rates have decreased for decades, CHD death rates may increase in the near future because of the worldwide epidemic of obesity.

Chronic Kidney Disease

Chronic kidney disease (CKD) refers to the gradual loss of kidney function. It is common, frequently unrecognized and may co-exist with other diseases, such as diabetes. CKD can progress to end-stage kidney diseases, and may even lead to death as severe complications are triggered. The following chart illustrates the historical trend and forecast of the prevalence of CKD in China from 2014 to 2035:



Source: Frost & Sullivan Report

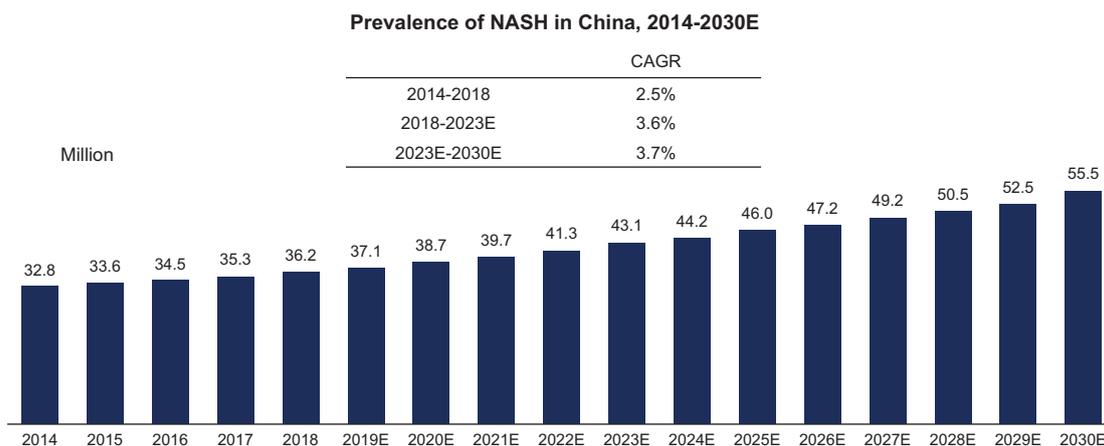
In addition to nutrition and lifestyle therapy, which involves patient education, self-monitoring of blood sugar, diet adjustment and exercise, drug therapy is another treatment option for CKD, mainly focusing on glycemic control, anti-hypertension and lipid regulation.

Diabetes is the leading cause of end-stage renal disease (ESRD) globally, accounting for approximately 40% of patients receiving renal replacement therapy each year. ESRD places a substantial economic burden on patients with treatment and rehabilitation expenses, and leads to loss in economic productivity and diminished social functions.

Non-Alcoholic Steatohepatitis

Non-Alcoholic Steatohepatitis (NASH) is one of the most severe forms of non-alcoholic fatty liver disease. NASH may evolve from initial symptoms such as fatigue, weight loss and stomachache, to fibrosis, liver cirrhosis or even liver cancer. The following chart illustrates the historical trend and forecast of the prevalence of NASH in China from 2014 to 2030:

INDUSTRY OVERVIEW



Source: Frost & Sullivan Report

NASH has huge unmet medical needs due to its large patient pool, no marketed drug, difficulties in developing drugs and cause for other severe diseases. With a prevalence of 24% worldwide, NASH is now the most common liver disorder. The increasing prevalence of NASH is related to the growing obesity epidemic and the disease is diagnosed in patients who have diabetes, high cholesterol or high triglycerides. Despite such a high prevalence rate, at present, there is no approved pharmacologic treatment for NASH. All the drugs applied are used to treat the complications of NASH, lower the risk of further progression, and prevent damages to the liver. Numerous obstacles make drug development for NASH treatment a challenge. The complexity of the pathogenesis of the disease, which involves multiple pathways, requires targeting of more than one pathway or a combination-based therapy. The complex interactions among numerous metabolic pathways, the immune system, and the gut prevent the development of a one drug-based therapy that can provide a cure for NASH. NASH is now considered to be the leading, and a rapidly increasing, cause of hepatocellular carcinoma, or primary liver cancer. More than 20% of patients with NASH progress to cirrhosis within a decade of diagnosis and, compared to the general population, have a ten-fold greater risk of liver-related mortality.

Changes in lifestyle, primarily through adjusting the diet and forming a habit of regular exercise, are currently the most effective method to treat NASH. Bariatric surgery can help relieve symptoms and lower the risk of developing cardiovascular diseases, but there was no evidence showing that bariatric surgery is able to treat NASH. Liver transplantation is also not a promising therapeutic option because of the limited liver sources and the high probability of recurrence in the transplanted liver.

Heparanase Inhibitor

Heparanase is a heparin sulfate specific endo- β -D glucuronidase. Studies show that enhanced expression of heparanase is observed in almost all types of cancer examined, which is tightly correlated with the tumor size, angiogenesis, metastasis and poor prognosis. Such finding placed heparanase as a type of cancer-associated enzyme. Clinical trials have been conducted for five subtypes of heparanase inhibitors globally, but only SST0001(ronaparstat) and PG545 are still under clinical study.

SST0001 (ronaparstat) is a modified heparin composed of 100% N-acetylated and 25% glycol split. Compared to unmodified heparin, ronaparstat is able to inhibit the heparanase enzymatic activity

INDUSTRY OVERVIEW

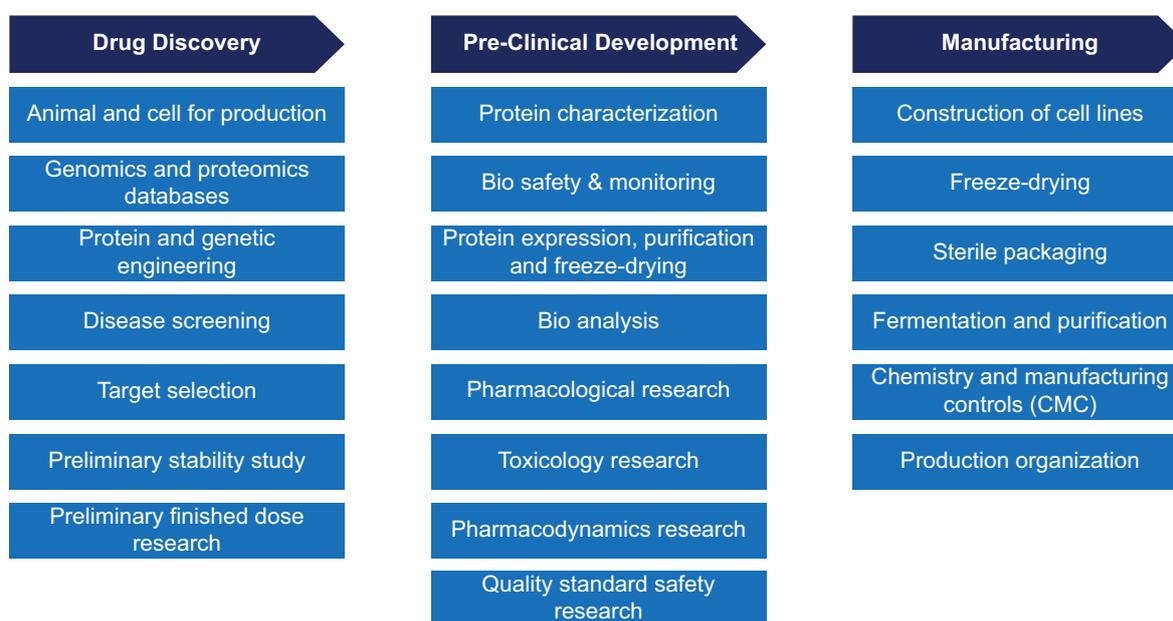
with a decreased ability to release extracellular matrix-bound FGF-2. Roneparstat was well tolerated and safe at all the dose levels tested. Patients could be exposed to the drug at the dose levels of 200 and 400 mg/day without showing clinically relevant toxicities.

Heparanase inhibitors act on the heparan sulfate chain of the extracellular matrix (ECM), which plays an important role in tumor metastasis, tumor progression and the adjustment of tumor’s micro-environment. Unlike conventional cytotoxic and targeted drugs, heparanase inhibitors are expected to have an integrated effect in inhibiting both tumor growth and tumor metastasis, and can be combined with cytotoxic drugs, targeted therapy or immunotherapy for cancer treatment.

BIOPHARMACEUTICAL CDMO MARKET

Biologics CDMO Value Chain

Contract Development and Manufacturing Organizations (CDMOs) provide both customized pharmaceutical manufacturing services and high value-added services, such as drug development and optimization of the drug synthesis process. The two major types of CDMOs are pharmaceutical CDMOs and biologics CDMOs, the latter of which continually drives the growth of the overall CDMO market. Biologics CDMOs mainly focus on biological drug manufacturing, advancement of drug production technology and optimization of drug synthesis process. The following diagram illustrates the integrated value chain of biologics CDMO:



**Service offerings vary based on company's core strength and focus*

Source: Frost & Sullivan Report

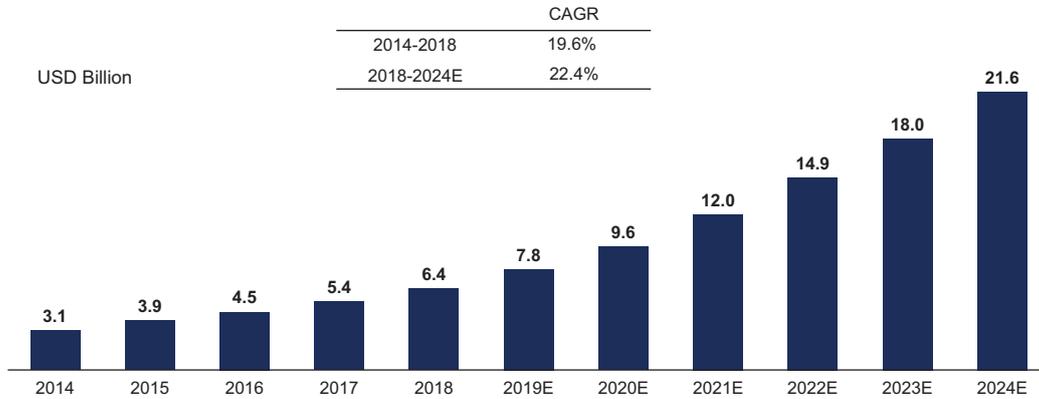
Market Size

With the increasing investment in biologics industry and the emergence of small and mid-sized pharmaceutical companies focusing on the development of innovative biologic drugs, the global biologics CDMO market has expanded rapidly in recent years. Global revenue of biologics CDMO

INDUSTRY OVERVIEW

increased from US\$3.1 billion in 2014 to US\$6.4 billion in 2018, representing a CAGR of 19.6%, which is expected to reach US\$21.6 billion in 2024 at a CAGR of 22.4%, as shown in the following chart:

Global Biologics CDMO Market Size and Forecast, 2014-2024E



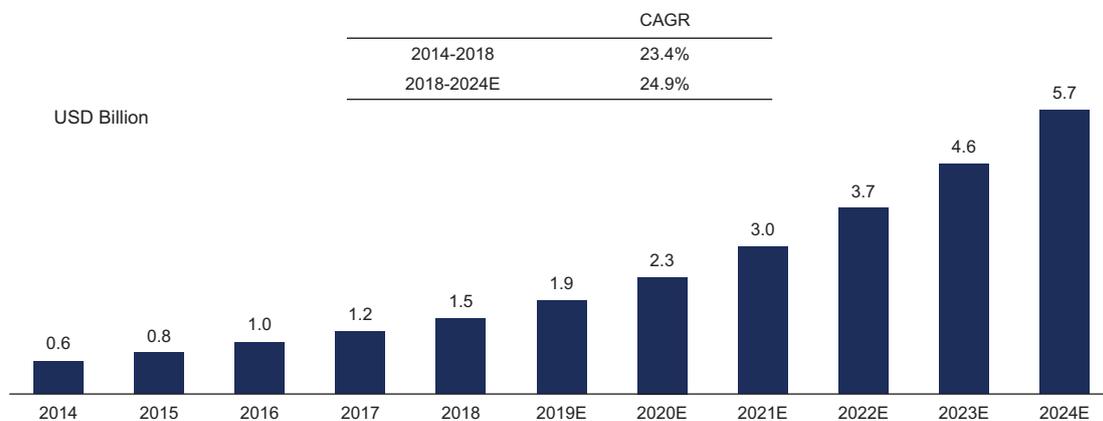
Source: Frost & Sullivan Report

As the top five players of global biologics CDMO market in total accounted for a market share of 52.1% in terms of revenue in 2018, the global biologics CDMO market is generally believed to be not concentrated, suggesting significant market potential for small and mid-sized biologics CDMO companies. Additionally, as a growing number of pharmaceutical companies are developing biologics and more biosimilars are expected to enter the market, there will be huge demand for biologics CDMO service with significant growth potential.

Gene Therapy CDMO Market

The next generation of therapy, gene therapy, is a set of strategies that modifies the expression of an individual’s genes or repair abnormal genes. Gene therapy has demonstrated substantial growth potential due to significant unmet clinical needs and recent commercial breakthroughs will further accelerate the growth of gene therapy. An increasing number of gene therapy focused CDMOs have been established to capture the growth opportunities of gene therapy market. The global gene therapy CDMO market increased from US\$0.6 billion in 2014 to US\$1.5 billion in 2018, at a CAGR of 23.4%, and is expected to reach US\$5.7 billion in 2024, at a CAGR of 24.9%.

Gene Therapy CDMO Market, 2014-2024E¹



Source: Frost & Sullivan Report

¹ Gene Therapy includes cell and gene therapy

INDUSTRY OVERVIEW

Plasmids DNA (pDNA) has been increasingly applied as non-viral vectors for gene therapy since 1990. The key mechanism of pDNA is endocytosis. Compared to viral and RNA-based vectors, plasmids are generally easier and cheaper to manufacture, transport and store and have a longer shelf life. The modular nature of plasmids also allows for direct molecular cloning, which enables it to become a superior vector for therapeutic use. The advantages of non-viral DNA vectors, such as pDNA, over viral vectors and RNA-based vectors have compelled researchers to improve their safety and utility for better clinical use. Because of the improved safety over viral vectors, pDNA has enabled a number of clinical trials.

The costs related to pDNA constitute the largest portion of variable costs for gene therapy production, which may exceed more than 60% when customized and CGMP-grade pDNA are used. Such high costs of production in addition to the increasing demand for pDNA due to its superior nature for gene therapy will encourage more CDMOs to enter the pDNA manufacturing field.

Entry Barriers

- *Ability to attract professional talents*—A full-service biologics CDMO business requires multi-disciplinary talents, such as R&D and sales professionals, to accomplish complex drug development, optimization of drug synthesis and other value-added services. R&D experts and strong sales force are crucial components of a successful CDMO, which help seek and secure collaboration opportunities. Hiring suitable R&D experts and in-house trainings to foster seasoned sales teams are time-consuming and involve high risks. New market entrants may find it difficult to compete for or cultivate such professional talents in the market.
- *Reputation for High Quality*—Biologics CDMO service providers are expected to not only complete the projects or provide the required services on time but also deliver high-quality products in compliance with the increasingly stringent regulations. New market entrants may find it challenging to establish a reputation for high quality in line with the evolving regulatory landscape.
- *High technical requirements*—Constant technical innovation is important for an established CDMO. For instance, the techniques of spray drying and continuous manufacturing can help a CDMO optimize the process and thus effectively lower the manufacturing costs. Such technical innovation requires a significant amount of R&D efforts and capital investment, which may hinder new players from entering into the market.

Growth Drivers

Global biologics market is expected to grow rapidly mainly driven by the superior efficacy of biologics, technological innovation, favorable government policies, increasing capital investment and emergence of small and mid-sized innovative companies as further discussed below. Such factors will therefore boost the demands for CDMO services for biologics and further drive the growth of biologics CDMO market.

- *Superior efficacy*—Biologics have demonstrated improved efficacy and fewer side effects in treating a broad spectrum of diseases that lacked effective therapies in the past, such as

INDUSTRY OVERVIEW

cancers and autoimmune diseases. The superior efficacy of biologics has led to an increasing acceptance of biologics among patients and doctors, which will generate strong market demand and stimulate the continuing growth of biologics market.

- *Advancement in Biotechnology*—Technological innovation in areas of genetics and biochemistry is crucial for the enhancement of a pharmaceutical company’s in-house R&D capabilities. It also helps to increase the company’s production yield and thereby lower the production costs. As such, advancement in biotechnology will continue driving the growth of the global biologics market.
- *Favorable policies in Emerging Markets*—The governments in developing countries have prioritized and designated the pharmaceutical industry as one of their “pillar industries” with the promulgation of favorable governmental policies and initiatives, such as expansion of the health insurance coverage and investment on medical infrastructure. As healthcare service and products become more accessible in those countries, the increasing sales in these markets will significantly contribute to the growth of global biologics sales in the next few years.
- *Increasing capital investment*—To maintain their leading market position, large pharmaceutical companies will continue to invest in both R&D and acquisition for innovative biologics candidates. Meanwhile, small and mid-sized pharmaceutical companies with a focus on innovative biologics are also able to attract more capital investment due to favorable governmental policies and increased public attention. Increases in global investment in biologics section will result in a rapid expand of biologics pipeline worldwide.
- *Emergence of Small and Mid-sized Innovative Companies*—With favorable governmental policies and increased capital investment, an increasing number of biotech startups have expanded their pipelines to innovative biologics. The competitive landscape of innovative biologics market will become less concentrated only among global pharmaceutical companies, as more market players are entering into the market. The increase in the number of market participants will stimulate the development of biologics market globally.

Future Trends

- *Developing Gene Therapy Focused CDMOs*—Approximately 7,000 rare diseases are identified worldwide, in which only 5% have FDA approved treatment options, indicating significant unmet medical needs. 80% of rare diseases are monogenic and gene therapy is becoming increasingly important for the treatment of rare diseases. In order to meet such growing demand, gene therapy focused CDMOs is indispensable so as to supplement the manufacturing capacity.
- *Broader service coverage*—CDMOs will become a one-stop shop covering a broader range of services, from early-stage drug development to commercialization. Such broader service coverage will enable the CDMOs to meet the demand of pharmaceutical companies seeking to consolidate their processes and to diminish the transactions with multiple suppliers or outsourcing partners. Through strategic investment and innovative collaborations, continuous investment in CDMO R&D capabilities is able to attract customers at the early stage of their drug development process, and offer more value-added services at the later stage.

INDUSTRY OVERVIEW

- *Industrialization of developing countries*—With the advantages of professional talents and lower manufacturing costs, CDMOs based in developing countries, such as China and India, have attracted the attention of many multi-national pharmaceutical companies (“MNCs”). As these CDMOs conform to the international standards, more orders from MNCs will be transferred to them.
- *Growing Importance of Biologics*—Therapeutic biologics have shown significant growth potential worldwide, primarily attributable to their superior efficacy and fewer side effects. Biosimilars will play an important role in the further expansion of the biologics market as the patent of some blockbuster biologic originators have expired. The in-house manufacturing capacity of the biopharmaceutical companies may not be sufficient to digest such growing demand and thus they have to outsource to CDMOs for drug manufacturing. In addition, as the drug structures are becoming more complex in the development of new drugs, pharmaceutical companies are increasingly relying on CDMOs for specialized expertise, which bolsters and secures the leading market position of CDMOs for the outsourced manufacture of biologics.

REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and to prepare an industry report on the relevant industries in which we operate. Frost & Sullivan is an independent global market research and consulting company founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking, and strategic and market planning for a variety of industries. We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the heparin drug market for potential [REDACTED]. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

Other bases and assumptions adopted by Frost & Sullivan in making its forecast include: (i) the social, economic and political environments of the EU, the PRC and the U.S. will remain stable during the forecast period, which will ensure a sustainable and steady development of the global healthcare industry; (ii) the global healthcare market will grow as expected due to rising healthcare demand and supply; and (iii) the global government will continue to support healthcare reform.

We have agreed to pay Frost & Sullivan a fee of RMB500,000 for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [REDACTED] or on the content of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [REDACTED]. We confirm that after taking reasonable care, there has been no adverse change in the market information since the date of the report prepared by Frost & Sullivan which may qualify, contradict or have an impact on the information set forth in this section in any material respect.

REGULATORY ENVIRONMENT

LAWS AND REGULATIONS RELATED TO OUR BUSINESS IN THE PRC

Regulations on Foreign Investment

The establishment, operation and management of corporate entities in China are governed by the Company Law of PRC (《中華人民共和國公司法》, the “**PRC Company Law**”), which was adopted by the Standing Committee of the National People’s Congress (“**SCNPC**”) on December 29, 1993, implemented on July 1, 1994, and subsequently amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018. Under the PRC Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The PRC Company Law also applies to foreign-invested limited liability companies. Pursuant to the PRC Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail.

Investment activities in the PRC by foreign investors are governed by the Guiding Foreign Investment Direction (《指導外商投資方向規定》), which was promulgated by the State Council on February 11, 2002 and came into effect on April 1, 2002, and the Special Administrative Measures (Negative List) for Foreign Investment Access (《外商投資准入特別管理措施(負面清單)(2019年版)》, the “**Negative List (2019 Edition)**”), which was amended and promulgated by the MOFCOM and NDRC on June 30, 2019 and took effect on July 30, 2019. The Negative List set out in a unified manner the restrictive measures, such as the requirements on shareholding percentages and management, for the access of foreign investments, and the industries that are prohibited for foreign investment. The Negative List covers 13 industries, and any field not falling in the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment.

Foreign Investment Law of the People’s Republic of China (《中華人民共和國外商投資法》) (“**Foreign Investment Law**”) was promulgated by SCNPC on March 15, 2019 and become effective on January 1, 2020. After the Foreign Investment Law came into force, the law on wholly foreign-owned enterprises (《中華人民共和國外資企業法》), the law on Sino-foreign equity joint ventures (《中華人民共和國中外合資經營企業法》) and the law on Sino-foreign contractual joint ventures (《中華人民共和國中外合作經營企業法》) have been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as foreign investors) directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law: 1) establishing by foreign investors of foreign-invested enterprises in China alone or jointly with other investors; 2) acquiring by foreign investors of shares, equity, property shares, or other similar interests of Chinese domestic enterprises; 3) investing by foreign investors in new projects in China alone or jointly with other investors; 4) other forms of investment prescribed by laws, administrative regulations or the State Council.

On December 26, 2019, the State Council issued the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), which came into effect on January 1, 2020. After the Regulations on Implementing the Foreign Investment Law of the PRC came into effect, the Regulation on Implementing the Sino-Foreign Equity Joint Venture Enterprise Law (《中華人民共和國中外合資經營企業法實施條例》), Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture Enterprise Law (《中外合資經營企業合營期限暫行規定》), the Regulations on Implementing the Wholly Foreign-Invested Enterprise Law (《中華人民共和國外資企業法實施細則》) and the Regulations on Implementing the Sino-foreign Cooperative Joint Venture Enterprise Law (《中華人民共和國外資企業法實施細則》) have been repealed simultaneously.

REGULATORY ENVIRONMENT

On December 30, 2019, the MOFCOM issued the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect on January 1, 2020. After the Measures for the Reporting of Foreign Investment Information came into effect, the Interim Measures on the Administration of Filing for Establishment and Change of Foreign Investment Enterprises (《外商投資企業設立及變更備案管理暫行辦法》) has been repealed simultaneously. Since January 1, 2020, for foreign investors carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to these measures.

Regulations on Overseas Investment

Pursuant to the Administrative Measures for Outbound Investment (《境外投資管理辦法》) (Order No. 3 [2014] of the MOFCOM, effective on October 6, 2014) promulgated by the MOFCOM, the MOFCOM and Provincial Competent Commerce Departments shall carry out administration either by record-filing or approval, depending on different circumstances of outbound investment by enterprises. Outbound investment by enterprises that involves sensitive countries and regions or sensitive industries shall be subject to administration by approval. Outbound investment by enterprises that falls under any other circumstances shall be subject to administration by record-filing.

Pursuant to the Administrative Measures for Outbound Investment by Enterprises (《企業境外投資管理辦法》) (Order No. 11 of the NDRC, effective on March 1, 2018), a domestic enterprise (the “**Investor**”) making an outbound investment shall obtain approval, conduct record-filing or other procedures applicable to outbound investment projects (the “**Projects**”), reporting relevant information, and cooperating with the supervision and inspection. Sensitive Projects carried out by Investors directly or through overseas enterprises controlled by them shall be subject to approval; non-sensitive Projects directly carried out by Investors, namely, non-sensitive projects involving investors’ direct contribution of assets or rights and interests or provision of financing or guarantee shall be subject to record-filing. The aforementioned “sensitive project” means a project involving a sensitive country or region or a sensitive industry. The NDRC promulgated the Catalog of Sensitive Sectors for Outbound Investment (2018 Edition) (《境外投資敏感行業目錄(2018年版)》), effective on March 1, 2018 to list the current sensitive industries in detail.

Regulations on Drug Research and Development & Registration Services

Research and Development of New Drugs

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》), last amended on August 26, 2019 and effective on December 1, 2019), the dossier on a new drug research and development, including the manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and the samples, shall, in accordance with the regulations of NMPA be truthfully submitted to the said department for approval before clinical trial is conducted. The medical products administration under the State Council shall, within 60 working days from the date on which the application for such clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed as approved. When a new drug has gone through the clinical trial and passed the evaluation, a drug registration certificate shall be issued upon approval by NMPA. The institutions for non-clinical safety evaluation and study and clinical trial organizations shall respectively implement the Good Laboratory Practice for Non-Clinical Laboratory Studies (the “**GLP**”) (《藥物非臨床研究質量管理規範》), Order No. 34 of the State Food

REGULATORY ENVIRONMENT

and Drug Administration, effective on September 1, 2017) and Good Clinical Practice (the "GCP") (《藥物臨床試驗質量管理規範》, Order No. 3 of the State Food and Drug Administration, effective on September 1, 2003). If certain actions in the preclinical trial research and clinical research conducted for a clinical application trial, and/or in the application procedures for registration of medicines, are in violation of the relevant rules and regulations, the CFDA is authorized to handle such cases pursuant to the Measures regarding Noncompliance with Relevant Rules of Research and Application for Registration of Medicines (《藥品研究和申報註冊違規處理辦法(試行)》) promulgated on and effective from September 1, 1999. On July 22, 2015, the CFDA issued Notice No. 117 (CFDA notice in relation to self-review of clinical trials data) (《國家食品藥品監督管理總局關於開展藥物臨床試驗數據自查核查工作的公告》), which required the current applicants in respect of the existing 1,622 drug manufacturing or drug import applications to the CFDA to reassess the clinical trials data in respect of each application.

Drug Registration

Examination and Approval of New Drug Application

On July 10, 2007, the NMPA promulgated the Amended version of the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), or the Registration Measures, which became effective on October 1, 2007. The Registration Measures mainly cover: (1) definitions of drug registration applications and regulatory responsibilities of the drug administration; (2) general requirements for drug registration, including application for registration of new drugs, generic drugs, imported drugs and the supplemental application, as well as the application for re-registration; (3) clinical trials; (4) application, examination and approval of new drugs, generic drugs and imported drugs; (5) supplemental applications and re-registrations of drugs; (6) inspections; (7) registration standards and specifications; (8) time limit; (9) re-examination; and (10) liabilities and other supplementary provisions. Under the Registration Measures, new drugs generally refer to those drugs that have not been previously marketed in China. In addition, certain marketed drugs may also be treated as new drugs if the type or application method of these drugs has been changed or new therapeutic functions have been added to these drugs. If all the regulatory requirements are satisfied, the NMPA will grant a new drug certificate and a drug registration number (assuming the applicant has a valid Pharmaceutical Manufacturing Permit and the requisite production conditions for the new medicine have been met). All pharmaceutical products that are produced in China must bear drug registration numbers issued by the NMPA, with the exception of certain Chinese herbs and Chinese herbal medicines in soluble form. Drug manufacturing enterprises must obtain the drug registration numbers before manufacturing any drug. A drug registration number issued by the NMPA is valid for five years and the applicant shall apply for renewal six months prior to its expiration date.

According to the Registration Measures, drug registration applications are divided into three different types, namely Domestic NDA, Domestic Generic Drug Application, and Imported Drug Application. Drugs which fall into one of three general types are divided according to the drug's working mechanism, namely whether the drug is classified as a chemical medicine, a biological product, a traditional Chinese medicine or a natural medicine. A new drug application refers to an application for registration of a drug that has not yet been marketed for sale in China. In addition, the registration of drugs that change the dosage form of the marketed drugs, change the route of administration, and increase the new indications shall be reported in accordance with the application procedures for new drugs. Under the Registration Measures, a Category 1 drug refers to a new drug that has never been marketed in any country, and such drug is eligible for special review or fast track approval by the NMPA.

REGULATORY ENVIRONMENT

In March 2016, the NMPA issued the Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) (the “**Reform Plan**”), which outlined the reclassifications of drug applications under the Registration Measures. Under the Reform Plan, Category 1 drugs refer to new drugs that have not been marketed anywhere in the world. Improved new drugs that are not marketed anywhere in the world fall into Category 2. Generic drugs, that have equivalent quality and efficacy to the originator’s drugs have been marketed abroad but not yet in China, fall into Category 3. Generic drugs, that have equivalent quality and efficacy to the originator’s drugs and have been marketed in China, fall into Category 4. Category 5 drugs are drugs which have already been marketed abroad, but are not yet approved in China. Category 1 drugs and Category 5 drugs can be registered through the Domestic NDA and the Imported Drug Application procedures under the Registration Measures, respectively.

According to the Special Examination and Approval of Registration of New Drugs (《新藥註冊特殊審批管理規定》), or the Special Examination and Approval Provisions, which was promulgated and implemented since January 7, 2009 by the NMPA, the NMPA conducts special examination and approval for new drug registration applications when: (1) the effective constituent of drug extracted from plants, animals, minerals, etc. as well as the preparations thereof have never been marketed in China, and the material medicines and the preparations thereof are newly discovered; (2) the chemical raw material medicines as well as the preparations thereof and the biological product have not been approved for marketing home and abroad; (3) the new drugs are for treating AIDS, malignant tumors and orphan diseases, etc., and have obvious advantages in clinic treatment; or (4) the new drugs are for treating diseases with no effective methods of treatment.

The Special Examination and Approval Provisions provide that the applicant may file for special examination and approval at the clinical trial application stage if the drug candidate falls within items (1) or (2). The provisions provide that for drug candidates that fall within items (3) or (4), the application for special examination and approval cannot be made until filing for production.

Fast Track Approval for Clinical Trial and Registration

In November 2015, the NMPA released the Circular Concerning Several Policies on Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》), which further clarified the following policies, potentially simplifying and accelerating the approval process of clinical trials:

- a one-time umbrella approval procedure allowing the overall approval of all phases of a new drug’s clinical trials, replacing the current phase-by-phase application and approval procedure, will be adopted for new drugs’ clinical trial applications; and
- a fast track drug registration or clinical trial approval pathway for the following applications: (1) registration of innovative new drugs for treating HIV, cancer, serious infectious diseases and orphan diseases; (2) registration of pediatric drugs; (3) registration of geriatric drugs and drugs treating PRC-prevalent diseases in elders; (4) registration of drugs listed in national major science and technology projects or national key research and development plan ; (5) registration of innovative drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits; (6) registration of foreign innovative drugs to be manufactured locally in China; (7) concurrent applications for new drug clinical trials which are already approved in the United States or European Union or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such

REGULATORY ENVIRONMENT

authorities’ onsite inspections in the United States or European Union and are manufactured using the same production line in China; and (8) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and manufacturing authorization applications for drugs with urgent clinical need and patent expiry within one year.

On December 21, 2017, the NMPA promulgated the Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》), which further clarified that a fast track clinical trial approval or drug registration pathway will be available to innovative drugs.

On May 17, 2018, the NMPA and NHC jointly promulgated the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》), which further simplified and accelerated the clinical trial approval process.

Sampling and Collecting Human Genetic Resources Filing

The Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》), promulgated by the Ministry of Science and Technology and the MOH on June 10, 1998, aimed at protecting and fair utilizing human genetic resources in the PRC. On July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) (“**Service Guide**”), which became effective on October 1, 2015. According to the Service Guide, the sampling and collection of human genetic resources through clinical trials shall be required to be filed with the China Human Genetic Resources Management Office through the online system. On October 26, 2017, the Ministry of Science and Technology promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》), simplifying the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC.

According to the Regulations of PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council on May 28, 2019 and implemented on July 1, 2019, collecting human genetic resources of China’s important genetic families and specific regions, or collection of those human genetic resources in such categories and quantities as prescribed by the administrative department for science and technology under the State Council, as well as preserving China’s human genetic resources and providing the basic platform for scientific research shall be subject to the approval of the administrative department for science and technology under the State Council.

As for utilisation of China’s human genetic resources for international cooperation in scientific research shall submit an application to the administrative department for science and technology under the State Council for approval. No approval is required in international clinical trial cooperation using China’s human genetic resources at clinical institutions in order to obtain marketing authorization for relevant drugs and medical devices in China, which will not involve exit of materials of human genetic resources. However, the two parties shall file the type, quantity and usage of the human genetic resource to be used with the administrative department of science and technology under the State Council before clinical trials. If it is necessary to transport, deliver by post or carry China’s materials

REGULATORY ENVIRONMENT

of human genetic resources abroad for the purpose of international cooperation in scientific research on the basis of China's human genetic resources or due to other special circumstances, the exit certification of materials of human genetic resources issued by the administrative department for science and technology under the State Council shall be secured.

Administrative Protection and Monitoring Periods for New Drugs

According to the Registration Measures, the Implementing Regulations of the Drug Administration Law (《藥品管理法實施條例》) and the Reform Plan, the NMPA may, for the purpose of protecting public health, provide for an administrative monitoring period of five years for Category 1 new drugs approved to be manufactured, commencing from the date of approval, to continually monitor the safety of those new drugs. During the monitoring period of a new drug, the NMPA will not accept other applications for new drugs containing the same active ingredient. This renders an actual five-year exclusivity protection for Category 1 new drugs. The only exception is that the NMPA will continue to handle any application if, prior to the commencement of the monitoring period, the NMPA has already approved the applicant's clinical trial for a similar new drug. If such application conforms to the relevant provisions, the NMPA may approve such applicant to manufacture or import the similar new drug during the remainder of the monitoring period.

Registration of Generic Drugs

According to the Registration Measures, the applicants which apply for registration of generic drugs shall be manufacturer of the same drugs. The applicant's drugs shall also be within the manufacturing scope specified in the Pharmaceutical Manufacturing Permit. Furthermore, clinical trials are required to be conducted in accordance with the Registration Measures. According to the Circular on Implementation of Record-filing Management of Bioequivalence Trials of Chemical Drug (《關於化學藥生物等效性試驗實行備案管理的公告》), the management of bioequivalence trials of chemical drug has been changed from examination and approval to record-filing. After completion of clinical trials, applicants for registration of generic drugs should submit materials of the respective clinical trials to the CDE. With reference to the technical review opinions, the NMPA will either grant a drug registration number or issue a disapproval notice.

Pursuant to the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the General Office of the State Council (《國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見》) promulgated on February 6, 2016 and the Opinions of Relevant Matters Concerning Implementing the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the NMPA (《關於落實〈國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見〉的有關事項的意見》) promulgated on March 31, 2016, generic drugs approved for marketing before the implementation of the new registration classification of chemical drugs, including domestic generic drugs, imported generic drugs and the indigenous varieties of the original developed drugs, shall carry out consistency evaluation. In principle, the consistency evaluation should be completed before the end of 2018 for the oral solid preparations of generic chemicals approved for sale before October 1, 2007 listed in the National Essential Drug List (2012 version) (《國家基本藥物目錄(2012年版)》). For any other generic drugs approved for marketing before the implementation of the new classification of registration of chemical drugs, after a drug produced by a pharmaceutical enterprise passes the consistency evaluation, other pharmaceutical enterprises shall complete the consistency evaluation for their identical drugs within three years in principle; no registration will be granted in case of failure to do so as required within the prescribed time limit.

REGULATORY ENVIRONMENT

Pursuant to the Circular on Relevant Matters Concerning Consistency Evaluation for Quality and Curative Effect of Generic Drugs (《關於仿製藥質量和療效一致性評價有關事項的公告》) further promulgated by NMPA on December 28, 2018, the time limit for evaluation of the varieties included in the National Essential Drug List (2018 version) will no longer be set uniformly. For generic drugs, including essential drug varieties, approved for listing before the implementation of new registration and classification of chemical drugs, after the first variety has passed the consistency evaluation, the same variety of other drug manufacturers should complete the consistency evaluation within 3 years in principle. If it is not completed within the time limit, the enterprise may apply to the local provincial drug regulatory authority for an extension of the evaluation if it is deemed to be clinically necessary and in short supply in the market. If the registration is not completed within the prescribed time limit, it shall not be re-registered.

Regulations on Drug Manufacturing

Pursuant to the Drug Administration Law of the PRC and the Implementing Regulations of the Drug Administration Law, a drug manufacturing enterprise is required to obtain a drug manufacturing license (藥品生產許可證) from the relevant provincial drug administration authority of the PRC. The grant of such license is subject to an inspection of the manufacturing facilities, and an inspection to determine whether the sanitary condition, quality assurance systems, management structure and equipment meet the required standards. Pursuant to the Regulations of Implementation of the Drug Administration Law of the PRC and the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》), effective on August 5, 2004 and amended on November 17, 2017), the drug manufacturing license is valid for five years and shall be renewed at least six months prior to its expiration date upon a re-examination by the relevant authority. In addition, the name, legal representative, registered address and type of the enterprise specified in the drug manufacturing certificate shall be identical to that set forth in the business license as approved and issued by the industrial and commercial administrative department.

The Good Manufacturing Practice for Drugs (2010 revised edition) (《藥品生產質量管理規範》), effective on March 1, 2011), comprises a set of detailed standard guidelines governing the manufacture of drugs, which includes institution and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, product operation, raw material management, maintenance of sales records and manner of handling customer complaints.

Pursuant to the Drug Administration Law of the PRC, the Measures on the Supervision and Administration of the Manufacture of Drugs (《藥品生產監督管理辦法》) and the Administrative Measures for Certification of the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》), effective on August 2, 2011), the application for Good Manufacturing Practice (the “GMP”) certificate shall be made to the relevant drug supervision and administration department by the new drug manufacturer or existing drug manufacturer which builds a new drug production workshop or adds new production forms in 30 days after obtaining the drug manufacturing license or production approval, in order to obtain the relevant certificate. A GMP certificate shall be renewed at least six months prior to its expiration date upon re-examination by the relevant authority.

Regulations on Drug Distribution

Medicine operation certificate

According to the PRC Drug Administration Law and its implementing regulations and the Measures for the Supervision and Administration of Circulation of Pharmaceuticals (藥品流通監督管理

REGULATORY ENVIRONMENT

辦法), which was issued by the NMPA on January 31, 2007 and came into effect on May 1, 2007, detailed provisions are imposed on aspects such as the purchase, sale, transportation and storage of medicines.

The establishment of a wholesale pharmaceutical distribution company requires the approval of the provincial medicine administrative authorities. Upon approval, the authority will grant a Medicine Operation Certificate in respect of the wholesale pharmaceutical product distribution company. The establishment of a retail pharmacy store requires the approval of the local medicine administrative authorities at or above the county level. Upon approval, the authority will grant an Operation Certificate in respect of the retail pharmacy store. Once these permits are received, the wholesale or retail pharmaceutical company (as the case may be) shall be registered with the relevant local branch of the SAIC.

Under the Measures for the Administration of Pharmaceutical Operation Certificate (《藥品經營許可證管理辦法》) promulgated on February 4, 2004 and became effective from April 1, 2004 and amended on November 17, 2017 by the NMPA, a Medicine Operation Certificate is valid for five years. Each holder of the Medicine Operation Certificate must apply for an extension of its permit six months prior to expiration.

Good supply practices

Each retail or wholesale operator of pharmaceutical products is required to obtain a GSP certificate from the relevant medicine administrative authorities prior to commencing its business. GSP constitutes the basic standards in management of operation quality of medicines and shall apply to enterprises exclusively or concurrently engaged in medicine operation within China. The current applicable GSP standards require pharmaceutical operators to implement strict controls on its operation of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection equipment and facilities, management and quality control. Under the Administrative Measures for Certification of Good Supply Practices (《藥品經營質量管理規範認證管理辦法》) promulgated on and became effective from April 24, 2003 by the NMPA, the GSP certificate is generally valid for five years and may be extended three months prior to the expiry of its valid term.

Regulations on Import and Export of Goods

Import and Export of Goods

Pursuant to the Administrative Provisions on the Registration of Customs Declaration Entities of the PRC (《中華人民共和國海關報關單位註冊登記管理規定》) (Order No. 221 of the General Administration of Customs, effective on March 13, 2014, amended on February 1, 2018 and July 1, 2018 respectively), the import and export of goods shall be declared by the consignor or consignee itself, or by a customs declaration enterprise entrusted by the consignor or consignee and duly registered with the customs authority. Consignors and consignees of imported and exported goods shall go through customs declaration entity registration formalities with the competent customs departments in accordance with the applicable provisions. After completing the registration formalities with the customs, consignors and consignees of the imported and exported goods may handle their own customs declarations at customs ports or localities where customs supervisory affairs are concentrated within the customs territory of the PRC.

REGULATORY ENVIRONMENT

Import and Export of Special Articles

Pursuant to the Administrative Provisions on the Sanitation and Quarantine of Entry/Exit Special Articles (《出入境特殊物品衛生檢疫管理規定》) (Order No. 160 of the General Administration of Quality Supervision, Inspection and Quarantine, effective on March 1, 2015 and amended on October 18, 2016, April 28, 2018, May 29, 2018 and November 23, 2018 respectively), the import or export of special articles, including micro-organisms, human tissues, biological products, blood and blood products shall be subject to the supervision and administration over health quarantine. The customs office is responsible for the health quarantine and approval of import and export of special articles in its relevant jurisdictions. The enterprise conducting import or export of special articles shall establish safety management system for special articles, and shall produce, use or sell the special articles in strict accordance with the purposes for the approval of such special articles.

Export of Drugs

According to the Approval by NMPA on Certain Issues of Pharmaceutical Products Export (《國家藥品監督管理局關於藥品出口有關問題的批覆》), promulgated and effective on September 20, 1999, whether the enterprise can obtain the right to operate import and export business and the qualification shall be approved by relevant foreign trade authority. The pharmaceutical products export shall mainly comply with the requirements of the importing country, so long as there is no special requirement by the importation country, the NMPA support the export in principal based on the national policy of encouraging exports. However, under the Pharmaceutical Administration Law, the export licenses issued by the relevant NMPA are required for the export of narcotics and psychotropic substances falling within the restricted scope prescribed by the State.

Other Related Regulations in the PRC Pharmaceutical Industry

Reimbursement under the National Medical Insurance Program

Pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《國務院關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998 which took effect on the same day, all employers in urban cities are required to enroll their employees in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees. The State Council promulgated Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) on July 10, 2007 which took effect on the same day, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. Pursuant to the Social Insurance Law of Peoples' Republic of China (《中華人民共和國社會保險法》) which was promulgated by the SCNPC on October 28, 2010, became effective on July 1, 2011, and amended on December 29, 2018, all employees are required to enroll in the basic medical insurance program and the insurance premium is jointly contributed by the employers and employees as required by the state.

The Notice Regarding the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《關於印發城鎮職工基本醫療保險用藥範圍管理暫行辦法的通知》) (“**Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products**”), jointly issued by several authorities including the Ministry of Labor and Social Security and the Ministry of Finance of the PRC (“**MOF**”), among others, on May 12, 1999, provides that a pharmaceutical product listed in the Medical Insurance

REGULATORY ENVIRONMENT

Catalog must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements:

- it is set forth in the Pharmacopeia (the prevailing version) of the PRC;
- it meets the standards promulgated by the NMPA; and
- if imported, it is approved by the NMPA for import.

According to Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products, the PRC Ministry of Labor and Social Security, together with other government authorities, has the power to determine the medicines included in the National Medical Insurance Catalog, which is divided into two parts, Part A and Part B. Provincial governments are required to include all Part A medicines listed on the National Medical Insurance Catalog in their provincial Medical Insurance Catalog, but have the discretion to adjust upwards or downwards by no more than 15% from the number of Part B medicines listed in the National Medical Insurance Catalog. As a result, the contents of Part B of the provincial Medical Insurance Catalogs may differ from region to region in the PRC.

Patients purchasing medicines included in Part A of the Medical Insurance Catalog are entitled to reimbursement in accordance with the regulations in respect of basic medical insurance. Patients purchasing medicines included in Part B of the Medical Insurance Catalog are required to pay a certain percentage of the purchase price and the remainder of the purchase price shall be reimbursed in accordance with the regulations in respect of basic medical insurance. The percentage of reimbursement for Part B medicines is stipulated by local authorities and in result may differ from region to region in the PRC.

National Essential Drug List

On August 18, 2009, MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National Essential Drug List (《國家基本藥物目錄管理辦法》) (the “**Measures on Essential Drugs**”) which became effective on the same day, and amended on February 13, 2015, and the Guidelines on the Implementation of the National List of Essential Drugs System (《關於建立國家基本藥物制度的實施意見》) (the “**Essential Drugs Guidelines**”), which aim to promote essential medicines sold to consumers at fair prices in the PRC and ensure that the general public in the PRC has equal access to the drugs contained in the National Essential Drug List. NHC and NATCM (“**National Administration of Traditional Chinese Medicine**”(國家中醫藥管理局)) promulgated the National Essential Drug List (《國家基本藥物目錄(2018年版)》) on September 30, 2018 which became effective on November 1, 2018.

According to these regulations, basic healthcare institutions funded by government, which primarily include county-level hospitals, county-level Chinese medicine hospitals, rural clinics and community clinics, shall store up and use drugs listed in National Essential Drug List. The drugs listed in National Essential Drug List shall be purchased by centralized tender process and shall be subject to the price control by NDRC. Remedial drugs in the National Essential Drug List are all listed in the Medical Insurance Catalog and the entire amount of the purchase price of such drugs is entitled to reimbursement.

REGULATORY ENVIRONMENT

Price Controls

According to the Pharmaceutical Administration Law, the Regulations of Implementation of the Law of the People’s Republic of China on the Administration of Pharmaceuticals, the pharmaceutical products are subject to fixed or directive pricing system or to be adjusted by the market. Those pharmaceutical products included in the Medical Insurance Catalogs and the National Essential Drug List and those drugs the production or trading of which are deemed to constitute monopolies, are subject to price controls by the PRC government in the form of fixed retail prices or maximum retail prices. Manufacturers and distributors cannot set the actual retail price for any given price-controlled product above the maximum retail price or deviate from the fixed retail price set by the government. The retail prices of pharmaceutical products that are subject to price controls are administered by the NDRC and provincial and regional price control authorities. From time to time, the NDRC publishes and updates a list of pharmaceutical products that are subject to price controls. According to the Notice Regarding Measures on Government Pricing of Pharmaceutical Products Issued by NDRC (《國家計委關於印發藥品政府定價辦法的通知》) effective on December 25, 2000, Maximum retail prices for pharmaceutical products shall be determined based on a variety of factors, including production costs, the profit margins that the relevant government authorities deem reasonable, the product’s type, and quality, as well as the prices of substitute pharmaceutical products.

Further, pursuant to the Notice Regarding Further Improvement of the Order of Market Price of Pharmaceutical Products and Medical Services (《關於進一步整頓藥品和醫療服務市場價格秩序的意見》) jointly promulgated by the NDRC, the State Council Legislative Affairs Office and the State Council Office for Rectifying, the MOH, the NMPA, the MOFCOM, the MOF and Ministry of Labor and Social Security on May 19, 2006 and effective on the same day, the PRC government exercises price control over pharmaceutical products included in the Medical Insurance Catalogs and made an overall adjustment of their prices by reducing the retail price of certain overpriced pharmaceutical products and increasing the retail price of certain underpriced pharmaceutical products in demand for clinical use but that have not been produced in large quantities by manufacturers due to their low retail price level. In particular, the retail price charged by hospitals at the county level or above may not exceed 115% of the procurement cost of the relevant pharmaceutical products or 125% for Chinese herbal pieces.

On May 4, 2015, the NDRC, the NHFPC, the MOHRSS, the Ministry of Industry and Information Technology of the PRC, the MOF, the MOFCOM and the NMPA issued the Opinion on Furthering Pharmaceutical Price Reform (《推進藥品價格改革的意見》) (the “**Price Reform Opinion**”) and the Notice on Issuing the Opinion on Furthering Pharmaceutical Price Reform (《關於印發推進藥品價格改革意見的通知》) (the “**Price Reform Notice**”). Pursuant to the Price Reform Notice, government price controls on pharmaceutical products (other than narcotic drugs and certain psychiatric drugs) will be lifted on June 1, 2015. According to the Price Reform Opinion, after price controls are lifted, prices of pharmaceutical products will be mainly determined by market competition. Instead of direct price controls, the government will regulate prices mainly by establishing a consolidated procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices.

Drug Purchases by Hospitals

According to the Opinion on the Guidance of the Reform of Urban Medical and Health Care System (《關於城鎮醫藥衛生體制改革的指導意見》) promulgated and took into effect on February 16,

REGULATORY ENVIRONMENT

2000 and the Opinion on the Implementation of Classification Management of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》) promulgated on July 18, 2000 and became effective from September 1, 2000, a medical institution must be defined as a profit-making or non-profit-making institution at the time when it is established. A non-profit-making medical institution is established to provide services to the general public, with its revenue used for maintaining and developing such institution, while a profit-making medical institution is established by investors for the purpose of investment return. The PRC government does not establish any profit-making medical institutions, while non-government entities may establish profit-making medical institutions. Any non-profit-making medical institutions must implement a collective tender system in respect of any drug purchases and any profit-making medical institutions need not to implement such a system according to PRC law.

According to the Notice on the Trial Implementation of the Centralized Tender with Respect to Drug Purchases by Medical Institutions (《關於印發醫療機構藥品集中招標採購試點工作若干規定的通知》) promulgated and was effective on July 7, 2000, the Notice on the Further Standardizing of the Centralized Tender with respect to Drug Purchases By Medical Institutions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated and became effective on August 8, 2001 and the Opinions concerning Further Regulating Purchase of Medicines by Medical Institutions through Centralized Tendering (《關於進一步規範醫療機構藥品集中採購工作的意見》) promulgated and took into effect on January 17, 2009, any non-profit-making medical institutions established and/or controlled by any government at a county level or above must implement the centralized tender system in respect of purchase of any drugs which are contained in the Medicines List for National Basic Medical Insurance and are generally used for clinical purposes and purchased in relatively large amount.

The Circular on the Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs (《醫療機構藥品集中採購工作規範》) promulgated and was effective on July 15, 2010, provides stipulations in detail in respect of the catalog for centralized procurement and methods, procedures, evaluators, expert database construction and management of drugs, further regulating the centralized drug procurement and clarifying the code of conduct on the part of purchasing parties. According to the Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs, any non-profit-making medical institutions established by the government at the county level or above or state-owned enterprises (including stock-holding enterprises) must participate in the centralized procurement of medical institutions. The centralized procurement management authority at provincial (municipal or district) level is responsible for compiling the catalog of drugs for centralized procurement by medical institutions within its own administrative region, and narcotic drugs and first class psychoactive drugs with respect to which the special administration is carried out by the state are not included in such catalog for centralized procurement; second class psychoactive drugs, radioactive pharmaceuticals, toxic drugs for medical use, crude drugs, traditional Chinese medicinal materials and traditional Chinese medicine decoction pieces may be excluded from such catalog for centralized procurement.

According to the Guidance Opinion of the General Office of the State Council on the Improvement of the Drug Centralized Procurement Work of Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) promulgated and came into effect on February 9, 2015, the centralized procurement work of public hospitals will be improved through the classification purchase of drugs. All drugs used by public hospitals (with the exception of traditional Chinese medicine decoction pieces) should be procured through a provincial centralized pharmaceutical procurement

REGULATORY ENVIRONMENT

platform. The provincial procurement agency should work out a summary of the procurement plans and budget submitted by hospitals and compile reasonably a drug procurement catalog of the hospitals with its own administration region, listing by classification the drugs to be procured through bids, negotiations, direct purchases by hospitals or to be manufactured by appointed manufacturers.

The Drug Centralized Procurement in “4+7 Cities” and Wider Areas

On November 15, 2018, the Joint Procurement Office published the Papers on Drug Centralized Procurement in “4+7 Cities” (《4+7藥品集中採購文件》, the “**Paper**”), which launched the national pilot scheme for drugs centralized tendering with minimum procurement quantities. The pilot scheme will be carried out in 11 cities, including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xian (the “**4+7 cities**”).

On January 1, 2019, the General Office of the State Council also published the Notice of Issuing Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》), which provides the detailed measures in the implementation of the national pilot scheme for drugs centralized tendering with minimum procurement quantities in the 4+7 cities.

According to the Implementing Opinions on Expanding the Pilot Program for Conducting Centralized Procurement and Use of Drugs by the State to Wider Areas (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) promulgated and came into effect September 9, 2019, together with the Documents on National Centralized Drug Procurement (GY-YD2019-2) (《全國藥品集中採購文件》) issued by the Joint Procurement Office on December 29, 2019, the model of centralized procurement with target quantity in the pilot program for conducting centralized procurement and use of drugs by the State will be promoted nationwide and all manufacturers of drugs within the scope of centralized procurement marketed in Mainland China, with the approval of the medical products administration, may participate in the pilot program.

The drug being offered for tender must belong to one of the following categories:

- an originator drug or reference preparations used for consistency evaluation designated by NMPA;
- a generic drug that has passed the consistency evaluation;
- a generic drug approved for registration according to the NMPA Notice No. 51(2016); or
- a drug included in the Catalogue of the Drugs Marketed in China.

The tenderer must also ensure that its annual production and sales capacity can satisfy the intended minimum quantity requirement.

Public hospitals must prioritize their drug purchasing from the successful bidder during the procurement cycle, calculated from the execution date of the successful bid result, until the quantity commitment has been satisfied. If the quantity commitment is satisfied, the excess is still procured at the selected price until the expiration of the procurement cycle.

Two-invoice System

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, as required at the executive meeting of the State Council dated April 6, 2016

REGULATORY ENVIRONMENT

and under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《深化醫藥衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, the “two-invoice System” (兩票制) will be fully implemented in the PRC. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) 《印發〈關於在公立醫療機構藥品採購中推行「兩票制」的實施意見(試行)〉的通知》 (the “**Circular**”), which was effective from December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the hospital, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the hospital. According to the Circular, two-invoice system will be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, while other regions are encouraged to implement such system, so that such system can be promoted in full swing nationwide in 2018.

Drug recall

According to the Measures on Drug Recall (《藥品召回管理辦法》) effective from December 10, 2007, a drug manufacturer should establish and improve its recall system by collecting relevant information about drug safety and making an investigation and evaluation with respect to any drugs with potential safety hazards. If there are any potential safety hazards that endanger human health and life safety in respect of any drugs sold in PRC, such manufacturer must start the drug recall procedures. Where a drug is recalled, the drug operating units and users should assist such manufacturer to satisfy its recall obligations by communicating the drug recall information and any feedback, controlling and recovering such drugs according to the recall plan.

Advertising Restriction

Pursuant to the Drug Administration Law of the PRC and the Measures on the Examination of Pharmaceuticals Products Advertisement (《藥品廣告審查辦法》) promulgated on March 13, 2007 and amended on December 21, 2018, an enterprise seeking to advertise its pharmaceutical products must apply for an advertising approval code number. The code number is issued by the relevant local administrative authority. The validity term of an advertisement approval number for pharmaceutical drugs is one year. The content of an approved advertisement may not be altered without prior approval. Where any alteration to the content of the advertisement is needed, a new advertisement approval number shall be obtained by submitting a reapplication. On October 26, 2018, the SCNPC promulgated the PRC Advertising Law (《中華人民共和國廣告法》) (as amended in 2018), according to which certain contents shall not be included in advertisement of drugs, such as an assertion or guarantee on the efficacy or the safety, stating a cure rate or effective rate.

Pharmaceutical Directions and Labels of Pharmaceutical Products

According to the Measures for the Administration of the Pharmaceutical Directions and Labels of Drugs (《藥品說明書和標籤管理規定》) effective on June 1, 2006, the Pharmaceutical Directions and labels of drugs should be reviewed and approved by the NMPA. A Pharmaceutical Directions should include the scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such

REGULATORY ENVIRONMENT

information as the drug’s name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug’s name, ingredients, character, specifications, description of the drug’s indications and contraindications, precautions, dosage, date of production, product batch number, valid term, approval number, manufacturing enterprise and any adverse reactions.

Commercial Briberies in Pharmaceutical Industry

Pursuant to the Regulations on the Establishment of Adverse Records with Respect to Commercial Briberies in the Medicine Purchase and Sales Industry (2013 revision) (《關於建立醫藥購銷領域商業賄賂不良記錄的規定(2013年修訂)》) enforced on March 1, 2014 by the NHFPC, where a manufacturer of drugs, medical devices and medical disposables, an enterprise, an agency or an individual offers staff of a medical institution any items of value or other benefits, the enterprise should be listed in the adverse records with respect to commercial bribery in the event of the following circumstances: (1) where the act has constituted a crime of bribery as determined by the ruling of a people’s court, or where the circumstance of crime is not serious enough for the imposition of criminal punishment and criminal punishment is exempted as decided by the people’s court in accordance with the Criminal Law; (2) where the circumstance of the crime of bribery is minor and the relevant people’s procuratorate has decided not to lodge a prosecution; (3) where a discipline inspection and supervision authority has initiated a case of bribery and conducted investigation, and punishment has been imposed in accordance with the law; (4) where administrative penalties against the act of bribery have been imposed by, inter alia, the finance administration, the industrial and commercial administration, the NMPA; (5) any other circumstances specified by laws, regulations and rules. If medical production and operation enterprises be listed into the Adverse Records of Commercial Briberies for the first time, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies in local province for two years since publication of the record, and public medical institution, and medical and health institutions receiving financial subsidies in other province shall lower their rating in bidding or purchasing process. If medical production and operation enterprises be listed into the Adverse Records of Commercial Bribery more than once in five years, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies nationwide for two years since publication of the record.

Environmental Regulations

Environmental Assessment and Acceptance of Environmental Protection Facilities

Pursuant to the Law of Environmental Impact Assessment of the PRC (《中華人民共和國環境影響評價法》) (Order No. 77 of the PRC President, effective on September 1, 2003 and amended on July 2, 2016, and December 29, 2018 respectively), Regulations on Environmental Protection Management for Construction Projects (《建設項目環境保護管理條例》) (Order No. 253 of the State Council, effective on November 29, 1998 and amended on July 16, 2017), Measures for the Administration of Environmental Protection Acceptance of Completed Construction Projects (《建設項目竣工環境保護驗收管理辦法》) (Order No. 13 of the State Environmental Protection Administration, effective on February 1, 2002 and amended on December 22, 2010), where effects may be exerted on the environment after the completion of construction projects, the construction enterprise shall submit an environmental impact report (form) or environmental impact registration form to the relevant environmental protection department. The project that is required to prepare the environmental impact

REGULATORY ENVIRONMENT

report (form) in accordance with the law shall obtain the approval from the relevant environmental protection department for its environmental impact assessment documents; otherwise it shall not start the construction. After the construction project is completed, the construction enterprise shall apply for environmental protection acceptance of the construction project and make acceptance report pursuant to the standard and formality set by the environmental protection authority.

Regulations on Pollution Permit

Pursuant to the Administrative Measures on Pollutant Emission Permits (Trial) (《排污許可管理辦法(試行)》) (Order No. 48 of the Ministry of Environmental Protection, effective on January 10, 2018), enterprises, institutions and other producers and operators (the “pollutant discharge enterprises”) that have been included in the Classification Management List for Fixed Source Pollution Permits shall apply for and obtain a discharge permit in accordance with the prescribed time limit. The pollutant discharge enterprises that are not included in the Classification Management List do not need to apply for a pollutant discharge permit. The pollutant discharge enterprise shall hold a pollutant discharge permit in accordance with the law and discharge pollutants in accordance with the discharge permit.

Pursuant to the Notice of the General Office of the State Council on Issuing the Implementation Plan for the Control of Pollutant Release Permit System (《國務院辦公廳關於印發控制污染物排放許可制實施方案的通知》) (No. 81 [2016] of the State Council’s Office, effective on November 10, 2016) and the Classification Management List for Fixed Source Pollution Permits (2017 Edition) (《固定污染源排污許可分類管理名錄(2017年版)》) (Order No. 45 of Ministry of Environmental Protection, effective on July 28, 2017), the state implements a focused management and a simplification of emission permits based on the pollutant-discharging enterprises and other manufacturing businesses’ amount of pollutants, emissions and the extent of environmental damage. The manufacturing of drug substance and manufacturing dose for chemical drugs are industries that shall obtain the discharge permit in accordance with the prescribed time limit. The Ministry of Environmental Protection shall be responsible for guiding the implementation and the supervision of the National Sewage Permit system. The municipal environmental protection department shall be responsible for issuing the Pollutant Discharge Permit in the district where the pollutant-discharging enterprise is located.

Safety Management Supervision

Pursuant to the Law on Work Safety of the PRC (《中華人民共和國安全生產法》) (Order No. 70 of the PRC President, effective on November 1, 2002 and amended on August 27, 2009 and August 31, 2014 respectively), enterprises engaged in production activities must strengthen safety production management, establish and improve the responsibility system for safe production and ensure a safe production environment. The state establishes and implements a system for the accountability of production safety accidents. If the company fails to comply with the provisions of the Law on Work Safety, the supervisory authority on production safety may issue a rectification order, impose a fine, order the company to cease production and operation, or revoke the relevant permit.

Some chemical materials needed for new drug research and development, such as toluene and hydrochloric acid, are hazardous chemicals. Pursuant to the Regulations on Safety Management of Hazardous Chemicals (《危險化學品安全管理條例》) (Order No. 344 of the State Council, effective on March 15, 2002 and amended on March 2, 2011 and December 7, 2013, respectively), the production, storage, use, operation, and transportation of hazardous chemicals must be in accordance with the

REGULATORY ENVIRONMENT

safety management regulations. The hazardous chemical units shall oblige to the safety conditions required by laws and administrative regulations and state and industry standards, establish and improve safety management rules and post safety responsibility systems, and provide safety education and legal education and occupation technical training for employees. Employees should accept such education and training, and may begin working only after qualifying the relevant assessment. Where it requires employees to have certain qualification to assume a post, an enterprise shall only designated employees having such qualification to assume the post.

Regulations on Employment

The Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) (Order No. 65 of the PRC President, effective on January 1, 2008 and amended on December 28, 2012) and the Regulations on Implementation of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) (Order No. 535 of the State Council, effective on September 18, 2008) provide for the establishment of labor relationship between employing entities and workers, as well as the concluding, performance, dissolution and revision of the labor contracts. To establish a labor relationship, a written labor contract shall be signed. In the event that no written labor contract is signed at the time when a labor relationship is established, such contract shall be signed within one month as of the date when the employing enterprise employs the employee.

Pursuant to Social Insurance Law of the PRC (《中華人民共和國社會保險法》), (Order No. 35 of the PRC President, effective on July 1, 2011, and amended on December 29, 2018), Interim Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) (Order No. 259 of the State Council, effective on January 22, 1999 and amended on March 24, 2019), Trial Measures for Enterprise Staff Maternity Insurance (《企業職工生育保險試行辦法》) (No. 504 [1994] the Ministry of Labor, effective on January 1, 1995), Regulations on Work-Related Injury Insurance (《工傷保險條例》) (Order No. 375 of the State Council, effective on January 1, 2004 and amended on December 20, 2010), and Regulations on Management of Housing Provident Fund (《住房公積金管理條例》) (Order No. 262 of the State Council, effective on April 3, 1999 and amended on March 24, 2002, March 24, 2019, respectively), employing entity must pay basic pension insurance, unemployment insurance, basic medical insurance, work-related injury insurance, maternity insurance and housing provident fund for its employees. If an employing entity fails to go through the formalities or does not pay the full amount as scheduled, the relevant administration department shall order it to make rectification or make up the payment within the prescribed time limit. If the rectification for social insurance registration is not made within the stipulated period, the employing entity shall be imposed a fine. If the payment for social insurance premiums is not made within the stipulated period, the relevant administration department shall impose a fine. If an employing entity fails to undertake payment and deposit registration of housing provident fund or fails to go through the formalities of opening housing provident fund account for its employees by the expiration of the time limit, a fine shall be imposed. If an employing entity fails to make the payment and deposit of the housing provident fund within a prescribed time limit, an application may be made to the people's court for compulsory enforcement.

Product Liability

Under current PRC law, manufacturers and vendors of defective products in the PRC may incur liability for loss and injury caused by such products. Pursuant to the General Principles of the Civil Law of the PRC (《中華人民共和國民法通則》), or the PRC Civil Law, promulgated on April 12, 1986

REGULATORY ENVIRONMENT

and amended on August 27, 2009, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury.

On February 22, 1993, the Product Quality Law of the PRC (《中華人民共和國產品質量法》) was promulgated to supplement the PRC Civil Law aiming to define responsibilities for product quality to protect the legitimate rights and interests of the end-users and consumers and to strengthen the supervision and control of the quality of products. The Product Quality Law was amended by the Ninth National People’s Congress on July 8, 2000 and was later amended by the Eleventh National People’s Congress on August 27, 2009 and the Thirteenth National People’s Congress on December 29, 2018. Pursuant to the amended Product Quality Law, manufacturers who produce defective products may be subject to civil or criminal liability and have their business licenses revoked.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 13, 1993 and was amended on October 25, 2013 to protect consumers’ rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendment on October 25, 2013, all business operators shall pay high attention to protect the customers’ privacy which they obtain during the business operation. In addition, in extreme situations, pharmaceutical product manufacturers and operators may be subject to criminal liabilities under applicable laws of the PRC if their goods or services lead to the death or injuries of customers or other third parties.

Regulations on Intellectual Property

Patent

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》) which was promulgated by the SCNPC on March 12, 1984 which became effective on April 1, 1985 and amended on September 4, 1992, August 25, 2000 and December 27, 2008, there are three types of patents in the PRC, namely invention patents, utility model patents and design patents and a patentable invention or utility model must meet three conditions: novelty, inventiveness and practical applicability. The State Intellectual CNIPA Property Office is responsible for receiving, examining and approving patent applications. A patent is valid for a term of 20 years in the case of an invention and a term of 10 years in the case of a utility model and design, starting from the application date. A third-party user must obtain consent or a proper license from the patent owner to use the patent except for certain specific circumstances provided by law. Otherwise, the use will constitute an infringement of the patent rights.

Trademark

Pursuant to the Trademark Law of the PRC (the “**Trademark Law**,” 《中華人民共和國商標法》) which was promulgated by the SCNPC on August 23, 1982 and revised on February 22, 1993, October 27, 2001, August 30, 2013 and April 23, 2019, the revised provisions became effective on November 1, 2019 and the Regulation on the Implementation of Trademark Law of the PRC (《中華人民共和國商標法實施條例》), which was promulgated on August 3, 2002 and last amended on April 23, 2019 and became effective on November 1, 2019, trademarks are registered with the Trademark Office of the State Administration of Industry and Commerce. The Trademark Law adopts the principle of “first-to-file” while handling trademark registration. Where registration is sought for a trademark that is identical or similar to another trademark which has already been registered or pending in application

REGULATORY ENVIRONMENT

for use in the same or similar category of commodities or services, the application for registration of such trademark may be rejected. Trademark registrations are effective for a renewable ten-year period, unless otherwise revoked. Trademark license agreements must be filed with the Trademark Office. The licensor shall supervise the quality of the commodities on which the trademark is used, and the licensee shall guarantee the quality of such commodities.

Trade Secrets

Pursuant to the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》) promulgated by the SCNPC on September 2, 1993 and as amended on November 4, 2017, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others’ trade secrets by (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, solicitation or coercion; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; or (3) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

Regulations on Taxation

Enterprise Income Tax

According to the Enterprise Income Tax Law of PRC (《中華人民共和國企業所得稅法》), which was promulgated by the NPC on March 16, 2007, implemented on January 1, 2008, and subsequently revised on February 24, 2017 and December 29, 2018 respectively, and the Implementation Rules for the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) enacted on December 6, 2007 by the State Council and became effective on January 1, 2008, and amended on April 23, 2019 (collectively, the “EIT Law”), a resident enterprise shall pay EIT on its income originating from both inside and outside PRC at an EIT rate of 25%. Foreign invested enterprises in the PRC falls into the category of resident enterprises, which shall pay EIT for the income originated from domestic and overseas sources at an EIT rate of 25%. A non-resident enterprise having no office or establishment inside China, or for a non-resident enterprise whose incomes has no actual connection to its office or establishment inside China must pay enterprise income tax on the incomes derived from China at a rate of 10%.

Pursuant to the Administrative Measures on Accreditation of High-tech Enterprises (《高新技術企業認定管理辦法》), which was adopted by the Ministry of Science and Technology, the MOF and SAT on January 29, 2016, and took effect from January 1, 2016, qualifications of an accredited high-tech enterprise shall be valid for three years from the date of issuance of the certificate. Upon obtaining the qualification as a high-tech enterprise, the enterprise shall complete tax reduction and exemption formalities with the tax authorities in charge pursuant to the provisions of Article 4 of these Measures.

REGULATORY ENVIRONMENT

Value-added Tax

According to the Interim Regulations of the PRC on Value-Added Tax (《中華人民共和國增值稅暫行條例》) which was promulgated by the State Council on December 13, 1993, and amended on November 10, 2008, February 6, 2016 and November 19, 2017, and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》) which was promulgated by the Ministry of Finance on December 25, 1993 and subsequently amended on December 15, 2008 and October 28, 2011 (collectively, the “VAT Law”), all enterprises and individuals that engage in the sale of goods, the provision of processing, repair and replacement services, sales of service, intangible assets and real estate and the importation of goods within the territory of the PRC shall pay value-added tax at the rate of 17%, except when specified otherwise.

In accordance with Circular on Comprehensively Promoting the Pilot Program of the Collection of Value-added Tax in Lieu of Business Tax (《關於全面推開營業稅改徵增值稅試點的通知》(財稅[2016]36號)), which was promulgated on March 23, 2016 and came into effect on May 1, 2016, upon approval of the State Council, the pilot program of the collection of VAT in lieu of business tax shall be promoted nationwide in a comprehensive manner starting from May 1, 2016.

The Notice on the Adjustment to VAT Rates (《關於調整增值稅稅率的通知》), promulgated by the MOF and the SAT on April 4, 2018 and became effective as of May 1, 2018 adjusted the applicative rate of VAT, and the deduction rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

According to the Announcement on Relevant Policies for Deepening Value-Added Tax Reform (《關於深化增值稅改革有關政策的公告》(財政部、稅務總局、海關總署公告2019年第39號)) promulgated by MOF, SAT and General Administration of Customs on March 20, 2019 and became effective on April 1, 2019, with respect to VAT taxable sales or imported goods of a VAT general taxpayer, where the VAT rate of 16% applies currently, it shall be adjusted to 13%.

LAWS AND REGULATIONS RELATED TO OUR BUSINESS IN THE U.S.

Regulation of Drugs and Biologics

In the U.S., the FDA regulates drugs and biologics under the Federal Food, Drug, and Cosmetic Act, the Public Health Services Act, and their implementing regulations. Before a new drug or biologic may be approved and marketed, it must undergo extensive testing, development and regulatory review to determine that it is safe and effective and that its manufacturing processes are capable of ensuring the product candidate’s identity, strength, quality, purity and potency. It is not possible to estimate the duration of this testing and development with respect to a given product candidate, although it often lasts many years and requires the expenditure of significant financial resources. The stages of this development process in the U.S. are generally as follows:

NDA, ANDA or BLA Preparation and Submission

Upon completion of product and manufacturing development, and preclinical and clinical trials, the sponsor assembles the statistically analyzed data from all phases of development, along with the chemistry and manufacturing and preclinical data and the proposed labelling, among other things, into a single marketing application, which, depending on the product candidate, may be a new drug

REGULATORY ENVIRONMENT

application (“NDA”), a full biologic license application (“BLA”), an ANDA, or a BLA for a biosimilar product. The FDA carefully scrutinizes the submitted information and data to determine whether the sponsors and any other companies, such as CROs and laboratories working on the sponsor’s behalf, have complied with the applicable regulations, and whether the drug or biologic is safe and effective for the specific use. Additionally, the FDA typically will inspect the facility or facilities where the product is manufactured, and will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontractors, are in compliance with GMP requirements and are capable of assuring consistent production of the product within required specifications. Additionally, before approving a marketing application, the FDA may inspect one or more clinical trial sites to assure compliance with GCPs. The FDA may also inspect others involved in the product candidate development process, such as preclinical trial sites and laboratories. Even after accepting the submission for review, the FDA may require additional testing or information before approval of the application. The FDA must deny approval of an application if applicable regulatory requirements are not satisfied. Moreover, after approval, some types of changes to the approved product, such as adding new indications, manufacturing and testing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. Following product approval, drug and biologic products must continue to be manufactured and tested in accordance with the FDA’s regulatory requirements, including GMPs.

FDA Enforcement

In the U.S., the FDA has authority to inspect facilities that conduct research on product candidates which are ultimately intended for marketing in the U.S., as well as facilities that manufacture and test products and product candidates intended for use in clinical trials or for marketing in the U.S. following FDA approval. The FDA may inspect such facilities, regardless of whether such facilities are located in the U.S. or overseas, including facilities belonging to entities other than the product or product candidate sponsor. Inspections by the FDA have the objective of confirming compliance with FDA regulatory requirements, including GLPs, GCPs and GMPs, and identifying and requiring correction of noncompliant conditions.

Inspections undertaken by the FDA, in which the inspector observes conditions that do not comply with the applicable regulatory requirements, may result in the FDA issuing a Form 483. A Form 483 contains observations which, in the inspector’s judgement, may constitute potential violations ranging from relatively minor to critical issues. The Form 483 does not constitute a final FDA determination of whether any condition constitutes a violation. Rather, the Form 483 is considered by the FDA, along with a full written report, evidence or documentation collected during the inspection, and any company responses. Based upon this information, the FDA determines what further action, if any, is appropriate. The inspected company is responsible for responding directly to the FDA with a corrective action plan addressing any cited objectionable conditions in the Form 483 and implementing that plan expeditiously.

The production of a Form 483 with significant or critical observations, or other determinations by the FDA of regulatory noncompliance can precipitate immediate and severe action by the FDA on the facility’s operations and business, and may cause serious and sometimes irreparable damage to a company’s reputation. Such actions may include, without limitation, costly corrective actions, rejection of study results as a basis for approval of marketing applications or supplements, restrictions on operations, including the discontinuation of services or closing of facilities, clinical holds, discontinuations or suspension of studies, warning letters, untitled letters, cyber letters, regulatory

REGULATORY ENVIRONMENT

authority issuance of adverse public statements or alerts, product recalls, fines, restitution, disgorgement of profits or revenue, product seizure or detention, FDA debarment or suspension, FDA disqualification of testing facilities and investigators, consent decrees or other settlement agreements, injunctions, and civil and criminal penalties.

Good Laboratory Practice (“GLP”), Good Clinical Practice (“GCP”) and Good Manufacturing Practice (“GMP”)

Certain regulatory authorities, including the FDA, require that submissions made to them are based on research, analysis or development studies conducted in accordance with GLP and GCP provisions and guidelines.

GLPs set forth the minimum basic requirements for the conduct of *in vivo* or *in vitro* experiments in which a test article is studied prospectively in a test system under laboratory conditions to determine its safety. In the U.S., GLPs include a number of requirements relating to the conduct of preclinical studies, internal company organization and personnel, facilities, equipment, operations, test and control articles, study protocols, operating procedures, records and reporting, quality assurance, and the care and use of animals in testing. Other agencies, such as the U.S. Department of Agriculture, also have requirements concerning the conduct of certain animal research and may have requirements for registrations, licenses, approvals, assurances, permits, certificates and similar authorizations. Moreover, Institutional Animal Care and Use Committees review animal research protocols before animal research may commence.

GCPs set forth standards for the conduct of clinical trials in order to ensure that data and reported results are credible and accurate, and that the rights, safety, well-being, integrity and confidentiality of trial participants are protected. GCPs include requirements concerning clinical study design, conduct, monitoring, auditing, analysis, recording and reporting, among other requirements. GCPs also require that all research subjects provide their informed consent in writing for their participation in any clinical trial and that all studies be reviewed and approved by an IRB.

Regulatory authorities also require that drugs and biologics, and their active pharmaceutical ingredients (“API”), intended for use in clinical trials or for the commercial market be manufactured and tested in accordance with GMP provisions and guidelines. The FDA requires that drug and biologic products used in clinical trials, approved products, and their API, be manufactured under GMPs. GMPs require that manufacturers and entities conducting certain laboratory testing adequately control manufacturing operations, which includes establishing quality management systems, quality control and assurance, obtaining raw materials that meet quality requirements, establishing operating procedures, detecting and investigating deviations, maintaining laboratory quality, maintaining records, samples and documentation, and ensuring the integrity of manufacturing and testing data. Poor control of production and testing processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of products or product candidates. Manufacturers and other entities involved in the manufacture of drugs and biologics, including control and contract laboratories, are required to annually register their establishments with the FDA. Certain facilities identified in regulatory applications and submissions, including facilities approved to produce finished dosage forms or API, biolanalytical study sites, CROs, and contract analytical testing sites must also annually provide identification information to the FDA. Additional state licenses, permits, and registrations may also be required.

REGULATORY ENVIRONMENT

Records for laboratory research, clinical studies, and manufacturing and testing must be maintained for specified periods for inspection by the FDA and other regulators. The FDA requires that electronic records and electronic signatures meet additional requirements to be considered trustworthy, reliable and generally equivalent to paper records and handwritten signatures. Noncompliance with GLP, GCP or GMP requirements can result in the disqualification of data collected during the clinical trial, as well as other enforcement actions.

Regulation of Controlled Substances

The use, research, testing, import and export, and manufacture of controlled substances and listed chemicals is regulated in the U.S. by the DEA through the Controlled Substances Act and the DEA's implementing regulations. The DEA regulations cover registration, security, recordkeeping, reporting, storage, shipping, distribution, acquisition, inventory and other requirements relating to controlled substances. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. The DEA also regulates chemicals that, in addition to legitimate uses, are used in the manufacture of controlled substances, and designates such chemicals as List I or List II chemicals. The DEA imposes additional requirements for Scheduled Listed Chemicals and requires registration for entities that manufacture, import, distribute, sell or export List I and Scheduled Listed Chemicals and also imposes record-keeping, security and reporting requirements. The DEA also establishes quotas for the manufacture, importation, and procurement of Scheduled Listed Chemicals. In addition, the DEA imposes specific requirements and restrictions for the retail sale of drug products containing a Scheduled Listed Chemical. Entities that handle only List II chemicals are not required to register with DEA but are subject to certain record-keeping and reporting requirements.

Fraud and Abuse and Anti-Corruption Laws and Regulations

Existing U.S. laws governing federal healthcare programs, including Medicare and Medicaid, as well as similar state laws, impose a variety of broadly described fraud and abuse prohibitions on healthcare providers, including clinical laboratories. These laws are interpreted liberally and enforced aggressively by multiple government agencies, including the U.S. Department of Justice, the U.S. Department of Health and Human Services' Office of Inspector General, and various state agencies.

In the event we collaborate with or invest in CROs, we may be subject to many federal and state healthcare laws, such as the federal Anti-Kickback Statute, the federal civil and criminal False Claims Acts, the civil monetary penalties statute and other laws relating to patient inducements, the Medicaid Drug Rebate statute and other price reporting requirements, the Veterans Health Care Act of 1992, the Patient Protection and Affordable Care Act of 2010, and similar state laws. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse, reimbursement programs, government procurement, and patients' rights may be applicable to our business. We would be subject to healthcare fraud and abuse regulation by both the federal government and the states in which we conduct our business.

We seek to conduct our business in compliance with all U.S. and state fraud and abuse laws. Sanctions for violations of these laws may include penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, suspension and debarment from government contracts, and refusal of orders under existing government contracts exclusion from participation in U.S. federal or state healthcare programs, corporate integrity agreements, and the curtailment or

REGULATORY ENVIRONMENT

restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results.

Achieving and sustaining compliance with applicable federal and state reimbursement and fraud laws can prove costly. Any action against us for violation of these laws, even if we successfully defend against it could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business.

We are required to comply with the U.S. Foreign Corrupt Practices Act (“**FCPA**”) and other U.S. and non-U.S. anti-corruption laws, which prohibit companies from engaging in bribery, including improperly offering, promising or providing money or anything else of value to non-U.S. officials and certain other recipients. It is our policy to implement safeguards to prohibit these practices by our employees and business partners with respect to our operations. In some cases, companies that violate the FCPA may be debarred by the U.S. government and/or lose their U.S. export privileges.

The Defense Production Act of 1950

Under the Defense Production Act of 1950, as amended by several later pieces of legislation, including most recently the Foreign Investment Risk Review Modernization Act of 2018 (“**DPA**”), the president of the U.S. is authorized to prohibit or suspend acquisitions, mergers or takeovers by foreign persons engaged in interstate commerce in the U.S. if the president determines that there is credible evidence that such foreign persons in exercising control of such acquired persons might take action that threatens to impair the national security of the U.S. and that other provisions of existing law do not provide adequate authority to protect national security. On October 10, 2018, the U.S. Department of Treasury (as the chair of CFIUS) issued interim regulations implementing certain provisions of the Foreign Investment Risk Review Modernization Act of 2018 (the “**FIRRMA interim regulations**”). The FIRRMA interim regulations initiate a pilot program which, among other changes, expands CFIUS jurisdiction to cover not only controlling investments, but also certain non-controlling investments involving foreign persons in U.S. businesses that utilize “critical technologies” in activity within or aimed at one of twenty-seven (27) designated industry sectors (“**Pilot Program Industries**”), and requires mandatory declarations advising CFIUS of foreign investments in such businesses (the “**CFIUS Pilot Program**”). The DPA and the FIRRMA interim regulations define “critical technologies” broadly, in a manner which includes certain biotechnology-related products, services or materials, and the definition may expand over time, as the U.S. government has the authority to further develop the set of technologies of interest through rulemaking. The FIRRMA interim regulations formally took effect on November 10, 2018 and are expected to remain in effect until such time as they are replaced by final regulations implementing the DPA.

Under the CFIUS Pilot Program, a party or parties to certain transactions that (i) close after November 10, 2018; (ii) involve certain types of investments by foreign persons in U.S. businesses; (iii) involve a U.S. business that produces, designs, tests, manufactures, fabricates or develops one or more critical technologies; and (iv) involves a U.S. Business that utilizes those critical technologies in activity within or aimed at one or more Pilot Program Industries, must submit a declaration with basic information regarding such transaction with CFIUS (unless the parties elect to file a notice instead) prior to the closing of the investment. Filing a declaration with CFIUS will be mandatory in such cases when the foreign party in the transaction will gain control of the U.S. target business as a result of such transaction or when the transaction grants the foreign party (i) a board seat, observer or nomination right, (ii) access to non-public information about the target’s technologies, or (iii) any other form of

REGULATORY ENVIRONMENT

involvement in the use, development, acquisition or release of the target’s critical technologies. Declarations must be filed no later than forty-five (45) days before the closing of the transaction. Once a declaration has been accepted by CFIUS, CFIUS has thirty (30) calendar days to determine its subsequent action, including approving the transaction, requesting that the parties file a notice or initiating a unilateral review, among others.

As we may be deemed a “foreign person” under the DPA, some biotechnology products and their applications may fall under the scope of critical technologies and may involve Pilot Program Industries. As a result, our future investments in or acquisitions of U.S. biotechnology businesses may be subject to the mandatory CFIUS filing and review process if and to the extent the U.S. target business produces, designs, tests, manufactures, fabricates or develops critical technology.

The FIRRMA interim regulations generally do not limit the scope and sustainability of ongoing research and development activities or revenue-generating services provided by us to our customers. Nor do the FIRRMA interim regulations generally limit arm’s-length research collaborations and business partnerships between us and academic/industrial institutions, except to the extent that such relationships involve us taking an equity stake in a U.S. business or joint venture involving a U.S. business, in which case the FIRRMA interim regulations may be implicated.

The breach of the above prohibition may lead to personal civil liability of its author. In addition, the French judge may take temporary measures in order to stop such breach, such as the prohibition of any action whereby the protected trade secret would be used or disclosed, the destruction of any support on which the trade secret has been reproduced illegally etc.

Notwithstanding the above, trade secrets cannot trump freedom of speech, including freedom of the press as proclaimed in the Charter of Fundamental Rights of the European Union. Neither can trade secrets be invoked against the exercise of the right of alert, nor against the right of information and consultation of employee representatives.

LAWS AND REGULATIONS RELATED TO OUR BUSINESS IN THE EU

Drug Authorisation

Drugs may only be marketed within the EU/EEA, if the competent authority has granted a valid Marketing Authorisation (“MA”) for the respective product. Before a MA is issued, the competent authority will assess the quality, efficacy and safety of a product. The national regulations on the authorisation of drugs for human use have been harmonized in the European Union (“EU”)/European Economic Area (“EEA”) by the Directive 2001/83/EC. It covers regulations for drugs on their (a) placing on the market, (b) manufacture and importation, (c) labelling a packaging, (d) wholesale distribution, (e) advertising, (f) pharmacovigilance and (g) supervision. Marketing Authorisations on basis of this Directive may only be granted to an applicant established in the European Community. Marketing Authorisations on basis of this Directive may only be granted to an applicant established in the European Community.

General Procedures of Marketing Authorisation

A marketing authorisation is either granted by the national regulatory authorities of the member states, or by the European Commission (with such process handled by the European Medicines Agency (“EMA”)), depending on the procedure that is used to obtain the marketing authorisation. There are four

REGULATORY ENVIRONMENT

different types of procedures: (1) the national procedure, (2) the mutual recognition procedure, (3) the decentralized procedure and (4) the centralized procedure.

The national procedure should be used by an applicant that is seeking a MA in only one member state and which is not compelled to use the centralized procedure due to the nature of the product (for example biosimilars). The national procedure is not permitted where a MA is already held in any member state of the EU.

The mutual recognition procedure (“MRP”) is used to facilitate the grant of a MA where the pharmaceutical product already holds a national MA in a member state at the time of application. One member state known as the Reference Member State (“RMS”) assesses the product first and further MAs can be sought from other member states, known as concerned member states (“CMS”).

The decentralized procedure (“DCP”) is used to simultaneously apply for MAs in more than one member state if the pharmaceutical product has not yet been authorized in any member state. If a MA has already been granted or applied for in another member state, the MRP should be used.

In the centralized procedure the EMA is responsible for the scientific evaluation of centralized marketing authorisation applications (MAA). Once granted by the European Commission, the centralized MA is valid in all EU member states, Iceland, Norway and Liechtenstein. The legal framework of this procedure is governed in Regulation 726/2004/EC, which requires or declares eligible certain drugs (such as biological drugs, orphan drugs and advanced therapy drugs) to use the centralized procedure.

This authorisation procedure allows pharmaceutical companies to submit a single marketing authorisation application to the EMA and to market the drug and make it available to patients and healthcare professionals throughout the European Economic Area on the basis of a single marketing authorisation.

Mandatory Centralized Procedure for Biosimilars

For some kind of drugs, applicants are compelled to use the centralized procedure. This is the case with biosimilars. A biosimilar is a biological drug highly similar to another already approved biological drug in the EU, for which marketing exclusivity rights have expired. The EMA is responsible for evaluating the majority of applications to market biosimilars before they can be approved and marketed in the EU. In this regard developers of biosimilars are required to demonstrate through comprehensive comparability studies with the ‘reference’ biological drug that (1) their biological drug is highly similar to the reference drug, notwithstanding natural variability inherent to all biological drugs and (2) there are no clinically meaningful differences between the biosimilar and the reference drug in terms of safety, quality and efficacy.

In contrast to generics, biosimilars must undergo phase III clinical trials in a particularly sensitive patient population to demonstrate similarity to the reference product. The clinical studies are designed to show that differences between the reference product and the biosimilar are not clinically significant.

The clinical development of a biosimilar starts with investigations to prove pharmacodynamics and pharmacokinetics comparable to the reference product. Studies to prove tolerability (including immunogenicity studies) are a part of these analyses. These data are then supplemented by a Phase III

REGULATORY ENVIRONMENT

study to establish clinical comparability and confirm the biosimilar’s tolerability and efficacy in a sensitive patient population.

Based on those requirements, Techdow had to prove the similarity of its Enoxaparin-Biosimilar (Inhixa®) to its reference product (Clexane®) by providing results of appropriate preclinical tests or clinical trials as part of the centralized marketing authorization procedure.

Legal effect of a Marketing Authorisation issued within the centralized procedure

A granted MA allows the Marketing Authorisation Holder (“MAH”) as well as a local representative of the MAH to place the drug on the market of all EU member states, Iceland, Norway and Liechtenstein.

The marketing authorisation is granted exclusively to the applicant for the authorisation of the specific drug in Europe. The drugs have the same packaging sizes all over Europe and are listed under the same name.

Authorised drugs are registered in the Union Register of medicinal products. It lists all medicinal products for human and veterinary use as well as orphan medicinal products that have received a marketing authorisation by the Commission through the centralised procedure.

A marketing authorisation is generally issued for a term of five years and can be renewed upon application. Thereafter, the marketing authorisation should normally be of unlimited validity unless otherwise determined by the competent regulatory authority. However, there are some circumstances that lead to the expiry of a marketing authorisation. For example a marketing authorisation shall expire, if the authorised drug is not placed on the market within three years of the granting of the marketing authorisation, or if the authorised drug, that was placed on the market in accordance with the marketing authorisation, is not placed on the market for three successive years (sunset clause).

Requirements for the MAH after obtaining a MA

Pharmacovigilance

Due to the fact, that the knowledge of the safety of drugs is not complete at the time of their first market authorisation, experiences gained from the use of a pharmaceutical product have to be systematically collected and evaluated after the approval. Therefore, the MAH must operate a pharmacovigilance system. The overall EU pharmacovigilance system operates through cooperation between the EU Member States, EMA and the European Commission. In some Member States, regional centres are in place under the coordination of the national competent authority.

Legal requirements related to the European Medicines Agency (EMA or the Agency) pharmacovigilance system for human medicines are laid down in Regulation (EC) No 726/2004, Directive 2001/83/EC and Commission Implementing Regulation (EU) No 520/2012.

The safety of biosimilars is monitored through pharmacovigilance activities in the same way as for other medicines.

To monitor the pharmacovigilance requirements pharmaceutical entrepreneurs are obliged to engage a Qualified Person for Pharmacovigilance (QPPV). This person is an individual residing within

REGULATORY ENVIRONMENT

the European Economic Area (EEA) and is personally responsible for the safety of a human pharmaceutical product within the EEA. His/her key roles are to establish and maintain pharmacovigilance system, to act as the contact person for competent authorities and to oversee the safety profiles of marketed products and any emerging safety concerns.

Compliance with Directive on falsified medicines for human use

In July 2011, the EU strengthened the protection of patients and consumers by adopting a new Directive on falsified medicines for human use. The Directive came into force on 21 July 2011 and aims to prevent falsified medicines entering the legal supply chain and reaching patients.

As one introduced safety control measure, MAHs are – as of 9 February 2019 – obliged to place two safety features on the packaging of most prescription-only medicines and some over-the-counter medicines. These are a unique identifier (a 2-dimension barcode) and an anti-tampering device placed on the packaging of their products.

Additionally, pharmaceutical entrepreneurs must fulfil a number of obligations, that require the connection to the European Medicines Verification System (“EMVS”).

Drug Manufacturing and Import in the EU

The manufacture and import of drugs in the EU are subject to a manufacturing and import authorisation. In order to obtain a manufacturing authorisation the applicant shall have at his disposal, suitable and sufficient premises, technical equipment and control facilities complying with the requirements for manufacture, control and storage of drugs. Furthermore, it is compulsory to have at least one qualified person that is responsible to guarantee compliance with manufacturing requirements. To ensure this obligation, a manufacturer can relate to the principles and guidelines of the good manufacturing practice (GMP), he also has to act compliant with.

According to the Directive 2003/94/EG for compliance with GMP, all manufacturers should operate an effective quality management system of their manufacturing operations, which requires the implementation of a pharmaceutical quality assurance system. The principles and guidelines of GMP should be set out in relation to quality management, personnel, premises and equipment, documentation, production, quality control, contracting out, complaints and product recall, and self-inspection.

To ensure that a drug manufacturer complies with GMP, the competent authorities of the Member States conduct repeated inspections according to Article 111 of the Directive 2001/83/EG. If the competent authority determines the compliance of the activities of the manufacturer with GMP it grants a GMP-certificate, that confirms the status of the permanent establishment at the time of the inspection.

In the EU, international GMP certificates by foreign public authorities may be recognized by the competent authority. The EU member states generally accept GMP audits/inspections and approvals of the competent national authorities of other EU member states because of the harmonization of the quality and pharmacovigilance regulations on the EU level. However, the sale and import of pharmaceuticals in other countries outside of the EU often requires an additional inspection and approval of the concrete manufacturing site by the foreign national public authority responsible for the supervision of manufacturing activities in the targeted country/market (e.g. the FDA concerning imports to the US). This concept applies for most Western countries.

REGULATORY ENVIRONMENT

Furthermore, for drugs imported from third countries, the importer shall ensure that they have been manufactured in accordance with standards which are at least equivalent to the GMP standards laid down by the EU.

From a regulation standpoint, the manufacturing of biosimilars follows in principle the same rules as the manufacturing of other drugs. However, due to its complex and sensitive product characteristics, the manufacturing of biosimilars requires particular care, as even the smallest changes in the manufacturing process may pose safety risks on the product.

Drug Distribution in the EU

In countries of the EU, entities active in the distribution of pharmaceutical products require a wholesale authorisation to permissibly procure, store and/or distribute pharmaceutical products. The wholesale authorisation is issued by the national competent authority of the Member State where the entity carries out the distribution activities. The same national authority is also responsible for inspecting the wholesale distributor.

Wholesale distributors must comply with the EU Good Distribution Practice (GDP) to obtain a wholesale authorisation. They can ensure that they meet all their legal obligations, laid down in Article 84 of the Directive 2001/83/EC, by following the GDP guidelines.

The compliance with GDP is approved with the granting of a GDP-certificate by the competent authority. According to the process in regard to a GMP-certificate, the competent authority conducts an inspection of the site of the wholesale distributor and examines its activities in respect of GDP-compliance. The GDP-certificate reflects the status of the premises at the time of inspections and should be renewed latest five years after the inspection, unless otherwise determined by the competent regulatory authority.

Reimbursement in the EU

Reimbursement of prescription-only pharmaceutical products under the existing social security systems is key for successfully marketing such products in the EU and internationally. However, there is no EU harmonization on the level of healthcare provided under national social security systems for the pricing and reimbursement for prescription-only pharmaceutical products. Rather, national legislators and the respective authorities in the EU (and elsewhere) are generally free to decide on the medicinal treatments they wish to reimburse and the prices they are willing to pay under their social security systems.

That being said, the pharmaceutical pricing and reimbursement systems established by EU countries differ significantly and are relatively complex. Each country uses different schemes and policies, adapted to its own economic and health needs. Also, these national systems are regularly reviewed or adapted in order to take account of political priorities, market developments, and patients' needs.

REGULATORY ENVIRONMENT

LAWS AND REGULATIONS RELATED TO OUR BUSINESS IN SELECTED EU COUNTRIES

Poland

General Regulatory Framework

Key legal acts concerning the medicinal products for human use:

- (a) Polish act on Pharmaceutical law dated September 6, 2001 (Journal of laws 2019 item 499, as amended) (“**Pharmaceutical Law**”);
- (b) Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001 on the Community code relating to medicinal products for human use;
- (c) Commission Directive 2003/94/EC of October 8, 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use;
- (d) Regulation (EC) no 726/2004 of the European Parliament and of the Council of March 31, 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; and
- (e) Numerous secondary legislation, in particular ordinances of the Polish Ministry of Health, such as the Ordinance of the Minister of Health on the Requirements of Good Manufacturing Practice dated November 9, 2015.

Marketing Authorization

No medicinal product may be placed on the market unless the relevant authorization has been issued by the competent authority. A marketing authorization is a decision issued by the competent authority confirming that a medicinal product may be marketed in a specific territory. The authorization is issued on the basis of the evaluation of the product’s safety, therapeutic efficacy and quality.

The system for authorizing the marketing of a medicinal product within the broadly defined EU legal system involves the existence of separate national procedures in this respect, provided, however, that Member States’ legal systems contain similar categories of procedures based on the same standards created by Directive 2001/83. This system also provides for the participation of the European Commission and the EMA in the so-called centralized procedure, under which certain categories of medicinal products are authorized. Decisions made in the centralized procedure enable a medicinal product to be authorized throughout the EU. Other medicinal products (not being subject to the centralized procedure), to be placed on the market in EU countries are subject to national procedures. The President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (President of the URPL) is the authority authorizing medicinal products for marketing in the territory of the Republic of Poland. The President of the URPL has been granted the competence to issue marketing authorizations for medicinal products. The description of the procedures for authorizing medicinal products for marketing and all the related formal requirements, are contained in the Pharmaceutical Law.

REGULATORY ENVIRONMENT

Import Authorization

Importation is any activity consisting in importing finished medicinal products from outside the EU or the European Free Trade Association (EFTA) Member States—parties to the European Economic Area (EEA) Agreement, including in particular the storage, quality control at batch release and distribution of such products. Consequently, the sole transport of medicinal products between EU or EFTA Member States is not considered as importation of medicinal products, but rather as wholesale trade in medicinal products.

Pursuant to Article 38(1) of the Pharmaceutical Law, in order to commence business activity in the field of importing medicinal products, it is necessary to obtain an importation authorization. The Main Pharmaceutical Inspectorate (Główny Inspektor Farmaceutyczny, GIF) is the authority competent to issue, refuse to issue, withdraw, or change the authorisations. GIF is also obliged to send a copy of the decision to grant an authorization for the manufacturing and/or importation of medicinal products to the European Medicines Agency (EMA).

Pursuant to Article 39(1) of the Pharmaceutical Law, the applicant seeking an authorization to import a medicinal product must append the application for the authorization with the Place of Business Documentation prepared in accordance with the requirements of the Good Manufacturing Practice, and a list containing the names, doses and pharmaceutical forms of the medicinal products to be imported.

Applications for medicinal product importation authorisations are processed within 90 days of the date of their submission. The running of this period may be suspended if the application needs to be supplemented.

Importation authorisations for medicinal products are granted for an unlimited period of time. If the importer of a medicinal product no longer fulfills the obligations laid down in Article 43(1) of the Pharmaceutical Law or the requirements specified in the authorization, the GIF will revoke, by way of a decision, the authorization to import medicinal products.

Importers of medicinal products are obliged to, without limitation:

- (a) import only those medicinal products which are covered by the authorization;
- (b) distribute the imported medicinal products;
- (c) give written notice to the GIF at least 30 days in advance of any intended modification of the conditions of importation of the medicinal product, and in particular to notify the GIF without undue delay of the need to replace a qualified person;
- (d) send the following to the GIF: an up-to-date place of business documentation, an up-to-date complete list of imported medicinal products;
- (e) keep archive samples of products;
- (f) make available to the GIF, for inspection, the premises where the medicine importation activity is carried out, the documentation and other data regarding the importation of the product, and enable the GIF to take samples;
- (g) enable the qualified person to perform his or her duties;
- (h) comply with the requirements of Good Manufacturing Practice;

REGULATORY ENVIRONMENT

- (i) ensure, on the basis of a risk assessment, that excipients for the manufacture of medicinal products have been manufactured in accordance with the Good Manufacturing Practice for excipients;
- (j) notify the GIF and the Marketing Authorization Holder of any suspected falsification of the product.

Reimbursement

In Poland, the main purpose of reimbursement is to ensure that the public payer (the National Health Fund) contributes to the purchase cost of a given product. However, this contribution should be understood more broadly as the fulfillment of the obligation to protect the health of citizens, which is regulated in Article 68(1) and (2) of the Constitution of the Republic of Poland. In fact, the protection of life and health is treated as a public subjective right realized through a system of guaranteed services financed from public funds, which also includes the reimbursement system. This care is to be based on equal access to health care services financed from state funds, independent of the income criterion. The rules for establishing the reimbursement budget, the manner of setting fixed prices and margins for pharmacy reimbursement and maximum prices and margins for the inpatient sector, the regulation of decision-making criteria concerning inclusion in the list of reimbursed products and setting of the official purchase price, and the maximum time limits for the completion of the reimbursement procedure, are set out in the act on reimbursement of medicines, foodstuffs for special nutritional uses and medical devices dated 12 May 2011 (Journal of laws 2019, item 784, as amended) (“**Reimbursement Act**”).

Official prices and margins used in the trading of reimbursed products are one of the cornerstones of the current reimbursement system. This involves the obligation for the individual marketing participants to comply with the official prices calculated as the official purchase prices plus the margins due in accordance with the Reimbursement Act. In the case of reimbursed products these margins can be broken down into fixed prices and margins for prescription products available in pharmacies and maximum prices and margins for reimbursed products used in the inpatient system: included in the chemotherapy list and drug programs.

Based on the current regulations, the analyzed budget is established as a maximum amount—the amount of funds spent on reimbursement may not exceed 17% of the total amount of public funds allocated for financing guaranteed services from public funds in the National Health Fund’s financial plan.

The Reimbursement Act provides for a statutory payback mechanism consisting in the obligation for the recipients of reimbursement decisions (businesses) to return a portion of the amounts obtained from reimbursement.

Applications for reimbursement can be submitted by marketing authorization holders, foodstuff business operators, manufacturers or distributors of medical devices, or their representatives (applicants).

The second stage of the reimbursement procedure, once the application has been submitted, consists of price negotiations with the Economic Committee, concluding with the Committee’s presenting its position in a resolution. The negotiations are conducted by the Committee’s negotiating team consisting of five members, who discuss the reimbursement terms proposed by the applicant. The

REGULATORY ENVIRONMENT

maximum time limit for the completion of all reimbursement procedures is 180 days irrespective of whether or not the product applied for has reimbursed equivalents. However, in practice, decisions in procedures concerning reimbursed equivalents are issued within a shorter time, usually within 60 days from the date of submission of the reimbursement application. Such procedures do not involve the evaluation of pharmacoeconomic analyzes, which are therefore not attached to the reimbursement application.

If there is no reimbursed equivalent, the whole range of HTA analyzes must be submitted and then evaluated by expert bodies, along with an additional fee for the verification analysis. Reimbursement for a given product is granted by way of an administrative decision issued by the Minister of Health.

All reimbursement decisions—regardless of the availability category of the given product—include: the identity of the applicant, the identification details of the product to be refunded, the reimbursement availability category, the level of co-payment and definition of the limit group, and also the official purchase price, the date of the decision’s becoming effective and the validity period of the decision.

Under the Reimbursement Act, the final reimbursement decision creates the basis for the inclusion of a given product in the list of reimbursed products as of the effective date indicated in the decision. Importantly, the reimbursement notice not only includes all the information contained in the reimbursement decision, but also new items calculated on the basis of statutory mechanisms. However, according to administrative courts, the notice remains informative only and it is rather the valid reimbursement decision that is the grounds for the reimbursement of a given product.

Brokers Arrangement

The Pharmaceutical Law provides also requirements for entities that intends only to act as an agent in trading medicinal products.

The major requirement from such entity is registration in the (Polish) National Register of Brokers of Medicinal Products runned by GIF.

The intermediation cannot cover wholesale trade in medicinal products and the supply of such products.

Intellectual Property

Legal Framework

Protection of industrial property in Poland includes inventions, industrial designs, trademarks, utility models, geographical indications and topographies of semiconductor products. The first three categories of goods are most significant in business practice. Thus the following overview will provide more detail in this respect.

In order to obtain protection for an invention, utility design, trademark or industrial design, an application should be filed with the Polish Patent Office (PPO). Two main institutions responsible for industrial property protection in the EU are EUIPO (European Union Intellectual Property Office), which provides trademark and design protection, and the EPO (European Patent Office), which grants patent protection.

REGULATORY ENVIRONMENT

From the IP perspective the key Polish legal acts are the following:

- (a) the Polish industrial protection law dated June 30, 2000 (Journal of laws 2017, item 776, as amended) (“**Industrial Property Act**”);
- (b) the Polish act on copyright and related rights dated February 4, 1994 (Journal of laws 2019, item 1231, as amended); and
- (c) the Polish civil code dated April 23, 1964 (Journal of Laws 2019 number 1145, consolidated text dated June 19, 2019).

Types of IP rights

Trademarks

Trademarks may be any marking if it is capable of distinguishing the goods or services of one entrepreneur undertaking from those of another. A trademark may in particular be words, drawings, letters, numerals, colors, spatial forms, including the form of the goods or of their packaging, and sound.

If the goods and services are offered in different European countries, it is worth considering registering the European Union trademark. A single registration made in the European Union Intellectual Property Office (EUIPO) in Alicante gives protection of a trademark in all 28 member states. The period of protection for Polish and European trademarks lasts for 10 years from filing the application for registration, but this term may be extended for successive 10-year periods.

The trademark registered in Poland may become protectable on the international market, by extending the right to countries, which are parties to the Madrid Agreement concluded in 1891. The international registration of trademarks is governed by the World Intellectual Property Organization (WIPO) in Geneva.

Industrial design

The Industrial Property Act offers the following definition of the term industrial design: “An industrial design is a form of a product or of its part which is new and has an individual character given to it especially by the characteristics of lines, contours, shapes, colors, product structure or material, and by its ornamentation”.

Registration of a new industrial design takes approx. 7 months in the PPO. The protection for Polish industrial design rights, is granted for a maximum period of 25 years, provided that every 5 years the right will be extended along with payment of fees.

Industrial design protection in Poland may also be obtained via registration of a Community Design. Registration of a Community Design is conducted by filing one application to EUIPO and is valid in all 28 European Union countries. Community Design application may include several design variants in one application. Applicants outside the EU must appoint an agent, or patent attorney is registered before any EU member state.

Patents

A patent is a right protecting an invention. Patents are granted for inventions which are new, involve an inventive step and which are susceptible to industrial application. The protection of an

REGULATORY ENVIRONMENT

invention starts from the moment of filing the patent application. However, it is subject to the subsequent granting of the patent.

The filing procedure lasts approx. 4 to 6 years. The PPO is obligated to publish the patent application within 18 months from its submission date. Nevertheless, publication may be expedited upon the applicant's request.

The term of a patent is 20 years from the filing date, provided that the annuity payments are made regularly. The patent protection does not have to be limited to the territory of Poland, but may also be granted for the European and international market. Through application with the PPO, a European patent may be granted, providing protection for an invention in over 30 European countries. In comparison, an international patent covers 148 countries, under the Patent Cooperation Treaty (PCT).

Enforcement of IP rights

Infringing intellectual property rights entails liability of the infringing party on civil, as well as criminal grounds. Criminal liability includes penalties for an appropriation of authorship (plagiarism), unlawful distribution of protected work, imitation, and counterfeiting of protected marks, or removal of original designations from products.

Civil lawsuits

In the case of infringement, the rights holder may use a variety of civil claims against the infringer, including a demand to cease the infringing activity, to reinstate a status compliant with the law, or repay the wrongly received benefit.

It should be also noted, that there are a number of procedural legal measures, which facilitate protection of intellectual property such as preliminary injunction, securing of the evidence and disclosure of information.

Typical remedies granted by a court in infringement actions:

- Cessation of infringement;
- Disposal of unlawfully manufactured/marketed goods;
- Publication of the judgment;
- Surrender of unlawfully obtained profit; and
- Compensation for damages.

Oppositions

Trademarks

Since April 15, 2016 the trademark registration procedure in Poland has been changed into an opposition system. Up to that time, the PPO would have examined all prerequisites of trademark registration (both relative and absolute grounds for refusal of trademark registration). At present, the PPO examines only absolute grounds and owners of earlier rights will need to file opposition to prevent later identical or similar registrations. The objection must be submitted to the PPO in writing, within 3 months from the date of the publication of the application for the trademarked in the Patent Office Bulletin.

REGULATORY ENVIRONMENT

Patent/Industrial Designs

Anyone may submit a substantiated opposition to a final and non-revisable the PPO decision to grant a patent, protection for a utility model or a right in registration within 6 months of the day information on the granting of the right is published in the “Patent Office’s Official Gazette”. The grounds for opposition will be circumstances that justify the cancelation of the patent (lack of patentability or protection- as described in more detail below).

Invalidations/ Cancelations

Trademarks

The protection right is subject to invalidation if the statutory requirements for the granting of that right have not been fulfilled or due to the existence of an earlier right. Any person may file a request for invalidation. The procedure includes the examination of grounds, pleadings and evidence submitted by the parties, and hearing of the involved parties. The PPO will then issue a decision invalidating a trademark or dismissing the request. The decision is subject to a judicial review before the administrative court in respect of any errors in law.

Patent/Industrial Designs

A patent may be invalidated in whole or in part on the request of a person who has a legal interest therein if this person demonstrates that the conditions to obtain a patent are not met or the invention was not depicted sufficiently clearly and completely for it to be carried out by a person skilled in the art, or addition if the patent was granted for an invention not covered by the scope of the application or the original application. Grounds for invalidating a right in registration to industrial designs may also be evidence that using an industrial design infringes third party moral or economic rights.

There is no administrative recourse. The decision is subject to judicial review before the administrative courts in respect of an error in law. The judgment of the regional administrative court may be further appealed in cassation proceedings before the Supreme Administrative Court. Both courts may revoke the decision only if the error was made in law and this error had an impact on the PPO’s decision.

Germany

Drug authorisation

In the event an applicant is seeking a MA only in Germany, the German Drug Law (*Arzneimittelgesetz, AMG*) regulates the relevant requirements. According to Section 21 AMG finished drugs in general may only be placed on the market, if they have been authorised by the competent authority (or in one of the other European procedures). Therefore, the German pharmaceutical entrepreneur may also rely on a MA granted in the centralized EMA procedure, e.g. as for a biosimilar. Finished drugs are drugs that are manufactured beforehand and placed on the market in packaging intended for distribution to the consumer, or other drugs intended for distribution to the consumer in the preparation of which any form of industrial process is used, or drugs that are produced commercially, except in pharmacies.

Exceptionally, for some drugs a marketing authorisation is not required (Section 21 Para 2, Section 36, Section 38 and 39a, Section 73 AMG), for example for drugs that are intended for use in clinical trials or homeopathic drugs, that only require a registration.

REGULATORY ENVIRONMENT

Formally a marketing authorisation requires an application of the pharmaceutical entrepreneur, i. e. the person who wishes to hold the marketing authorisation or any person who wishes to place the drug by parallel distribution or otherwise on the market under his/her own name.

The application must be addressed to the competent authority. According to Section 77 AMG the competent regulatory authority in Germany to grant a MA for human medicines is either the *Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM* or the *Paul-Ehrlich-Institut, PEI* (inter alia for sera, vaccines, blood preparations). They examine whether a drug is effective and harmless and whether it has the required pharmaceutical quality.

The necessary approval documents are submitted by the pharmaceutical entrepreneur. They shall include analytical, pharmacological-toxicological and clinical tests as well as expert opinions. In addition, the pharmaceutical entrepreneur must submit instructions for use and technical information, labelling texts and information on package sizes. Additionally, the exact description of the intended pharmacovigilance or risk management system is part of the marketing authorisation documents.

According to Section 25 Para 2 AMG the competent authority may only refuse to grant the marketing authorisation if for example the submitted documents are incomplete, the drug has not been sufficiently tested in accordance with the confirmed state of scientific knowledge, the drug is not manufactured in accordance with recognised pharmaceutical rules or does not meet appropriate quality standards or any other reason stated in Section 25 Para 2 No. 1 to 7 AMG.

If there is no such reason, the competent authority issues the marketing authorisation, together with a marketing authorisation number.

Manufacturing Authorisation

For the manufacture of drugs at whatever stage in the manufacturing process a manufacturing authorisation is required in Germany according to Section 13 AMG. Such manufacturing authorisation is connected to, and issued for, specific premises and covers specific manufacturing activities and product classes. In Germany, the public authority competent for granting such manufacturing authorisation is the regional authority competent for the supervision of pharmaceutical manufacturing. It is determined by the states and is usually the general regional government authority (*Regierungspräsidium*) or the local or regional public health authority (*Gesundheitsamt*).

The European Directive on GMP-requirements (Directive 2003/83/EG) has been implemented in Germany in particular by the Pharmaceuticals and Active Ingredient Manufacturing Regulation (*Arzneimittel- und Wirkstoffherstellungsverordnung, AMWHV*) and related guidelines. According to Section 3 AMWHV compliance with the GMP-guideline is required. Therefore, the issuance of a manufacturing authorisation requires the compliance of premises and processes with applicable GMP-requirements, inter alia, the engagement of a qualified person (*Sachkundige Person*) responsible for the manufacturing and quality control activities as well as premises appropriate for the manufacturing steps concerned.

The procedure of evaluating the compliance with GMP in Germany does not differ from the procedure at European level. Thus, the competent authority issues the manufacturing authorisation after an inspection of the applicants premise and activities and in combination with the issuance of a GMP-certificate.

REGULATORY ENVIRONMENT

In Germany, manufacturing authorisations are in principle issued for an indefinite period. However, the competent public authority audits the compliance with applicable GMP-requirements on a regular basis (usually every second year). The results of these audits/inspections provide the basis for the authority’s decision to either maintain or potentially withdraw or suspend the manufacturing authorisation. Any deficiencies detected are classified according to the potential impact on the health of patients as critical deficiencies (potentially life-threatening or serious damage to patient health), serious deficiencies (potential or concrete impact on pharmaceutical but not critical) and other deficiencies (no noticeable impact on pharmaceutical and no demonstrable significant risk).

According to Section 96 No. 4 AMG the manufacturing of pharmaceuticals without a manufacturing authorisation is prohibited and even constitutes a criminal offense.

Import Authorisation

According to Section 72 AMG the professional or commercial import of drugs from countries which are not Member States of the EU or EEA, requires an import authorisation. The requirements are predominantly based on the regulations on the manufacturing authorisation. In practice, manufacturing and import authorisations are often issued together, because mostly pharmaceutical entrepreneurs perform manufacturing activities as well as import activities in relation to one drug.

Nevertheless, the existence of an import authorisation alone does not permit the import of the products mentioned in the authorisation. Rather, according to Section 72a Para 1 AMG it is required, to prove by certificate or attest of the competent authority that (a) the manufacture was performed in compliance with all requirements in relation to the manufacturing of drugs or (b) import is in the interests of the general public. Furthermore, the import authorisation does not replace the marketing authorisation or registration. According to Section 73 Para 1 AMG the introduction, i.e. the transport of drugs into the scope of the AMG is in principle only permitted if a corresponding authorisation or registration has been obtained or the medicinal product is exempted from authorisation or registration and the importer holds an import authorisation.

Wholesale authorization

In Germany, such wholesale authorisation is again issued by the competent regional authority for specific premises only. According to Section 52a para. 6 AMG, a manufacturing authorisation and/or import authorisation includes the authorisation to engage in wholesale activities regarding all products covered by the scope of the respective manufacturing and/or import authorisation.

To obtain a wholesale authorisation, the applicant shall (1) name the specific sites, as well as the activities and drugs for which the authorisation is to be issued, (2) submit evidence that he/she is in possession of suitable and adequate premises, installations and facilities in order to ensure the proper storage and distribution and, where envisaged, proper decanting, packaging and labelling of drugs, (3) appoint a responsible person who possesses the required expert knowledge to perform the activity (“*Großhandelsbeauftragter*”) and (4) enclose a statement in which he/she commits himself in writing to observe the regulations governing the proper operation of a wholesale enterprise.

The regulations the applicant shall observe are, in addition to the provisions of the AMG, the guidelines on good distribution practice (GDP) and the German Regulation on Wholesale Trade and Mediation of Drugs (AM-HandelsV).

REGULATORY ENVIRONMENT

Reimbursement and pricing in Germany

For the vast majority of the German population, healthcare is provided by the statutory health insurance (“GKV”).

Under the present GKV-system, all prescription-only drugs with MA are generally eligible for reimbursement unless the product and/or indication has been excluded by statute or directive issued by the Joint Federal Committee (*Gemeinsamer Bundesausschuss—GBA*). An example for such statutory exclusion are drugs for so-called ‘life style’ indications (obesity, erectile dysfunction, etc.).

Special rules may apply for drugs directly applied on patients by doctors in their practice or in a hospital. Such products are typically reimbursed as part of the lump-sum reimbursement for a certain type of treatment (“DRG-System”).

In relation to the pricing of drugs pharmaceutical entrepreneurs are initially free to determine the price for their drugs. However, to keep health insurance contributions affordable, the German legislator has introduced various pricing regulations for prescription-only drugs.

Pharmacies and wholesalers impose surcharges on their purchase prices to cover their own costs and fees. The amount of these surcharges is limited by the German Drug Price Regulation (*Arzneimittelpreisverordnung, AMPPreisV*).

Furthermore, there are fixed prices for groups of similar drugs in Germany. Although those fixed prices are not prices for drugs set by law, they form the maximum amounts for the reimbursement of drugs by the statutory health insurance funds. This means, that the GKV will only pay the costs for a drug up to the fixed amount.

Fixed amounts are determined in a two-stage procedure: First, the GBA determines for which groups of drugs reference prices can be set. In these groups, drugs with the same or pharmacologically and therapeutically comparable active substances as well as with therapeutically comparable effects are grouped together. Secondly, the Federal Association of Health Insurance Funds (*GKV-Spitzenverband*) sets a fixed price for each fixed group formed by the GBA (based on Section 35 German Social Code V (SGB V)).

According to the database of the German Institute for Medical Documentation and Information (*DIMDI*) *Inhixa*[®] is part of a reference price group. Despite this resulting fixed price, health insurance funds can negotiate further discounts or price reductions with pharmaceutical entrepreneurs in rebate agreements (typically through tender procedures). This is relevant as the pharmacies are obliged to dispense the cheapest of substitutable drugs, unless otherwise prescribed by the doctor (Section 129 SGB V).

In general, the above rules apply to all drugs including biosimilars and in particular for generic drugs. However, in relation to the substitutability of drugs, Section 129 SGB V does not yet provide for an automatic substitution of biosimilars with its reference drugs. However, the new “Law for more security in the supply of medicines” (*Gesetzes für mehr Sicherheit in der Arzneimittelversorgung—GSAV*) entered into force in August 2019 will establish rules that shall increase the substitution rate of biological reference drugs with biosimilars as of 2022 by pharmacists. There are concerns that the new law may lead to a similar developments that have been observed with regard to generic drugs in Germany. Drug experts argue that through rebate agreements and the associated substitution obligation

REGULATORY ENVIRONMENT

for pharmacists it would in future be the GKV (i. e. the lowest agreed price) and no longer the physicians who would decide which biosimilar the patients received.

For manufacturers and / or distributors of biosimilars in Germany, there is a risk that the new regulations in Germany provided by the GSAV may lead to price reductions in the market for biosimilars (comparable to the generic drugs market).

Intellectual Property

German National IP Rights

German law recognizes various forms of intellectual property rights (“**IP**”), most importantly patents, utility models, trademarks, design rights and copyrights.

Patents are in general granted for technical inventions which are new and provide for an invention. They have a maximum protection period of 20 years. By way of so-called supplemental protection certificates, this can be prolonged by 5 years for medical products and plant protection products. Patents must be registered with the German Patent and Trademark Office, and are examined for formal and material requirements.

Trademarks grant protection for signs that give an indication of origin (including words, devices, colors, shapes, sounds, and other forms.) and which are neither descriptive nor generic. Trademarks must be registered with the German Patent and Trademark Office, and are examined for formal and material requirements. Older third party rights are however not considered during registration examination, but must be raised by their respective owners (e.g. by way of opposition). Trademarks can be renewed every 10 years, no maximum protection period exists. Beside registered trademarks, German law recognizes trademarks by use (also called common-law trademarks) as well as certain protection for (company) names and titles.

Design rights grant protection for the form of a product if the design is new, has individual character, and where the design is not due to technical requirements. Design rights need to be registered with the German Patent and Trademark Office, but are only examined for formal requirements. The maximum protection period is 25 years.

Copyrights grant protection for individual works of art; also e.g. photographs, software, or databases can qualify as such. They do not need to be (and cannot be) registered but come into existence with creation. The maximum protection period is 70 years after the death of the author. Other than all other IP rights listed above, copyrights cannot be transferred under German law, but only usage and exploitation rights can be granted by way of license agreement.

European Union IP Rights

Beside the German national IP rights, the European Union IP rights apply to Germany as part of the EU. These are the European Union Trade Mark (“**EUTM**”) and the European Union Design Right (*Community Design Right*, (“**CDR**”)), which grant a uniform protection for all then-current EU Member States. A pan-European patent right is planned, but not yet in force.

EUTMs need to be applied for with the EU Intellectual Property Office (“**EUIPO**”), and can be registered after a formal and material check. Third party rights are not considered ex officio but need to be raised by their respective owners (e.g. by way of opposition). EUTMs can be renewed every 10 years, no maximum protection period exists.

REGULATORY ENVIRONMENT

Registered CDRs also need to be applied for and registered with the EUIPO, but are only checked for formal requirements. They have a maximum protection period of 25 years. Also unregistered CDRs are recognized; these have a maximum protection period of 3 years and come into existence with their first public disclosure.

Similar protection rights

German law further provides for protection of trade secrets. Under the Trade Secret Protection Act, which was enacted in April 2019, any kind of information that (i) is not generally known amongst the relevant circles of trade, (ii) is of commercial value, and (iii) is subject to reasonable protection measures enjoys protection against unlawful acquisition, use and disclosure. Especially the requirements to implement reasonable protection measures is new for Germany, requiring companies to review their conduct. If a company uses trade secrets of others and was (or should have been aware) that the trade secret was acquired unlawfully, this may also constitute unlawful conduct.

In addition, German law provides for specific rules against unfair competition. These primarily prohibit aggressive or misleading advertising, and to some degree also grant protection against imitation of goods. For medicinal products, specific rules exist that further specify and narrow the scope of allowed advertising.

Claims and enforcement

All of the above IP rights, trade secrets protection and unfair competition law grant claims for, amongst other, cease-and-desist, damages, and (mostly) recall or destruction of infringing goods. These claims are often enforced by way of interim injunction proceedings.

Spain

Marketing authorization

In the event an applicant is seeking a marketing authorization only in Spain, the Spanish Royal Legislative Decree 1/2015 of 24 July, approving the revised text of the Law on Guarantees and the Rational Use of Medicines and Medical Devices (“**RLD 1/2015**”), regulates the relevant requirements.

According to article 9 of RLD 1/2015, industrially manufactured medicines may only be placed on the market if they have been previously authorised by the competent authority—the Spanish Agency of Medicines and Medical Devices (the “**AEMPS**”)- or in one of the other European procedures. Therefore, the Spanish pharmaceutical entrepreneur may also rely on a marketing authorization granted in the centralized EMA procedure, e.g. as for a biosimilar. Additionally, the aforementioned products shall be registered with the Spanish Registry of Medicines. In this regard, the AEMPS shall proceed *ex officio* to incorporate a marketing authorization granted in the EMA procedure to the mentioned registry.

Moreover, pursuant to article 9.2 of RLD 1/2015, when a medicine has obtained a marketing authorization, all additional doses, pharmaceutical forms, routes of administration and additional presentations, as well as any other changes and additions to the authorization dossier, must be authorised or notified, as the case may be. Such variations shall be considered as belonging to the same global marketing authorization, in particular for the purposes of applying the period of data exclusivity (i.e. period in which another company cannot use the originator’s data in support of another marketing authorization application). Furthermore, any amendment, transfer or termination of the marketing authorization shall be registered in the Spanish Registry of Medicines.

REGULATORY ENVIRONMENT

Marketing authorization applications must be addressed to the AEMPS, which will examine whether the relevant medicine is effective and harmless and whether it has the required pharmaceutical quality. Applications shall also contain details of any precautionary and safety measures to be taken for the storage of the medicines, its administration to patients and for the disposal of waste products, together with an indication of any potential risks which the medicinal product might pose to the environment. In addition, a qualified person responsible for pharmacovigilance is required. Finally, the administrative file for a marketing authorization shall include expert reports, chemical, pharmaceutical and biological information for medicines containing chemical and/or biological active ingredients, and the results of pharmaceutical, preclinical and clinical tests, among others.

According to article 20 of RLD 1/2015, the AEMPS may only refuse to grant the marketing authorization in the following scenarios: (i) when the risk-benefit balance is not favourable; (ii) when the therapeutic effectiveness is not sufficiently justified; (iii) when the qualitative and quantitative composition of the medicine is not as declared or is not of appropriate quality; and (iv) when the data and information contained in documents provided with the application are incorrect or do not comply with the relevant implementing regulations.

The marketing authorization shall be valid for five years and it can be renewed subject to a reassessment of the risk/benefit balance. Renewal of the marketing authorization shall be for an unlimited period, unless pharmacovigilance reasons justify a new procedure for renewal.

In addition to the above, the applicant shall take into consideration the provisions of Royal Decree 1345/2007, of 11 of October, regulating the authorization procedure, registration and conditions of dispensing of industrially manufactured medicines, in regards to the specific procedures depending on the type of medicine.

Manufacturing authorization

Medicine manufacturing at whatever stage in the manufacturing process, including the fractioning, packaging and presentation for sale, even if the medicine is manufactured exclusively with the purpose of exporting, requires the prior authorization of the AEMPS according to article 63 of RLD 1/2015. Such Manufacturing authorization shall be made public by the AEMPS, as well as any amendment thereof, or its termination.

Royal Decree 824/2010, of 25 of June, regulating pharmaceutical laboratories, manufacturers of active pharmaceutical ingredients and foreign trade in medicines and investigational medicines (“RD 824/2010”) implements RLD 1/2015 in this regard.

In order to obtain a manufacturing authorization, the applicant shall: (i) detail the medicines and pharmaceutical forms which it intends to manufacture, as well as the place, establishment or laboratory of manufacture and control; (ii) hold the possession of premises, adequate and sufficient technical and control equipment for proper manufacture, control and preservation in accordance with legal requirements; and (iii) appoint a person responsible for the manufacture, a person responsible for quality control and a responsible person who possesses the required expert knowledge to perform the activity (“*Director Técnico*”).

Additionally, the manufacturing authorization must be registered with the Spanish Registry of Pharmaceutical Laboratories and the Spanish Registry of Manufacturers, Importers or Distributors of Active Ingredients, as appropriate.

REGULATORY ENVIRONMENT

The European Directive on GMP requirements (Directive 2001/83/EC) has been implemented in Spain by RD 824/2010, which requires GMP-guideline compliance.

The procedure of evaluating the compliance with GMP in Spain does not differ from the procedure at European level. When an inspection visit has been carried out and conformity with the rules of correct manufacture has been verified, the relevant authorities will issue a certificate of compliance with said rules (GMP-certificate) (in accordance with article 43 and 45 of RD 824/2010).

In Spain, manufacturing authorizations are generally issued for an indefinite period. However, the competent public authority audits the compliance with the general and GMP requirements on a regular basis (usually every three years). The results of these audits/inspections provide the basis for the authority’s decision to either maintain or potentially withdraw or suspend the manufacturing authorization.

Import authorization

According to article 63 of RLD 1/2015, the professional or commercial import of medicines from countries which are not Member States of the EU or EEA, requires an import authorization. The requirements are predominantly similar to those required for the manufacturing authorization.

In practice, manufacturing and import authorizations are often issued together, because mostly pharmaceutical entrepreneurs perform manufacturing activities as well as import activities in relation to one medicine.

Together with the import authorization, the following requirements shall be complied with when importing active ingredients: (i) they shall be manufactured in accordance with the provisions in force in the exporting country regarding standards of good manufacturing practice at least equivalent to those laid down in the legal framework for the European Union; and (ii) they have to be accompanied of a certificate or attest of the competent authority of the export country stating: (a) that the provisions in force, in the exporting country, regarding standards of good manufacturing practice applicable to the premises in which the exported active ingredients are manufactured, are at least equivalent to those established in the legal framework of the European Union; (b) that the manufacturing premises concerned is subject to regular, strict and transparent controls and effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure protection of public health at least equivalent to that established in the European Union; and (c) that in cases of non-compliance, the exporting third country shall report to the European Union without delay (according to article 57 of RD 824/2010).

Wholesale authorization

According to article 68 of RLD 1/2015, the wholesale authorization is granted by the competent regional authority in which the applicant’s storehouse has its domicile, notwithstanding the obligation of reporting its activities to the health authorities of the Autonomous Communities (“*Comunidades Autónomas*”) in which it carries out a wholesale activity. Moreover, the initiation of the wholesale activity must be reported to the AEMPS.

Notwithstanding the above, the AEMPS is the competent authority to grant authorizations regarding the wholesale of medicines under customs control or supervision, in accordance with article 16 of Royal Decree 782/2013, of 11 of October, regulating the distribution of medicines for human use (“**RD 782/2013**”).

REGULATORY ENVIRONMENT

Pursuant to article 14 of RD 782/2013 the competent authority issues the wholesale authorization after an inspection of the applicants premises and activities, with the purpose of verifying the existence of appropriate personnel, material and operational resources to guarantee the correct development of their activity.

To obtain a wholesale authorization, the applicant shall comply with the requirements provided for in article 69 of RLD 1/2015 and article 8 of RD 782/2013, including the appointment of a responsible person with the expert knowledge to perform the activity (“*Director Técnico*”).

The wholesale authorization shall be granted notwithstanding the obligation to obtain a good distribution practice certificate (GDP).

Finally, according to article 110 *et seq.* of RLD 1/2015, the marketing, manufacturing or distribution of pharmaceuticals without the corresponding authorization constitutes a very serious infringement and may even be considered a criminal offense.

Reimbursement and pricing in Spain

For the vast majority of the Spanish population, healthcare is provided by the National Health System (“*Sistema Nacional de Salud*”).

On the one hand, articles 92 and 93 of RLD 1/2015 regulate the inclusion of medicines within the financing of the National Health System through a “selective” and “non-indiscriminate” financing, taking into account general, objective and published criteria, including, amongst others, the severity, duration and sequels of the different pathologies for which they are indicated, and the specific needs of certain groups.

The Ministry of Health, Social Services and Equality (“**Ministry of Health**”) will review the groups, subgroups, categories and/or classes of medicines whose financing is not deemed necessary to cover the basic health needs of the Spanish population. In any case, medicines not subject to medical prescription, medicines not used for the treatment of a clearly determined pathology and products for cosmetic, dietetic and other similar products will not be included in the pharmaceutical provision. Neither will the National Health System finance medicines indicated for the treatment of syndromes and/or symptoms of less severity, nor those which, although authorised in accordance with the regulations in force at the time, do not meet current therapeutic needs, understanding as such an unfavourable benefit/risk balance in the diseases for which they are indicated.

The relevant body within the Ministry of Health will update, by means of a reasoned decision, the list of medicines excluded from pharmaceutical provision in the National Health System.

Furthermore, pursuant to article 102 of RLD 1/2015, medicines shall be dispensed to the patient by means of a medical prescription or hospital dispensing order, through pharmacy offices or services. The patient shall pay a contribution at the time the medicine is dispensed, which shall be proportional to his or her level of income.

On the other hand, article 94 of RLD 1/2015 regulates the pricing of medicines. In general, the scope of the administrative intervention on industrial medicine prices in Spain is currently limited to medicines financed by the National Health System, hence, excluding (i) medicines excluded from public financing, and (ii) medicines not subject to medical prescription.

REGULATORY ENVIRONMENT

In any case, marketing authorization holders may commercialise medicines not subject to medical prescription in the Spanish territory at “notified prices”, meaning that the price is communicated to the Ministry of Health, so that the latter may object to it on grounds of public interest.

Regarding medicines financed by the National Health System and those medicines which require a medical prescription, the Interministerial Committee on the Price of Medicines (“*Comisión Interministerial de Precios de los Medicamentos*”), subject to the Ministry of Health, shall set, on a reasoned basis and in accordance with objective criteria, the prices of said medicines.

Finally, in 2019, the Ministry of Health published an action plan to promote the use of “market regulating medicines” in the National Health System in reference to biosimilar medicines and generic medicines (“*Plan de Acción para fomentar la utilización de los medicamentos reguladores del mercado en el Sistema Nacional de Salud: medicamentos biosimilares y medicamentos genéricos*”).

Intellectual Property

Spanish national IP rights

Spanish law recognizes various forms of intellectual property rights (IP), most importantly patents, utility models, trademarks, design rights and copyrights.

Patents are in general granted for technical inventions which are new and provide for an invention. They have a maximum protection period of 20 years. By way of so-called supplemental protection certificates (*Certificado Complementario de Protección*), this can be prolonged by 5 years for medical products and plant protection products. Patents must be registered with the Spanish Patent and Trademark Office (*Oficina Española de Patentes y Marcas*), and are examined for formal and material requirements.

Trademarks grant protection for signs that give an indication of origin (including words, devices, colors, shapes, sounds, and other forms) and which are neither descriptive nor generic. Trademarks must be registered with the Spanish Patent and Trademark Office, and are examined for formal and material requirements. Older third party rights are however not considered during registration examination, but must be raised by their respective owners (e.g. by way of opposition). Trademarks can be renewed every 10 years, no maximum protection period exists. Beside registered trademarks, German law recognizes trademarks by use (also called common-law trademarks) as well as certain protection for (company) names and titles.

Design rights grant protection for the form of a product if the design is new, has individual character, and where the design is not due to technical requirements. Design rights need to be registered with the Spanish Patent and Trademark Office, but are only examined for formal requirements. The maximum protection period is 25 years.

Copyrights grant protection for individual works of art; also e.g. photographs, software, or databases can qualify as such. They do not need to be (and cannot be) registered but come into existence with creation. The maximum protection period is 70 years after the death of the author. Other than all other IP rights listed above, copyrights cannot be transferred under Spanish law, but only usage and exploitation rights can be granted by way of license agreement.

REGULATORY ENVIRONMENT

Similar protection rights

Spanish law further provides for protection of trade secrets. Under the Trade Secret Protection Act (*Ley de Secretos Empresariales*), which was enacted in February 2019, any kind of information that (i) is not generally known amongst the relevant circles of trade, (ii) is of commercial value, and (iii) is subject to reasonable protection measures enjoys protection against unlawful acquisition, use and disclosure. If a company uses trade secrets of others and was (or should have been aware) that the trade secret was acquired unlawfully, this may also constitute unlawful conduct.

In addition, Spanish law provides for specific rules against unfair competition (*Ley de Competencia Desleal*). These primarily prohibit aggressive or misleading advertising, and to some degree also grant protection against imitation of goods.

Claims and enforcement

All of the above IP rights, trade secrets protection and unfair competition law grant claims for, amongst other, cease-and-desist, damages, and (mostly) recall or destruction of infringing goods. These claims are often enforced by way of interim injunction proceedings.

UK

General Regulatory Framework

Currently, the regulatory regime for medicines in the UK is similar to that in Germany, as medicines regulation is significantly harmonised under EU law. Directive 2001/83/EC is transposed into English law primarily through the Human Medicines Regulations 2012 (SI 2012/1916) (the “**UK Regulations**”).

Regulatory oversight of medicines in the UK is principally carried out by the Medicines and Healthcare Products Regulatory Agency (“**MHRA**”), which is the national competent authority. Alongside the MHRA, there are a number of other government bodies involved in the wider regulatory framework, including the EMA at the supra-national level.

However, this position and the overview set out below only apply at present in the UK. The decision of the UK to leave the European Union in 2016, i.e. the Brexit referendum, has left the future of its approach to medicines regulation uncertain. The impact of Brexit vis-à-vis medicines regulation is addressed further at the section headed “Brexit” below.

Drug authorization

As mentioned in the section headed “General Procedures of Marketing Authorization” above, there are four routes that can be taken across the EU to obtain drug authorizations in Member States (such as the UK), including the national procedure which can be used by applicants to market drugs solely in the UK. According to Regulation 46 of the UK Regulations, medicinal products must not be sold, supplied or offered for sale or supply in the UK without a marketing authorization obtained via one of these four procedures.

In certain circumstances the national procedure is not available to market drugs in the UK and instead the centralized EU procedure must be used (for instance, for biosimilars). Although the Inhixa product, as a biosimilar, was authorised via the centralized procedure, it is likely that the rules relating to UK national marketing authorizations will become relevant after Brexit, for the reasons set out in the section headed “Brexit” below.

REGULATORY ENVIRONMENT

Applications for a UK marketing authorization are made directly to the MHRA in accordance with Regulation 49 of the UK Regulations, which sets out a number of key requirements for the application. Once granted, a UK marketing authorization is valid for an initial term of five years (Regulation 65(1)(a)). Thereafter, once it has been successfully renewed the marketing authorization is typically valid indefinitely unless a safety concern subsequently arises (Regulation 65(1)(b)).

However, if the medicine is not placed on the UK market within three years of the marketing authorization being granted, or if taken off the market for a period of three consecutive years, the authorization will no longer be valid under Regulation 67. Further, the MHRA may revoke a UK marketing authorization at any time if any of the conditions under Regulation 68 are met, such as the MHRA determining that the product to which the authorization relates is harmful and/or that its positive therapeutic effects do not outweigh the risks to public health.

Holders of UK marketing authorizations must comply with a number of obligations prescribed by Regulations 73-78 of the UK Regulations.

Finally, there are a number of exceptions to the general requirement for a marketing authorization pursuant to Regulation 46. These exceptions are specified in Part 10 of the UK Regulations.

Manufacturing/Importations authorizations

Regulation 17 of the UK Regulations requires an entity to have a manufacturer’s licence in the UK in order to manufacture, assemble or import from a non-EEA state any medicinal product, or possess a medicinal product for the purposes of any of these activities.¹

There are various types of manufacturer’s licence available in the UK, the most common of which is a manufacturer/importer licence. Applications for a manufacturer’s licence in the UK are made to the MHRA and must indicate the descriptions of the medicinal products for which the licence is required (Regulation 21). The MHRA must then decide to grant or refuse the application within a period of 90 days beginning immediately the day on which the application was received (Regulation 23).

The relevant factors that the MHRA takes into account in its determination whether or not to grant a manufacturer’s licence are listed at Regulation 22(1), and the statutory conditions for a manufacturer’s licence are set out at Regulations 37-41 of the UK Regulations, and have effect as if they were provisions of the licence. In particular, Regulation 37(2) specifies that the holder of a manufacturer’s licence must comply with the principles and guidelines of GMP as set out in the Good Manufacturing Practice Directive (Directive 2003/94/EC). This obligation applies to both (i) the manufacture/assembly of products and (ii) the importation of products from outside the EEA.

Compliance with GMP in the UK is overseen by the MHRA, which also issues its own guidance to UK-based holders of manufacturer’s licences. As is the case in Germany, a ‘qualified person’ must be named on the licence to ensure that the legal requirements of GMP are met in accordance with Regulation 41 of the UK Regulations. Regular inspections are carried out by the MHRA every 2-3 years on these sites to ensure ongoing compliance with GMP, and licence holders are also issued with a corresponding certificate of GMP compliance to demonstrate this.

¹ There is an exception to the need for this licence for entities which solely provide facilities for transporting the product, or act as an ‘import agent’ by importing the medicinal product solely to the order of another entity which itself possesses a manufacturer’s licence authorising such importation.

REGULATORY ENVIRONMENT

Manufacturer licences granted by the MHRA remain in force until the licence is revoked by the MHRA, or the licence is surrendered by the holder (Regulation 25). Once granted, any changes to the information shown on the manufacturer’s licence must be notified and approved by the MHRA through the submission of a variation application.

Wholesale authorization

According to Regulation 18 of the UK Regulations, an entity in the UK cannot distribute a medicinal product by way of wholesale dealing or possess a medicinal product for the purpose of such distribution without having first obtained a wholesale dealer’s licence. Broadly, a wholesale dealer’s licence is required in the three following circumstances:

- (a) procuring, holding, supplying or selling medicinal products for human use sourced in the UK or another EEA Member State, to anyone other than members of the public;
- (b) importing medicinal products from a non-EEA Member State for export to a non-EEA Member State; and/or
- (c) exporting medicinal products to a non-EEA Member State.

The above includes virtual operations where no physical handling of the products takes place.

Applications for a wholesale dealer’s licence are made to the MHRA, and as with manufacturer’s licences in the UK, will not be granted unless and until the MHRA is satisfied that the information in the application is accurate and legally compliant following an initial site inspection.

The holder of a wholesale dealer’s licence must comply with the obligations set out under Regulations 43-45 of the UK Regulations. These include an obligation to comply with principles of GDP published by the European Commission in accordance with Article 84 of Directive 2001/83/EC (Regulation 43(1)), and to appoint a “responsible person” who is sufficiently qualified and trained in GDP to have ultimate responsibility for ensuring that the conditions under which the licence was granted are complied with (Regulation 45). Routine site inspections are also carried out on the sites named on wholesale dealer’s licences to ensure continued compliance with the principles of GDP.

Reimbursement

The UK medicines market is highly complex, and it differs from most other European markets due to the existence of the National Health Service (“NHS”), where patients are not required to have either statutory or private health insurance.

The manner in which the NHS procures medicines differs between England, Scotland, Wales and Northern Ireland, and within England there are ten regional pharmacy purchasing groups.

Separate from centralized NHS procurement, there is also a system of reimbursing private pharmacies for the dispensing of prescriptions to out-patients, which is intended to incentivise the use of generic rather than branded medicines where possible. The systems of payment for prescriptions also differ between the constituent countries of the UK.

The full details of the reimbursement system in the UK are beyond the scope of this note.

REGULATORY ENVIRONMENT

Brexit

The UK’s planned withdrawal from the EU on January 31, 2020 (“exit day”) will have both short-term and longer-term implications on its medicines regulatory regime. There are a number of relevant pieces of primary and secondary legislation, some of which are currently still passing through the UK Parliament.

First, until exit day the UK will remain a full member of the EU and therefore remains subject to EU law, meaning that the regulations set out above at paragraphs 3.1 to 3.4 will continue to apply until January 31, 2020 at the very least.

After exit day, the effect of EU law in the UK, and therefore the status of the current regulatory framework, will depend on whether or not both the UK and the EU have ratified a withdrawal agreement setting out the terms of the UK’s departure in accordance with Article 50 of the Treaty on the Functioning of the European Union (“TFEU”) before the deadline, or whether the UK leaves the EU without any withdrawal agreement in place.

No Deal Scenario

In preparation for a potential ‘no deal’ scenario, i.e. where no agreement is reached with the EU before exit day, the UK Parliament has enacted the European Union (Withdrawal) Act 2018 (“EUWA”). This provides for the repeal of the European Communities Act 1972 on exit day, effectively rendering EU law no longer applicable in the UK, and incorporates all EU law that had effect in the UK immediately prior to exit day directly into UK law. The EUWA also gives UK ministers powers to pass secondary legislation to amend UK law, so that any necessary changes can be quickly made to reflect the UK’s departure from the EU.

The UK government has exercised these powers in respect of medicines regulation primarily through the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019/775) (the “Brexit SI”),² in order to ensure that UK law in this area is fit for purpose in a no deal scenario.

The Brexit SI amends the UK Regulations in the event of no deal with immediate effect following exit day to enable the MHRA to act as a standalone regulator outside of the EU framework on the basis of UK law

Some of the key changes to UK law that would apply in a no deal scenario pursuant to the Brexit SI (and EUWA) are set out below:

- (a) all EU centrally authorised marketing authorizations in place immediately prior to exit day will be converted into UK marketing authorizations;
- (b) to sell medicines in the UK after exit day which do not have a prior marketing authorization in place, a UK marketing authorization will need to be obtained via one of the three new national routes (targeted assessment, accelerated assessment, and rolling review);
- (c) wholesale dealer licences will initially remain in force, but may need to be reviewed and various new requirements will apply, including the appointment of a Responsible Person for imports; and

² As amended under SI 2019/1385

REGULATORY ENVIRONMENT

- (d) in relation to pharmacovigilance, after a 21 month grace period the QPPV will need to be based in the UK, as opposed to within the EEA as prescribed under the current rules.

Other functions currently exercised by the EMA as regards UK medicines regulation will also be transferred to the MHRA under the Brexit SI, should no deal be reached.

Deal Scenario

Following the UK Conservative Party’s election victory on December 12, 2019, it is now almost certain that the UK will leave the EU on exit day with the October 2019 withdrawal agreement with the EU in place, thereby avoiding a no deal scenario and the abovementioned changes that the Brexit SI would implement.

However, before the UK can ratify the EU withdrawal agreement, Parliament will need to pass the European Union (Withdrawal Agreement) Bill 2019-20 (the “WAB”) to implement its terms into UK law. Please note that the EU withdrawal agreement and the WAB are separate; the EU withdrawal agreement is an agreement between the UK and the EU, whereas the WAB is UK legislation that must be passed by the UK Parliament before the EU withdrawal agreement can take effect. The WAB has already passed its ‘second reading’ in the House of Commons and is widely expected to become law before exit day.

Assuming it becomes law, the WAB will amend the EUWA to ensure that EU law continues to apply in the UK for the duration of a transition period lasting until December 31, 2020, which will become the UK’s full departure date from the EU. Additionally, it will ensure that certain provisions of the EUWA (and secondary legislation granted pursuant to the EUWA) take effect at the end of the transition period, rather than on exit day (i.e. January 31, 2020). The WAB will also enable the mass deferral of the effects of no deal statutory instruments such as the Brexit SI which are currently due to come into effect on exit day until the end of the transition period (paragraph 5, schedule 1 to the WAB).

The main consequence of this in the context of medicines regulation in the UK is that the rules that would apply in a no deal scenario could potentially still take effect immediately after December 31, 2020, notwithstanding the fact that the UK has left the EU with a withdrawal agreement in place on January 31, 2020. If no trade agreement/treaty that encompasses medicines regulation is reached between the EU and UK in future negotiations during the transition period, then UK law will default to the no deal medicines regulation position under the EUWA, subject to any further variations that the UK government may wish to make.

If a trade agreement/treaty is reached between the EU and UK before December 31, 2020, it is likely that such agreement will determine the terms of medicines regulation in UK going forward. However, as the details of the agreement have yet to be negotiated, it is not yet possible to say exactly how medicines will be regulated in the EU in future, although the rules are unlikely to depart dramatically from the existing EU laws in the medium term.

In the long-term, the regulation of medicines in the UK will be determined by the agreement reached between the UK and the EU on their future relationship, or whether such an agreement is reached at all. The October 2019 Political Declaration between the EU and UK—which is an indicative statement of intent for the future relationship between the parties—stated that they would “explore the

REGULATORY ENVIRONMENT

possibility of cooperation of United Kingdom authorities with Union agencies such as the European Medicines Agency (EMA)”. However, there is no guarantee that a future agreement will be reached within the transition period, let alone what the terms of that agreement in relation to medicines regulation will be.

A further point to note is that, if the WAB becomes law before exit day and implements the terms of the October 2019 withdrawal agreement, Northern Ireland will be treated differently from the rest of the UK and would have to align with specific EU rules, including rules on the authorization and supervision of medicines. In practice, this would result in the MHRA having to apply a different set of rules and standards in Northern Ireland from the rest of the UK. This could potentially raise a number of issues from a legal and regulatory standpoint.

Finally, to summarise the position in the UK post-Brexit:

- the current regulatory framework based on both EU law and UK law at paragraphs 3.1-3.4 above will continue to apply in the UK until at least January 31, 2020;
- it is highly likely that this framework will then continue to apply from January 31, 2020 until December 31, 2020, assuming the WAB becomes law before exit day and all of the other requirements of Article 50 of the TFEU are met for the UK’s orderly (initial) withdrawal from the EU; and
- after December 31, 2020, the nature of the UK’s medicines regulatory framework is presently uncertain, and is still subject to negotiation between the EU and the UK.

Intellectual Property

The Intellectual Property Act 2014 protects businesses’ IP rights in the UK and abroad as it synchronizes UK law with that of EU intellectual property law. There are several different forms of intellectual property rights available in the United Kingdom, each with its own formality, level of protection, and duration period.

In the United Kingdom, patents are subject to the Patents Act 1977. To obtain patent rights an application can be filed either directly with the UK patent office, the European Patent Office, or under the Patent Cooperation Treaty, of which the UK is a member. A patent will exist for 20 years from the original application date.

The Registered Designs Act 1949 is the governing piece of legislation regarding design rights and it defines a ‘registered design’ under s1(2) as: “...the appearance of the whole or part of a product resulting from the features of, in particular the lines, contours, shape, texture and/or materials of the product itself and/ or its ornamentation”. A registered design right lasts for 25 years from the registration date.

In terms of copyright, no formality is required to register this right in the United Kingdom. Copyright will subsist in the artistic work for 70 years from the death of the creator.

A trademark is obtained through registration and shall be protected for 10 years, however, you can choose to renew this to offer a further 10 years’ protection upon the first 10 years expiry.

REGULATORY ENVIRONMENT

Italy

Drug authorization

Medicinal products may only be placed on the market in Italy on the basis of an Autorizzazione all’Immissione in Commercio (AIC), i.e. a marketing licence (marketing authorization (MA)) (Article 6 Legislative Decree no. 219/2006 (implementing Directives 2001/83/EC and 2003/94/EC). The Ministry of Health issues the MA by a Ministerial Decree.

In order to obtain the MA the applicant has to file an application in the form of a dossier including information concerning chemical-pharmaceutical, preclinical and clinical studies, having a standard format structure (CTD—Common Technical Document). The data and the studies submitted in support of the MA application have to comply with the guidelines established at European level.

AIFA (Agenzia Italiana del Farmaco—the Italian Medicines Agency) is the body responsible for both granting MAs and negotiating reimbursement prices for medicinal products.

AIFA verifies the conformity of the documentation submitted by the applicant and verifies that the medicinal product is manufactured according to good manufacturing practices (GMP), that its components (active substance and other components) are suitable and that the control methods used by the manufacturer are satisfactory.

With the support of the Technical Scientific Commission (CTS) and the Istituto Superiore di Sanità (ISS), AIFA carries out the evaluation of the data submitted by pharmaceutical companies concerning the chemical-pharmaceutical, biological, pharmaco-toxicological and clinical characteristics of each medicinal product intended to be placed on the Italian market, in order to ensure its safety and efficacy requirements.

A CTS sub-commission checks the documentation and issues an opinion on the possibility of granting an MA for the medicinal product. The CTS plenary session then ratifies the opinion expressed by the sub-commission and designates the class for price reimbursement. Price negotiations are managed by AIFA’s Price & Reimbursement Committee.

Historically in Italy a medicinal product could only be sold once the MA had been published in the Official Journal of the Italian Republic (OJIR), which was not before the reimbursement price had also been determined. The publication in the OJIR would then include not only the MA but also the relevant reimbursement price and category. Therefore, grant of an MA in Italy often lagged significantly behind those of linked MAs in other EU countries. However, Law Decree 158/2012 converted into Law no. 189/2012 (the “Balduzzi Decree”), which came into force on 14 September 2012, allowed for demerger of grant of MAs and reimbursement prices. In May 2013, AIFA issued a communication to all pharmaceutical companies confirming that it would apply the Decree’s provisions.

The overall timing from application to grant for national MAs is extremely difficult to estimate, albeit it is set by the law in 210 days.

In exceptional cases, in Italy, free access to a pharmacological therapy is allowed before AIFA authorizes its marketing or, for already authorised medicinal product, for indications other than those for which the latter has been authorised in Italy (off-label use).

REGULATORY ENVIRONMENT

The pathways for early access to a medicinal product are:

Law no. 648/1996

Compassionate use

AIFA National Fund (Law no. 326/2003—so-called “5% Fund”)

Non-repetitive use of advanced therapies

Law no. 648/1996 and AIFA Fund provide for the reimbursement of the medicinal product, by the National Health Service and by AIFA, respectively.

The compassionate use provides for the direct and free supply by the manufacturer of the medicinal product.

The non-repetitive use of advanced therapies involves the preparation of the medicinal product directly from a cell factory and the requesting clinical centre takes charge of the related expenses.

Finally, it is possible to access treatment with a medicinal product on the market but for an indication other than that for which it has been authorised (Law no. 94/98 art.3, paragraph 2—former Di Bella Law), even in the presence of regularly authorised therapeutic alternatives. In this case, however, the therapy is at the patient’s expense or at the expense of the hospital in case of hospitalization.

Manufacturing authorization

For the manufacture of medicinal product at whatever stage in the manufacturing process a manufacturing authorization is required in Italy according to Article 50 and ff. of Legislative Decree no. 219/2006. Such manufacturing authorization is connected to, and issued for, specific premises and covers specific manufacturing activities and product classes. In Italy, the public authority competent for granting such manufacturing authorization is AIFA—Office for GMP Inspections and authorizations.

Recently, Law no. 37/2019 introduced additional amendments to Article 50 and ff. of Legislative Decree no. 219/2006 by implementation of the Commission Directive (EU) 2017/1572 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice (GMP) for medicinal products for human use. These amendments establishes a strengthening of the obligations of the manufacturer (and importer—see below) to ensure quality and safety of the medicinal products.

Article 50 establishes inter alia that in order to obtain the manufacturing authorization, the applicant shall: a) specify the medicinal products and pharmaceutical forms that it intends to manufacture or import, as well as the place of manufacturing and controls; b) have at its disposal, for the manufacturing or import of the same medicinal products, adequate and sufficient premises, technical equipment and facilities and control possibilities, both for the manufacturing and control and for the storage of the medicinal products; c) have at least one qualified person (QP).

The procedure of evaluating the compliance with GMP in Italy is aligned to that at European level. Thus, AIFA issues the manufacturing authorization after an inspection of the applicant’s premises and activities.

REGULATORY ENVIRONMENT

AIFA enters the information relating to the authorizations granted in the European Union database and publishes on its institutional website the list of premises authorised to manufacture and control medicinal products on 30 June each year.

AIFA controls the compliance with applicable GMP-requirements through audits/inspections. The results of these audits/inspections provide the basis for AIFA’s decision to issue, maintain or potentially withdraw or suspend the manufacturing authorization. Any deficiency detected with respect to the GMP is classified according to the potential impact on the health of patients. They include: critical deficiencies (potentially life-threatening or serious damage to patient health), serious deficiencies (potential or concrete impact on pharmaceutical but not critical) and other deficiencies (no noticeable impact on pharmaceutical and no demonstrable significant risk but incorrect application of GMP).

Import authorization

Article 55 of Legislative Decree 219/2006 provides that the rules set forth in Articles 50-53 of the same Legislative Decree apply to the import of medicinal products from countries which are not Member States of the EU or EEA. This means that the importer requires an import authorization issued by AIFA and the regulations on the manufacturing authorization also apply to import of medicinal products. In practice, manufacturing and import authorizations are often issued together, because mostly pharmaceutical entrepreneurs perform manufacturing activities as well as import activities in relation to one drug.

When the drugs come from countries which are not Member States of the EU or EEA, in addition to the import authorization it is needed that their manufacture was performed in compliance with rules on manufacturing at least equivalent to those in force in the EU and by a duly authorised manufacturer (Article 61 of Legislative Decree 219/2006).

Wholesale authorization

In Italy, wholesale distribution of medicinal products is subject to the possession of an authorization issued by the autonomous region or province or other competent authorities, as identified by the legislation of the regions or autonomous provinces themselves. This authorization specifies for which premises, established on their territory, it is valid (Article 100, paragraph 1, of Legislative Decree 219/2006).

Wholesale distribution of pharmaceutical products is allowed only for authorised products.

According to Article 100, paragraph 3, a manufacturing authorization includes the authorization to engage in wholesale activities regarding the products covered by the scope of the respective manufacturing authorization.

To obtain a wholesale authorization, the applicant shall (1) have suitable premises, installations and equipment sufficient to ensure the proper storage and distribution of medicinal products; (2) have adequate personnel and appoint a responsible person having certain requirements, including inter alia a degree in pharmacy or chemistry or pharmaceutical chemistry and technology or industrial chemistry (3) undertake to comply with the applicable obligations. The specific premises and medicinal products for which the wholesale distribution is performed shall be indicated in the authorization. In order to carry out wholesale distribution through several warehouses located in different regions, the applicant

REGULATORY ENVIRONMENT

must obtain separate authorizations, applying to each competent authority. Prior to the issue of the wholesale authorization an inspection of the premises is carried out.

The holder of the wholesale authorization for distribution must purchase medicines only from authorised entities and it is authorised to sell them only to persons/companies/entities authorised to distribute/purchase drugs.

The wholesaler is obliged to comply with defined delivery times and an assortment obligation (Article 105 of Legislative Decree 219/2006).

With exception for the obligations set forth in Article 105, paragraphs 1 and 3, the rules on the wholesale authorization also apply to the activities of those holding, for subsequent distribution, medicinal products for human use on the basis of storage contracts concluded with the MA holders of medicinal products or their representatives (so-called “custodians” or first-line distribution opposed to the so-called second-line distribution by the wholesalers properly called).

Currently, in Italy the European GDP of 1994 have been implemented by the Ministerial Decree of July 6, 1999—Approval of the guidelines on Good Practice in the Distribution of Medicines for Human Use.

Although Article 110 of Legislative Decree 219/2006 requires timely implementation of the guidelines, the 2013 European GDP have not yet been formally implemented in Italy.

Reimbursement in Italy

In Italy a medicinal product may be given one of the following price classifications: “A” (reimbursed), “H” (hospital only reimbursed), “C” (not reimbursed), and “C-nn” (i.e. “C-non-negotiated”). “C-nn” was introduced under the Balduzzi Decree, to allow for the possibility of splitting the grants of the MA and reimbursement price. A medicinal product will have the C-nn price classification if the MA has been published in the OJIR before the determination of the price—which can occur if: (i) no request for price negotiation has yet been filed by the applicant; or (ii) if the price negotiation procedure has not been completed when the time limit for publication of the MA has been reached (AIFA now has much shorter time limits for MA publication). The C-nn classification will then be changed once the reimbursement price negotiation procedure is concluded.

Article 11(1bis) of the Balduzzi Decree provides for a pricing linkage system. The Balduzzi Decree directed AIFA to refrain from granting a reimbursement price to an approved generic product when the reference product is still protected by a patent or SPC. Where the price negotiation is completed before the expiry of patent /SPC rights, the order publishing the reimbursement price for the product will indicate that the product has been included in class C-nn until the expiry of the patent/SPC rights. It will also indicate the prospective classification of the product as a reimbursed product along with the relevant price, such classification to enter into force as of the date of expiry of the patent/SPC rights identified by the Ministry of Economic Development (which is in charge of the Italian Patent Office). Lists of relevant patents (not covered by SPCs) and SPCs were published.

The Balduzzi Decree also introduced a shortcut to the process of agreeing a generic or biosimilar product a price by negotiation between the generic company and AIFA, that process typically requiring several sessions of AIFA’s price committee and taking a period of months. The shortcut allows the automatic grant of a reimbursement price of a generic or biosimilar product, and

REGULATORY ENVIRONMENT

this process was clarified by a further Decree of April 4, 2013 which came into force on July 1, 2013. The Balduzzi Decree stated that generic or biosimilar products would be automatically granted a reimbursement price provided that the generic company proposed a price of clear convenience to the National Health Service. However, the Balduzzi Decree left open the question of what “clear convenience” meant. Under the Decree, a table was published on 6 June 2013 setting out a series of percentage discounts over the originator’s price, depending on the value of annual sales of the originator’s product. A reimbursement price will be granted automatically if the generic or biosimilar proposes a price with a percentage reduction at least as great as the relevant percentage set out in the Decree. The percentage thresholds range between 45% to 75% off the public price of the originator’s product for category A products (reimbursed products) and between 30% and 50% off the ex-factory price for category H products (hospital only reimbursed).

Pricing of the drugs applicable to Inhixa, specifically pricing of biosimilars

The procedure for the determination of the reimbursable price of medicinal products is regulated by Articles 11 and 12 of the “Balduzzi Decree”. See above answer E.

For biosimilars the above provisions foresee that within 60 days from the publication of the MA grant in the EU Official Gazette, AIFA will publish on the Italian Official Gazette an official “decree of acknowledgement” (DA) of the centralized MA. The actual timing of the procedure is heavily impacted by the duration of price negotiation with Italian health authority AIFA. There are two different scenarios here. The first is fast, the second may be a lot slower.

The first scenario is that the biosimilar will complete price negotiations with AIFA before the publication of the DA. The DA will automatically classify the biosimilar as reimbursable either in “Class A” or “Class H” (Class H is specifically for hospital only products, whilst Class A is for all other reimbursable products). The DA will include the relevant price. In this scenario the biosimilar will have finalized the Italian part of regulatory procedure within the official deadline of 60 days from publication of MA grant in the EU Official Gazette.

In the second slower scenario, the biosimilar will not be able to complete price negotiations with AIFA before publication of the DA the Italian Official Gazette. In this case the DA will merely report a so-called “Cnn” price classification (“C” stands for “Class C” (i.e. NOT-reimbursable product and “nn” stands for “Not Negotiated”). At this point the biosimilar will have to complete price negotiation and only after a price has been determined AIFA will issue a formal notice (called “determina”) which will contain both indication of the class (either H or A) and the price.

Based on Art. 12 of Law Decree no. 158/2012 (so called “Balduzzi Decree”) in this second scenario the timing for price classification and negotiation should not exceed 180 days from the submission of the price proposal.

It is evident that the length of price negotiations will depend on the biosimilar’s attitude in proposing their price. According to AIFA’s “Second Position Paper on Biosimilars” dated 27 March 2018 the price of the latter must be at least 20% lower than the reference product. However, we know that AIFA is increasingly aggressive in requesting much more substantial price cuts.

A possibly highly relevant point concerns the application to biosimilars of Article 11 of the Balduzzi Decree—providing that medicinal products that are “equivalent” to products which are still

REGULATORY ENVIRONMENT

protected by a patent or SPC cannot be included in “Class A” or “Class H”, until after the expiry of the relevant rights (see above answer E)—which expressly mentions equivalent products (“normal” generic) but remains silent on biosimilars.

At the present stage we are not in a position to verify whether the reference lists for the patents/SPC includes IP rights of relevance for Inhixa (the patent list does not identify the medicinal product covered by the listed patents, whereas the updates to the SPC list—which originally did not refer to the active substance of Inhixa—appear not to be available in the updated Italian Patent Office website). We remain at your disposal for conducting additional researches upon your request.

In any event please consider that both AIFA and the Administrative Courts held that whereas the Balduzzi Decree normally applies in relation to compound patents protecting an active substance, patents different from those on active substances would not deserve such a protection per se, but only if their scope of protection concerns an element which justifies the finding that the product according to the patent is “truly innovative” as opposed to already existing products. In light of the above, it is likely that the Balduzzi regulatory system would effectively apply only in the event the patent covering the active substance of Inhixa is included in the relevant patent list.

Specific regulations for biosimilar drug, if any, relating to the marketing/import of such drugs

We are not aware of specific regulations for biosimilar drug in Italy relating to the marketing/import of such drugs. The main issues concerning biosimilars in Italy as identified by AIFA’s “Second Position Paper on Biosimilars” relate—in addition to the applicability of the pricing rules illustrated in answer F—to the possible application of Law no. 648/1996 (re: off-label use—see answer A) to biosimilar products and the automatic “substitutability” issue (Ref. EMEA/74562/2006 Rev. 1; EMA/837805/2011). Please let us know if you want us to further elaborate on this.

Intellectual Property

Industrial and intellectual property rights (“IPRs”) are regulated in Italy by the general principles laid down in the Italian Civil Code and in the Italian Legislative Decree No. 30 of February 10, 2005, as amended (the Intellectual Property Code, “IPC”), and, in relation to copyright, by Italian Law No. 633 of April 22, 1941 (the Italian Copyright Law, “ICL”). Italy is also a party to several international treaties and conventions related to IPRs, including the European Patent Convention.

In general, IPRs, except for trademarks, are granted in Italy for a limited period and there is a right to obtain a declaration of voidness if the IPRs do not meet legal requirements for their protection.

All applications and requests, with the exception of what is provided for by international conventions and agreements, are to be filed with the Italian Patent and Trademark Office (“IPTO”). Once filed, depending on the type of IPRs, the IPTO carries out its examination and checks the occurrence of the formal and, to a certain extent, substantial requirements of the application.

IPRs are litigated in Italy before the specialized divisions established within Italian courts (i.e. *Sezioni Specializzate delle Imprese*).

The owner of IPRs has several options to react against infringement in Italy depending on the scale and type of infringement. The owner might commence civil and/or criminal proceedings and can

REGULATORY ENVIRONMENT

alert the customs authorities in case of counterfeiting. A range of interim measures, including preliminary injunction, is available in civil proceedings.

Patents for invention

Under Italian Law, the claimed invention must consist of patentable subject-matter; *inter alia*, discovery, scientific theories and mathematical methods are not *per se* patentable. In addition, the invention must: (i) be new; (ii) involve an inventive step; (iii) be capable of industrial application; and (iv) be disclosed in a clear and complete manner in the patent application.

Patent applications made on or after 1st July 2008 have been able to include a novelty search conducted by the European Patent Office on behalf of the IPTO, with the search results provided to the applicant.

Patents have a maximum duration of 20 years starting from the date on which the application is filed, and may not be renewed, nor may their duration be extended.

Patents may expire in case of failure to pay the relevant annual fees. By way of so-called supplemental protection certificates (“SPC”), the duration can be extended of further 5 years for medical products.

Utility models

They consist in a shape of a product capable to confer effectiveness to, or ease the application of, machines or parts of them, instruments, tools or objects of general use.

They last for 10 years from the date on which the application is filed.

Trade secrets

The IPC sets forth protection of trade secrets as IPR, even if not on the basis on a registration title.

Article 98 of the IPC requires that a trade secret must meet the following three requirements: (i) confidentiality, i.e. the information protected cannot be well-known or readily accessible to experts and operators in the field; (ii) commercial value, which must derive from the fact that the information is a trade secret; (iii) reasonable efforts must be made by the holder of the information to keep it confidential.

Trademarks and other distinctive signs

Marks, business names and trade names are the typical forms of distinctive sign in the Italian legal system. With specific respect to trade marks, there are various categories, which differ based on the nature of the sign. In principle, a trade mark is capable of registration where it has the essential purpose of identifying a specific product or business, and it has distinctiveness (consequently, descriptive or generic words cannot be registered as trademarks). Italian Legislative Decree No. 15 of February 20, 2019 no longer requires the graphic representation of the sign in order to register it as trademark. This amendment broadens the scope of protection of the trademark, considering that also new types of signs (such as smells or sounds) may be protected as a trademark.

REGULATORY ENVIRONMENT

Registered trademarks are protected for 10 years starting from the application date and can be renewed with respect to the same signs and the same products and services for further 10-year periods, for an indefinite number of times.

The Italian system also recognizes unregistered trademarks (or *de facto* trademarks).

The essential condition to be met to obtain trademark protection for unregistered trademarks is to demonstrate that the unregistered mark is perceived by the general public as an indication of the origin of the product or has become well known/notorious in the relevant market.

If the unregistered trademark is known only at a local level, the owner of the previous unregistered trademark is always allowed to continue the use of the sign within the limits of such use (so-called “*diritto di preuso*”).

Copyright and software

Copyright protects works of the mind having a creative character and belonging to literature, music, figurative arts, architecture, theater or cinematography, whatever their mode or form of expression. The ICL indicates no specific level of creativity required to qualify for protection; in practice, a minimum of creativity is generally regarded as sufficient. Copyrights come into existence as a result of the creation itself. This means that registration is not compulsory. However, works can be registered with the Italian Society of Authors and Publishers (SIAE) and the Italian Ministry of Cultural Heritage and Activities (Mibact).

The ICL expressly lists software among copyrightable subject-matters and allows copyright protection on condition that the software is original and the result of the author’s intellectual creation. In accordance with the European Patent Convention, software cannot be protected by patent law as such, but only if has a technical effect that is new and non-obvious.

Economic rights in copyright generally are protected for 70 years after the death of the author. The moral rights are instead perpetual.

Industrial Design

The registration as a design is subject pursuant to the IPC to the requirement of (i) novelty; (ii) individual character (i.e. the general impression of the appearance of the design); and (iii) lawfulness. The duration of the protection is 5 years, renewable for up to a maximum of 25 years.

Pursuant to the Italian legal framework, industrial design is also granted copyright protection provided that it displays not only creative features, but also ‘artistic value’ (*valore artistico*). The ‘artistic value’ requires, as interpreted by the Italian courts, evidence of public rewards or acknowledgments by art critics, museums or exhibits.

France

Medicinal product marketing authorization

In the event an applicant is seeking a MA (*autorisation de mise sur le marché*) only in France, the French Public Health Code (*Code de la santé publique* or “CSP”) sets out the relevant requirements. According to Article L. 5121-8 of the CSP, proprietary medicinal products (*spécialités*

REGULATORY ENVIRONMENT

pharmaceutiques) or any other industrially medicinal product for human use may only be placed on the market if they have been authorised by the competent authority (at French or EU level). Therefore, the French pharmaceutical entrepreneur may also rely on a MA granted through the centralized EMA procedure (e.g., biosimilars). Proprietary medicinal products are ready-prepared medicinal products that are placed on the market under a special trademark and in a special packaging.

As an exception, for some medicinal products a MA is not required (Articles L. 5121-12, L. 5121-13, L. 5121-14-1 and L. 5124-8 of the CSP). This is the case for example as regards certain homeopathic products or traditional herbal medicinal products that only require a registration.

Formally a MA requires an application of the French pharmaceutical entrepreneur, i.e. the person who wishes to be granted the MA.

For a French MA, the application must be addressed to the competent authority. According to Article L. 5121-8 of the CSP, the competent regulatory authority in France to grant a MA for human use medicinal products is the *Agence nationale de sécurité du médicament et des produits de santé* (“ANSM”). The ANSM examines whether a medicinal product is effective and harmless and whether it has the required pharmaceutical quality.

The required application documents submitted by the pharmaceutical entrepreneur shall include (among others) the full composition of the medicinal product, preclinical and clinical tests as well as experts opinions. In addition, the pharmaceutical entrepreneur must submit instructions for use and technical information. Additionally, the exact description of the intended pharmacovigilance or risk management system is part of the MA application documents.

According to Article L. 5121-9 of the CSP, the competent authority must deny the MA if the submitted documents and information do not comply with the required application file, if the assessment of the positive therapeutic effects of the medicinal product in relation to the risks for the patient’s health or public health associated with its quality, safety or efficiency is not deemed favorable, if the medicinal product does not correspond to the declared qualitative and quantitative composition or if the claimed therapeutic effect is lacking or insufficiently evidenced by the applicant.

Otherwise, the competent authority shall issue the MA, as the case may be with requirements. The MA is issued for a five-year period and may be renewed without time limitation. It can be suspended, withdrawn or modified for specific reasons set out the CSP.

Manufacturing authorization

Medicinal products can only be manufactured by authorised pharmaceutical establishments (*établissements pharmaceutiques*) (Articles L. 5124-1 and R. 5124-2.1° of the CSP), it being understood that any entity (*entreprise*) having at least one pharmaceutical establishment must be owned by a pharmacist (*pharmacien*) or by a company having a pharmacist involved in its management or general management. This pharmacist is the “qualified person” within the meaning of EU regulations.

Any French pharmaceutical entrepreneur shall thus request the authorization to open a pharmaceutical establishment for medicinal products manufacturing purposes.

The authorization is issued for specific premises and covers specific medicinal products. Such authorization is granted by the ANSM.

REGULATORY ENVIRONMENT

The European Directive on GMP-requirements (Directive 2003/94/EG) has been implemented in France in particular by the Ministerial Decision of May 26, 2006 modifying the Ministerial Order of May 10, 1995 on the manufacturing guidelines (*Décision du 26 mai 2006 modifiant l'arrêté du mai 10 1995 modifié relatif aux bonnes pratiques de fabrication*) which has been repealed and ultimately replaced by the decision of May 6, 2019 on the manufacturing guidelines. According to articles R. 5124-3 and R. 5124-46 of the CSP and article 2 of the decision of May 6, 2019, the authorised pharmaceutical establishments shall comply with the manufacturing guidelines and be granted with a GMP compliance certificate issued by the ANSM.

In France, manufacturing authorizations are in principle issued for an indefinite time period. However, the competent public authority may control the compliance with applicable GMP-requirements (Article L. 5313-1 of the CSP). The results of these audits/inspections provide the basis for the authority's decision to either maintain or potentially withdraw or suspend the manufacturing authorization (Articles L. 5124-3 and R. 5124-15 of the CSP). Non-compliance with the GMP-requirements constitutes a criminal offence (Article L. 5421-1 of the CSP).

In addition, according to Article L. 5423-3 of the CSP, the manufacturing of medicinal products without a manufacturing authorization is prohibited and even constitutes a criminal offence.

Import authorization

Medicinal products can be imported by authorised pharmaceutical establishments (Articles L. 5124-1 and R. 5124-2.2° of the CSP). Any French pharmaceutical entrepreneur shall thus request the authorization to open a pharmaceutical establishment for medicinal products import purposes. Such authorization is granted by the ANSM. The requirements are predominantly based on those applicable to the manufacturing authorization. In practice, manufacturing and import authorizations are often both applied for, as most pharmaceutical entrepreneurs perform both medicinal products manufacturing and import activities. As a result, one unique authorization for the opening of a pharmaceutical establishment may be granted by the ANSM to a pharmaceutical establishment for the performance of several activities including medicinal products manufacturing and import.

Even if the pharmaceutical establishment has been granted a general import authorization, according to Article L. 5124-13 of the CSP, the import of medicinal products requires an import authorization for each product, even in the case where the medicinal products are imported from EU or EEA Member States.

However, such import authorization is not required when the medicinal product already benefits from a MA in France (see above).

There are two categories of import authorization:

- the general import authorization;
- the parallel import autorisation.

General import authorization

For a finished product in its commercial packaging, an import authorization is required for each importation. For a product other than a finished product in its commercial packaging, the import authorization covers a set of import transactions over the course of a maximum one-year period and for a fixed aggregate quantity.

REGULATORY ENVIRONMENT

Such authorization is not required in the case where the medicinal product having been granted a MA in a EU Member State is imported from this EU Member State, provided that it is (i) stored in a pharmaceutical facility and (ii) intended exclusively for export to EU third-countries.

The general import authorization is issued by the ANSM and can be suspended or removed by the latter.

An import authorization differs from a MA authorization and does not replace it.

As already said, a medicinal product having been granted a MA in France does not require such an import authorization if the imported product complies with the French MA.

Parallel import authorization

A parallel import authorization refers to a medicinal product that is imported from a EU or EEA Member State in which a MA has been issued, and where (i) the quantitative and qualitative composition in terms of active substances and excipients, (ii) the pharmaceutical form and (iii) the therapeutic effects are identical to those of a proprietary medicinal product that has been granted a MA by the ANSM.

The parallel import authorization is issued by the ANSM for a five-year period and may be renewed. It can be suspended or removed in the case where the proprietary medicinal product does no longer comply with the conditions prescribed in the authorization.

A parallel import authorization does not replace a marketing authorization or registration

An advice to applicants of parallel importation of medicinal products (*avis aux demandeurs d'autorisations d'importation parallèle en France de spécialités pharmaceutiques à usage humain*) dated 30 September 2016 and issued by the ANSM provides more details on the parallel import authorization.

Wholesale authorization

The wholesale of medicinal products in France can only be performed by authorised pharmaceutical establishments (Articles L. 5124-1 and R. 5124-2.4° of the CSP for depositories which only stock medicinal products and Article R. 5124-2.5° of the CSP for wholesalers which buy and stock medicinal products). Any French pharmaceutical entrepreneur shall thus request the authorization to open a pharmaceutical establishment for medicinal products wholesale purposes. Such authorization is granted by the ANSM.

The granting of the wholesale authorization is subject to the filing of an application containing (among others) (1) the identification of the specific sites, as well as the activities and medicinal products for which the authorization is requested and (2) a technical note describing the installations and facilities in order to ensure the proper storage and distribution of the medicinal products.

In addition to the provisions of the CSP, the applicant shall comply with the guidelines on good distribution practice (GDP) of the ANSM published in May 2014, Official Gazette 2014/9 *bis* (*Décision du 20 février 2014 relative aux bonnes pratiques de distribution en gros de médicaments à usage humain et modifiant l'arrêté du 30 juin 2000*).

REGULATORY ENVIRONMENT

The social security financing law for 2020 (“**LFSS 2020**”) No. 2019-1446 of 24 December 2019 provides a new legal regime for certain wholesale activities known as the parallel distribution.

A parallel distribution is related to a medicinal product having been granted an EU MA.

As a biosimilar must have been granted an EU MA, it can be subject to parallel distribution.

According to new Article L. 5124-13-2 of the CSP arising from the LFSS 2020, a new decree will determine (i) the obligations of the companies performing the parallel wholesale of medicinal products and (ii) the conditions under which the medicinal products that are subject to parallel wholesale are marketed in France.

Reimbursement and pricing

For the French population, healthcare is provided by the statutory health insurance (*sécurité sociale*).

Under the current social security-system, all prescription-only medicinal products with MA may be eligible for reimbursement. The prescription shall be issued by an health professional (*professionnel de santé*). In addition, such medicinal products shall be on one or two of the two following lists: the “list of reimbursed medicinal products” (*liste des médicaments remboursables*) and the “list of medicinal products approved by communities” (*liste des médicaments agréés à l’usage des collectivités et divers services publics*).

The medicinal products bought in a pharmacy may be fully or partially reimbursed, depending on the category of medicinal products, the prescription conditions and the issuance conditions.

As regards the pricing, a framework agreement between the Economic Committee of Health Products (*comité économique des produits de santé* or “**CEPS**”) and the French syndicate of pharmaceutical industries (*les entreprises du médicament* or “**LEEM**”) outlines the main priorities of the pricing policy of medicinal products.

In addition, for each medicinal product, based on the application filed by the pharmaceutical company (including the proposed price of the product), the CEPS will propose a price for the corresponding product based on the opinion of the Transparency Commission of the ANSM. Such opinion assesses the SMR (medical service rendered (*service médical rendu*) by the medicinal product) and the ASMR (improvement of the medical service rendered (*amélioration du service médical rendu*)). Generally, an agreement is signed between the CEPS and the pharmaceutical company regarding this medicinal product for a four-year period. This agreement may include obligations to comply with, including the carrying out of new clinical studies.

Specific regulations for biosimilars

A biosimilar is a medicinal product that is similar to a reference biological medicinal product which has been authorised in Europe for more than eight (8) years and whose patent has expired. Biosimilars are not generics. Those products differ from a pharmacologic point of view. As regards biosimilars, a similarity must exist with the reference biological medicinal product. Efficacy and side effects must be equivalent. In addition, the clinical development must demonstrate equivalent tolerance and efficacy.

REGULATORY ENVIRONMENT

The regulatory framework applicable to biosimilars is set out in Article L. 5121-1.15° and Articles R. 5121-9-1 to R. 5121-9-4 of the CSP.

A biosimilar is prescribed by a doctor under its International Nonproprietary Name (INN) and not its trademark.

On the website of the ANSM, there is a reference list of biosimilar biologic groups. The products with the same INN are in the same group.

Under EU regulations applicable to biosimilars, two notions play a key role:

- interchangeability: which is a medical act, on initiative of the doctor, to replace a biological medicinal product by a biosimilar having the same clinical effect as the reference biological medicinal product or another biosimilar of this medicinal product. The initiative of the doctor may occur at any time during the treatment and has to be done in the interest of the patient under three conditions: inform the patient, obtain his agreement, ensure a proper clinical survey and traceability of the products.
- substitution: which means the delivery by a pharmacist of an equivalent medicinal product without referring to the doctor.

Under EU regulations applicable to biosimilars, the decision to authorise interchangeability and substitution is taken at Member State level.

Article 42 of the LFSS 2020 has removed from the CSP the provisions of Articles L. 5125-23-2 and L. 5125-23-3 which referred to a right of substitution of biosimilars by pharmacists. So, it is no longer applicable in France.

The LFSS 2020 has also (i) introduced the right for companies to file a MA application before the expiry of the patent of the reference biological medicinal product, and (ii) created a working group to determine the conditions of interchangeability of biosimilars. However, in any cases, the marketing remains only possible at the expiry of the reference biological medicinal product patent.

Pricing of biosimilars

There is no specific pricing procedure for biosimilars.

Contrary to the pricing of generics, a very strict scheme of rebate in comparison of the reference medicinal product price does not exist for biosimilars.

In the CEPS/LEEM framework agreement of December 31, 2015, which is in force until the end of 2020, it is indicated that fixation and regulation of biosimilars prices and their reference biological medicinal products will be specified in an amendment to this framework agreement. This amendment has however not yet been concluded. It is also indicated that the procedure for admission of biosimilars to reimbursement will be accelerated (75 days after the Transparency Commission advice and if not, an explanation to justify it).

Intellectual Property

Under French law, intellectual property law is governed by the provisions of the French Intellectual Property Code (*Code de la propriété intellectuelle*) which is harmonized with the EU protection of intellectual work.

REGULATORY ENVIRONMENT

In France, the National Institute of Industrial Property (*Institut National de la Propriété Industrielle, or INPI*) is the main regulatory entity responsible for receiving, examining and deciding on the registry and protection of patents, trademarks and other intellectual property works such as creative rights and designs applications.

A third-party user must obtain consent or a proper license from the owners to use them except for certain specific circumstances provided by law. Otherwise, the use will constitute a counterfeit (i.e. an infringement of these exclusive rights).

Patent

The French Intellectual Property Code provides that an invention is patentable if it is new, inventive, susceptible of industrial application and is not excluded from patentable subject matter.

According to Article L 611-2 of the French Intellectual Property Code, a French patent is valid for a term of 20 years maximum, starting from the application date. Patents remain in force by the payment of annuities. They must be paid no later than the last day of the anniversary month of the application filing. After a maximum period of 20 years, the invention is in the public domain, i.e. it no longer enjoys protection and anyone can exploit it, however a supplementary protection certificate can be issued in very specific circumstances under the terms of Article L 611-3 of the French Intellectual Property Code.

A French patent is obtained through its registration before National Institute of Industrial Property (*Institut National de la Propriété Industrielle, or INPI*) and the application procedure is set out in Articles L 612-1 *et seq* and in Articles R 612-1 *et seq* of the French Intellectual Property Code.

Trademark

According to the French Intellectual Property Code, for a sign to be registered as a trademark, it has to meet the following conditions: it must be licit, distinctive, and available. French Government implemented the Directive (EU) 2015/2436 into the French Intellectual Property Code by the transposition Ordinance of November 13, 2019, published in the Official Journal on November 14, 2019. According to such Ordinance, a sign may be represented “in any appropriate form by means of commonly available technology, and therefore not necessarily by graphic means, provided that such representation offers satisfactory guarantees for this purpose”, with the sole condition that the representation is “clear, precise, distinct, easily accessible, intelligible, durable and objective”.

Therefore, a request for registration may be rejected if the sign is identical or similar to a trademark or a sign pending for registration in the same or similar category of commodities or services.

The ownership of a trademark is obtained through its registration before the French National Institute of Industrial Property and the application procedure is set out in Articles L 712-1 *et seq* of the French Intellectual Property Code.

French trademark registrations are effective for a 10 year period, indefinitely renewable.

Whenever a trademark is subject to transfer or license agreements, to a contribution to a company, or to pledges, these agreements must be published with the French National Institute of Industrial Property.

REGULATORY ENVIRONMENT

Industrial designs

Under the French Intellectual Property Code, industrial designs can be protected by an exclusive right if the two following conditions are met : to be new and to have a specific character. This protection grants to their creator a monopoly over the use of these designs. Indeed, French legislators believed that the appearance of products is of strategic importance for commercial and industrial companies at several levels : distinction from the competition, attraction of the consumers, result of financial and human investments, etc.

When eligible, protection is granted by the French National Institute of Industrial Property for a renewable five-year period starting from the application date, to a maximum of 25 years. However, it is possible to initially request a renewable ten-year period of protection upon filing (in exchange of payment of an additional fee), up to the same maximum period of 25 years.

Trade secrets

In 2018, French legislators implemented in the French Commercial Code (Article L.151-1&seq) a European Union Directive 2016/943 of the European Parliament and of the Council dated June 8, 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

It provides for the protection of information which is not generally known or easily accessible for people in the concerned business or activity, and “*has an actual or potential commercial value because of its secret nature*” and “*is subject to reasonable protective measures by its legitimate holder, taking into account the circumstances, to maintain its secret nature.*” This provision makes it illegal to obtain, use or disclose this information with no agreement of its legitimate holder.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OVERVIEW

We are a leading China-based pharmaceutical company with global business in pharmaceutical, innovative biotech and CDMO sectors.

The history of our Company can be traced back to April 21, 1998 when Shenzhen Hepalink Industrial Development Company Limited (深圳市海普瑞實業發展有限公司), our Company’s predecessor, was established with a registered share capital of RMB2 million, funded primarily by our founders.

The shareholding structure of Shenzhen Hepalink Industrial Development Company Limited as of the date of the establishment was as follows:

<u>Name of the Shareholders</u>	<u>Percentage of shareholding (%)</u>
Mr. Li Li (李鋈)	51.00%
Ms. Li Tan (李坦)	38.00%
Mr. Shan Yu (單宇)	10.00%
Shenzhen Jizao Fiberglass Co., Ltd. (深圳市冀棗玻璃鋼有限公司)	1.00%

Details of the background of our founders, Mr. Li, Ms. Li and Mr. Shan are set out in the section headed “Directors, Supervisors and Senior Management” in this document.

On January 19, 2001, Shenzhen Hepalink Industrial Development Company Limited was renamed as Shenzhen Hepalink Biotechnology Company Limited (深圳市海普瑞生物技術有限公司) and it was further renamed as Shenzhen Hepalink Pharmaceutical Company Limited (深圳市海普瑞藥業有限公司) on September 28, 2002. On December 27, 2007, upon approval by the Ministry of Commerce, it was restructured into a foreign invested joint-stock limited company and was renamed as Shenzhen Hepalink Pharmaceutical Co., Ltd (深圳市海普瑞藥業股份有限公司). The Company was further renamed as Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司) on February 20, 2017. In respect of the conversions, our PRC legal adviser has confirmed that the Company has obtained all the approvals for the restructuring from the relevant authorities and the restructuring complies with the relevant laws and regulations.

Since May 6, 2010, our A Shares have been listed on the Shenzhen Stock Exchange with the stock code of 002399. As of the Latest Practicable Date, our Company had not received any notice from the Shenzhen Stock Exchange alleging any material non-compliance incidents on the part of our Company. Save as otherwise disclosed in this document, the Company confirms that since the date of listing of A Shares on the Shenzhen Stock Exchange, the Company has been operating in compliance with the applicable listing rules of the Shenzhen Stock Exchange in all material respects and there is no matter that should be brought to the attention of the Hong Kong Stock Exchange.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

BUSINESS DEVELOPMENT MILESTONES

The following table shows various milestones in the history of our business development:

- | | |
|------|--|
| 2003 | <ul style="list-style-type: none">● In October, we obtained our first Good Manufacturing Practice (GMP) certificate for Pharmaceutical Products in the PRC for heparin. |
| 2005 | <ul style="list-style-type: none">● In June, our manufacturing facility in Nanshan, Shenzhen, first passed the inspection certified by the FDA in the United States.● In August, we received the first NMPA approval for our LMWH (enoxaparin sodium) product to enter the PRC market. |
| 2007 | <ul style="list-style-type: none">● In September, GS Pharma injected US\$4,917,600 in our Company and our Company was converted into a sino-foreign joint venture company.● In December, our Company was converted into a foreign invested joint-stock limited company and renamed as Shenzhen Hepalink Pharmaceutical Co. Ltd. (深圳市海普瑞藥業股份有限公司). |
| 2008 | <ul style="list-style-type: none">● In February, we obtained our first Certificate of Suitability to the monographs of the European Pharmacopeia (CEP) in Europe for heparin sodium. |
| 2010 | <ul style="list-style-type: none">● In May, our A Shares became listed on the Shenzhen Stock Exchange. |
| 2014 | <ul style="list-style-type: none">● In April, we acquired SPL in the United States, which enabled us to enter into the field of pancreatic enzyme products. |
| 2015 | <ul style="list-style-type: none">● In July, we began investing in Resverlogix in Canada for the research and development of clinical stage cardiovascular drugs.● In October, we acquired Cytovance in the United States to provide CDMO services and other businesses. |
| 2016 | <ul style="list-style-type: none">● In November, we began investing in Kymab Group Limited in the United Kingdom to develop antibiotic drugs in the field of novel human antibody-based therapies in immune diseases. |
| 2018 | <ul style="list-style-type: none">● In February, we began investing in Curemark, LLC in the United States to research and develop drugs for pancreatic enzyme preparations.● In February, we formed a joint venture with Aridis Pharmaceutical Inc., a research and development company in the United States, to promote the development of drugs (AR-301 and AR-101) in the PRC.● In May, we acquired 100% equity interest of Topknow to expand our business operations to include the manufacture and sale of enoxaparin sodium injection. |
| 2019 | <ul style="list-style-type: none">● In July, we obtained NMPA approval for clinical trial of AR-301 in China and began conducting its phase III clinical trial as part of its global MRCT. |

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

MAJOR SHAREHOLDING CHANGE AND INCREASE IN THE SHARE CAPITAL OF OUR COMPANY

1. Share capital injection in November 1998

In November 1998, Mr. Li, Ms. Li, Yuanzheng Investment and Mr. Shan agreed to inject capital in an aggregate amount of RMB18 million to the share capital of Shenzhen Hepalink Industrial Development Company Limited. Upon completion of the capital injection, Mr. Li, Ms. Li, Yuanzheng Investment, and Mr. Shan held 35%, 30%, 30% and 5% of the equity interests of Shenzhen Hepalink Industrial Development Company Limited, respectively and our share capital was increased to RMB20 million.

2. Transfer of equity interests held by our founders to Topknow in November 2000

On November 14, 2000, Mr. Li, Ms. Li and Mr. Shan entered into an equity transfer agreement, pursuant to which each of them transferred their respective 35%, 30% and 5% equity interests in Shenzhen Hepalink Industrial Development Company Limited to Topknow at a consideration of RMB 7 million, RMB 6 million and RMB 1 million, respectively. The consideration was determined with reference to the registered share capital of Shenzhen Hepalink Industrial Development Company Limited. Upon the completion of the equity transfer in December 2000, Topknow and Yuanzheng Investment held 70% and 30% of the equity interest of Shenzhen Hepalink Industrial Development Company Limited, respectively.

3. Transfer of equity interests held by Yuanzheng Investment in June 2007

On June 12, 2007, Yuanzheng Investment, Topknow and Mr. Li entered into an equity transfer investment, pursuant to which Yuanzheng Investment agreed to transfer 18.93% and 4% equity interests of Shenzhen Hepalink Pharmaceutical Company Limited to Topknow and Mr. Li respectively. The consideration was determined after taking into account the Company’s net asset value, term of investment and the profitability of the Company. Upon the completion of the equity transfer in June 2007, Topknow and Mr. Li held 96% and 4% equity interests of Shenzhen Hepalink Pharmaceutical Company Limited, respectively.

4. Transfer of equity interests held by Topknow in August 2007

On August 12, 2007, Topknow entered into an equity transfer agreement, pursuant to which Topknow agreed to transfer 96% equity interest in Shenzhen Hepalink Pharmaceutical Company Limited to: (i) Leren Technology, (ii) Jintiantu, (iii) Shuidi Shichuan and (iv) Feilaishi at a total consideration of RMB 26.8 million. The consideration was determined with reference to the registered share capital of Shenzhen Hepalink Pharmaceutical Company Limited. On the same date, Mr. Li entered an equity transfer agreement to transfer 4% of the equity interest of Shenzhen Hepalink Pharmaceutical Company Limited to Yingshi Information at a consideration of RMB1.12 million. The consideration was determined with reference to the assets appraisal value of Shenzhen Hepalink Pharmaceutical Company Limited. Upon the completion of the above equity transfer in September 2007, Leren Technology, Jintiantu, Shuidi Shichuan, Feilaishi and Yingshi Information held 46.92%, 40.48%, 4.6%, 4% and 4% equity interest in Shenzhen Hepalink Pharmaceutical Company Limited, respectively.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

5. Capital injection by GS Pharma in September 2007

On September 3, 2007, Shenzhen Hepalink Pharmaceutical Company Limited and its then shareholders entered into a share capital increase and shareholding change agreement, pursuant to which GS Pharma agreed to inject US\$4,917,600 to the share capital of Shenzhen Hepalink Pharmaceutical Company Limited. The consideration for the capital injection was determined with reference to then net asset value of Shenzhen Hepalink Pharmaceutical Company Limited. Upon completion of the capital injection by GS Pharma in September 2007, Shenzhen Hepalink Pharmaceutical Company Limited was converted into a sino-foreign joint venture company. Leren Technology, Jintiantu, GS Pharma, Shuidi Shichuan, Feilaishi and Yingshi Information held 41.05%, 35.42%, 12.50%, 4.03%, 3.50% and 3.50% equity interest in Shenzhen Hepalink Pharmaceutical Company Limited, respectively.

6. Restructuring and increase in the share capital in 2007

In December 2007, upon approval by the Ministry of Commerce, Shenzhen Hepalink Pharmaceutical Company Limited was converted into a foreign investment joint-stock limited company with a registered capital of RMB90 million and was renamed as Shenzhen Hepalink Pharmaceutical Co., Ltd (深圳市海普瑞藥業股份有限公司).

7. Increase in the share capital in 2009

In June 2009, upon approval at a shareholders’ general meeting, we further increased our registered capital to RMB360 million through capitalization of capital reserves.

8. A Shares Offering and Listing on the Shenzhen Stock Exchange in 2010

As approved by the CSRC, our Company completed the IPO of our A Shares which were issued at an offer price of RMB148.00 per A Share under the A Share Offering, and our A Shares have been listed on the Shenzhen Stock Exchange under the stock code of 002399 since May 6, 2010. Our Company raised net proceeds of approximately RMB5.7 billion from the A Shares Offering after deducting underwriting commission of approximately RMB218.0 million and offering related expenses. Following completion of our A Shares offering in May 6, 2010, our registered share capital was further increased to RMB400,100,000.

The shareholding structure of our Company immediately after the A Shares Offering was as follows:

<u>Name of the Shareholder</u>	<u>Number of A Shares held</u>	<u>Approximate percentage of Shareholding (%)</u>
Leren Technology	147,780,000	36.94
Jintiantu	127,512,000	31.87
GS Pharma	45,000,000	11.25
Shuidi Shichuan	14,508,000	3.63
Feilaishi	12,600,000	3.15
Yingshi Information	12,600,000	3.15
Other A Shares Shareholders	40,100,000	10.02
Total	400,100,000	100%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

9. Increase in share capital in 2011

In July 2011, upon approval at a shareholders’ general meeting, we increased our registered capital to RMB800,200,000 through capitalization of capital reserves.

10. Reduction in share capital in April 2016

In April 2016, the Company completed the repurchase of 20,698,935 A Shares, pursuant to a shareholders’ resolution dated August 27, 2015 authorizing the Company to repurchase Shares of up to RMB 1 billion, thus our registered capital decreased to RMB779,501,065.

11. Increase in share capital in June 2016

In June 2016, upon approval at a shareholders’ general meeting, we increased our registered capital to RMB1,247,201,704 through capitalization of capital reserves. The shareholding structure of our Company immediately after the increase in share capital up to the Latest Practicable Date was as follows:

<u>Name of the Shareholder</u>	<u>Number of A Shares held</u>	<u>Approximate percentage of Shareholding (%)</u>
Leren Technology	474,029,899	38.01
Jintiantu	408,041,280	32.72
Shuidi Shichuan	46,425,600	3.72
Feilaishi	40,320,000	3.23
Other A Shares Shareholders	278,384,925	22.32
Total	1,247,201,704	100%

MAJOR ACQUISITIONS AND DISPOSALS

Since our establishment, our Group has made strategic investments and acquisitions that are intended to further our strategic objectives. Our Group has also streamlined our business through disposals of certain subsidiaries or equity interests.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Major Acquisitions

The following table sets forth details of our major acquisitions during the Track Record Period:

<u>Date of completion</u>	<u>Equity interests acquired</u>	<u>Principal business activities of the target</u>	<u>Transferor</u>	<u>Amount of consideration</u>
January 2017 through September 2019	Subscription of an aggregate of 8,487,385 Series C shares and 3,500,000 convertible preferred shares of Kymab Group Limited	Research and development of antibiotic drugs in novel human antibody-based therapies in immune diseases	NA	US\$40,000,000
June 2017 through March 2019	Subscription of an aggregate of 68,443,191 shares of Resverlogix	Research and development of clinical stage cardiovascular drugs	NA	CAD89,400,000 and US\$15,000,000
February 2018 through May 2019	Subscription of 144,118 common units of Curemark, LLC	Research and development of drugs for pancreatic enzyme preparations	NA	US\$56,185,000 ⁽¹⁾
May 2018	Acquisition of 100% equity interest in Topknow	Research and development, manufacture and distribution of LMWH pharmaceutical products	Our Controlling Shareholders, Mr. Shan, Shuidi Shichuan and other shareholders of Topknow who are Independent Third Parties	RMB2,400,000,000

Notes:

(1) The amount of consideration comprises a cash consideration of US\$5,000,000 and the provision of pancreatin products and preparation services to Curemark, LLC of US\$51,185,000. For details, please refer to “Note 20. Equity Investments Designated at Fair Value through Other Comprehensive Income” in “Appendix I—Accountants’ Report” in this document.

The consideration of the above acquisitions was determined after arm’s length negotiations among the parties with reference to the valuation of the entities and the past and future earning capacity of the entities. The above transactions have been properly and legally completed and settled and the approvals from the relevant authorities have been obtained.

Further Information in Respect of the Acquisition of Topknow

Topknow is a limited liability company established by Mr. Li, Ms. Li and Mr. Shan in China on June 7, 2000. It is principally engaged in the research and development, manufacture and distribution of heparin pharmaceutical products, in particular Enoxaparin sodium injection products. Topknow has been controlled by Mr. Li and Ms. Li since its incorporation. Pursuant to the equity transfer agreement, our Controlling Shareholders, along with Mr. Shan and Shuidi Shichuan, guaranteed (the “**Profit Guarantee**”) that if Topknow’s net profit falls below RMB190,600,000, RMB286,800,000 and RMB340,800,000, respectively, for the years ended December 31, 2018, 2019 and 2020 (the “**Shortfall**”), each of them shall be jointly and severally liable to compensate our Company up to the amount of consideration they obtained from the acquisition. The Profit Guarantee does not represent

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

the anticipated level of future profits of Topknow and should not be considered in any way as an indication of the projected profit of Topknow or the Company for the relevant years. The payment by the Controlling Shareholders, Mr. Shan and Shuidi Shichuan to compensate the Shortfall (if any) will not constitute a new connected transaction of the Company upon [REDACTED] because it is made pursuant to a pre-existing agreement. Topknow met the net profits for the year ended December 31, 2018. For the year ended December 31, 2019, Topknow is not expected to meet the net profits and, based on the projected profit performance of Topknow as at September 30, 2019, the Company recognized other receivables from the Controlling Shareholders, Mr. Shan and Shuidi Shichuan of RMB248,552,000 with the corresponding entry recognized in other reserves. Accordingly, the expected Shortfall for the year ended December 31, 2019 did not have any impact on the revenue and profits of the Group for the year. For details, please refer to “Consolidated Statement of Changes in Equity” and “Note 46. Related Party Transactions” in “Appendix I—Accountants’ Report” in this document.

As both the Company and Topknow are ultimately controlled by Mr. Li and Ms. Li, the acquisition of Topknow constitutes a business combination under common control. Accordingly, the consolidated financial statements of the Company were prepared as if Topknow had been combined throughout the Track Record Period. For details, please refer to “Note 40. Business Combination” in “Appendix I—Accountants’ Report” in this document.

Major Disposal

The following table sets forth details of our major disposal during the Track Record Period:

<u>Date of completion</u>	<u>Equity interests disposed</u>	<u>Principal business activities of the target</u>	<u>Transferee</u>	<u>Amount of consideration</u>
June 2018	85% equity interest in Hepatunn	Manufacture, sales, import and export of injections and creams	Pangu Chenchen (Shanghai) Enterprise Management Center (Limited Partnership), an Independent Third Party	RMB34,000,000

The consideration of the above disposal was determined after arm’s length negotiations among the parties with reference to the Company’s investment amount in Hepatunn. The above transaction has been properly and legally completed and settled and the approvals from the relevant authorities have been obtained.

Deconsolidation of HighTide

HighTide is a limited liability company incorporated in the Cayman Islands on June 9, 2015 and is principally engaged in the research and development of pharmaceutical products. The Group previously held 53.81% equity interest in HighTide. On March 25, 2019, the Company’s share percentage in HighTide which was a former subsidiary of the Company was diluted from 53.81% to 48.74% as a result of the addition of new shareholders. As a result, the Group had lost control over HighTide. The fair value of the remaining 48.74% equity interest of HighTide held by the Group after the deemed disposal was RMB626,706,000 and a remeasurement gain of fair value of RMB573,865,000 was recorded. On August 12, 2019, the Group’s equity interests in HighTide was further diluted to 47.02%. For details, please refer to “Note 18. Investments in Associates” in “Appendix I—Accountants’ Report” in this document.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR PRINCIPAL SUBSIDIARIES

The following chart sets out the detailed information of our principal subsidiaries as of the Latest Practicable Date.

No.	Name of subsidiaries	Place of incorporation	Date of incorporation	Registered/Issued capital	Shareholding of our Company	Main scope of business
1.	Shenzhen Techdow	PRC	June 29, 2004	RMB150,000,000	100%	Production and sales of enoxaparin sodium injection
2.	Shandong Ruisheng	PRC	July 15, 2010	RMB30,000,000	100%	Production and sales of crude heparin
3.	Topknow	PRC	June 7, 2000	RMB230,000,000	100%	Research and development, manufacture and distribution of heparin pharmaceutical products
4.	Hepalink (Hong Kong)	Hong Kong	November 23, 2010	HK\$330,221,445	100%	Trading and import & export
5.	Techdow (Hong Kong)	Hong Kong	May 22, 2013	HK\$233,960,000	100%	Trading and import & export
6.	Hepalink USA	USA	October 25, 2013	10,000 shares	100%	Investment holding
7.	SPL	USA	July 13, 2006	500,000 shares	100%	Investment holding
8.	Scientific Protein Laboratories	USA	January 22, 2004	1,000 shares	100%	Manufacture of heparin and pancreatin API
9.	Mobren Transport	USA	December 23, 1997	1,000 shares	100%	Manufacture of heparin (eluate)
10.	Cytovance	USA	March 11, 2011	1,806,885 shares	100%	CDMO services

Detailed information of our other subsidiaries is set out in “Note 1. Corporate Information” in “Appendix I—Accountants’ Report” in this document.

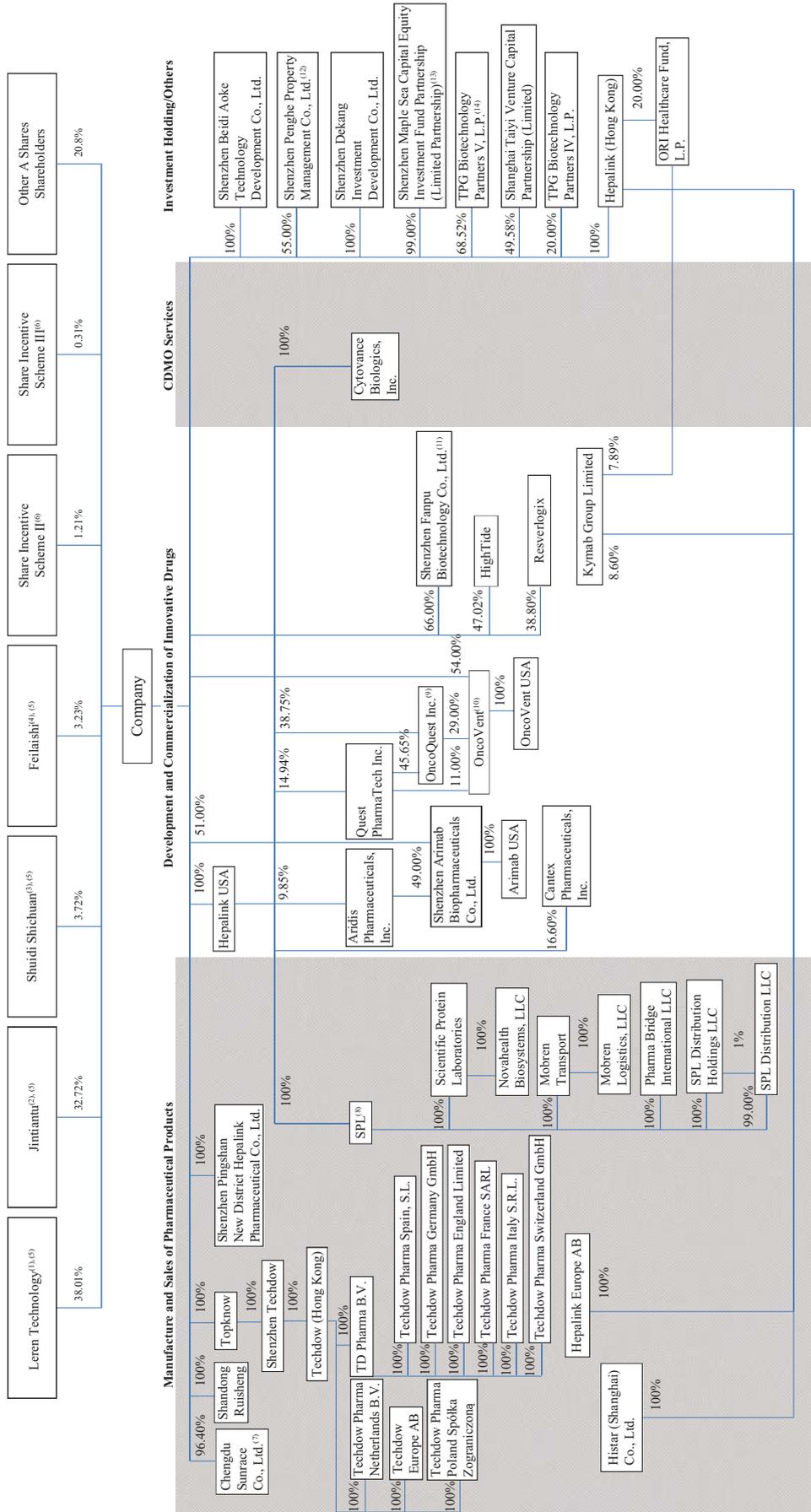
REASONS FOR THE [REDACTED]

Our Company is seeking a [REDACTED] on the Hong Kong Stock Exchange in order to raise further capital for the development and expansion of our Company’s business, and to further raise our profile as a business with a global presence and thus, enhance our ability to attract new customers, business partners, strategic investors and key management personnel.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

SHAREHOLDING STRUCTURE PRIOR TO THE [REDACTED]

The following chart sets forth our simplified shareholding structure, subsidiaries and principal investee companies immediately before the [REDACTED]:



Notes:

(1) Leren Technology is owned as to 99.00% by Mr. Li and 1.00% by Ms. Li, respectively.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (2) Jintiantu is owned as to 99.00% by Ms. Li as a general partner and 1% by Mr. Li as a limited partner, respectively.
- (3) Shuidi Shichuan is owned as to 99.00% by Mr. Shan and 1.00% by Ms. Li, respectively.
- (4) Mr. Li is the sole owner of Feilaishi.
- (5) Mr. Li and Ms. Li are the spouse of each other and Mr. Shan is the brother of Ms. Li.
- (6) Guolian Securities Co., Ltd. and CMS Asset Management Co., Ltd. hold A Shares as asset managers for the benefit of the participants of the Share Incentive Schemes II and III, respectively. For further details on the Schemes, see “Appendix VI—Statutory and General Information”.
- (7) The remaining 3.60% in Chengtu Sunrace Co., Ltd. is held by Mr. Lu Wenxing, an Independent Third Party.
- (8) SPL engages primarily in the manufacture and sale of pharmaceutical products. It also provides CDMO services on top of its primary business. For details, see “Business—Our CDMO Business”.
- (9) The remaining 15.60% in OncoQuest Inc. is held by Synergy Alpha Investment Fund as to 6.00% and other private investors as to less than 5% each, all of which are Independent Third Parties.
- (10) The remaining 6.00% equity interest in OncoVent is held by Dierepharma HK Limited, an Independent Third Party.
- (11) The remaining 34.00% in Shenzhen Fanpu Biotechnology Co., Ltd. is held by Mr. Zhou Hongwei and Mr. He Yan as to 30.30% and 3.70%, respectively, both of which are Independent Third Parties.
- (12) The remaining 45.00% in Shenzhen Penghe Property Management Co., Ltd. is held by Yulong Computer Communication Technology (Shenzhen) Co., Ltd. and Shenzhen Xizhilang Food R&D Center Co., Ltd. as to 35.00% and 10.00%, respectively, both of which are Independent Third Parties.
- (13) The remaining 1.00% in Shenzhen Maple Sea Capital Equity Investment Fund Partnership (Limited Partnership) is held by Beijing Maple Sea Capital Management Center (Limited Partnership), which is owned as to 25.00% by our wholly-owned subsidiary, Shenzhen Dekang Investment Development Co., Ltd.
- (14) Our Company holds 68.52% in TPG Biotechnology Partners V, L.P. as a limited partner. The remaining 31.48% is held by Independent Third Parties as to less than 10% each.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (2) Jintiantu is owned as to 99.00% by Ms. Li as a general partner and 1.00% by Mr. Li as a limited partner, respectively.
- (3) Shuidi Shichuan is owned as to 99% by Mr. Shan and 1% by Ms. Li, respectively.
- (4) Mr. Li is the sole owner of Feilaishi.
- (5) Mr. Li and Ms. Li are the spouse of each other and Mr. Shan is the brother of Ms. Li.
- (6) Guolian Securities Co., Ltd. and CMS Asset Management Co., Ltd. hold A Shares as asset managers for the benefit of the participants of the Share Incentive Schemes II and III, respectively. For further details on the Schemes, see “Appendix VI—Statutory and General Information”.
- (7) The remaining 3.60% in Chengtu Sunrace Co., Ltd. is held by Mr. Lu Wenxing, an Independent Third Party.
- (8) SPL engages primarily in the manufacture and sale of pharmaceutical products. It also provides CDMO services on top of its primary business. For details, see “Business—Our CDMO Business”.
- (9) The remaining 15.60% in OncoQuest Inc. is held by Synergy Alpha Investment Fund as to 6.00% and other private investors as to less than 5% each, all of which are Independent Third Parties.
- (10) The remaining 6.00% equity interest in OncoVent is held by Dierepharma HK Limited, an Independent Third Party.
- (11) The remaining 34.00% in Shenzhen Fanpu Biotechnology Co., Ltd. is held by Mr. Zhou Hongwei and Mr. He Yan as to 30.30% and 3.70%, respectively, both of which are Independent Third Parties.
- (12) The remaining 45.00% in Shenzhen Penghe Property Management Co., Ltd. is held by Yulong Computer Communication Technology (Shenzhen) Co., Ltd. and Shenzhen Xizhilang Food R&D Center Co., Ltd. as to 35.00% and 10.00%, respectively, both of which are Independent Third Parties.
- (13) The remaining 1% in Shenzhen Maple Sea Capital Equity Investment Fund Partnership (Limited Partnership) is held by Beijing Maple Sea Capital Management Center (Limited Partnership), which is owned as to 25% by our wholly-owned subsidiary, Shenzhen Dekang Investment Development Co., Ltd.
- (14) Our Company holds 68.52% in TPG Biotechnology Partners V, L.P. as a limited partner. The remaining 31.48% is held by Independent Third Parties as to less than 10% each.

BUSINESS

Overview

Driven by our innovations across the industry value chain, our mission is to become a leading global pharmaceutical company targeting high-mortality diseases with significant unmet medical needs.

We are a leading China-based pharmaceutical company with global business in pharmaceutical, innovative biotech and CDMO sectors. We ranked the first by both export value and export volume of injectable finished doses in 2018 among China-based pharmaceutical companies, with major sales into the EU market.

Founded by a group of seasoned polysaccharide-chemists with scientific insights and profound understanding of immunology, we have built up a portfolio of both leading drugs in the anticoagulant and antithrombotic therapeutic areas and innovative drug candidates focusing on diseases with an immune system disorder axis, including oncology, autoimmune, metabolic and other areas. These diseases are among the largest unmet medical needs globally and represent the leading causes of morbidity and mortality.

Our leading drugs, Inhixa, Neoparin and Prolongin are three different brands of enoxaparin sodium injection which in total have been approved in 36 countries and sold in 15 countries. We have also supplied enoxaparin sodium injection to our customers in 13 other countries. We are the only China-based pharmaceutical company with cumulative sales of enoxaparin sodium injections in the EU exceeding 100 million doses. Enoxaparin is the “gold standard” anticoagulant and antithrombotic drug for various indications, such as venous thromboembolism (VTE) and pulmonary embolism (PE), with huge market demands and significant growth potential. According to Frost & Sullivan, the global usage of enoxaparin exceeded 763.2 million syringes/vials in 2018, and is expected to reach 1,444.3 million syringes/vials in 2024. Its usage in China was 41.9 million syringes/vials in 2018, which is expected to increase at a CAGR of 47.5% to 431.7 million syringes/vials in 2024.

We are the largest China-based and fourth largest global manufacturer and marketer of enoxaparin sodium injection, with a global market share of 5.4%, based on 2018 worldwide sales according to Frost & Sullivan. In China we are the second largest supplier in the enoxaparin injection market with a market share of 11.3%, second only to the originator firm, according to Frost & Sullivan. We implement localized and differentiated marketing strategies in the three major enoxaparin markets, the EU, China and the U.S. Our marketing strategies incorporate a combination of direct sales, distributor network and supply agreement partnerships. Our effective marketing efforts have resulted in rapid growth of our enoxaparin injection sales. In the EU, sales volume of our enoxaparin sodium injection grew by 164% to 47.8 million syringes/vials in 2018 from 18.1 million syringes/vials in 2017, and grew by 105% to 60.2 million syringes/vials in the nine months ended September 30, 2019 from 29.4 million syringes/vials in the nine months ended September 30, 2018. In China, sales volume of our enoxaparin sodium injection grew by 81% to 5.8 million syringes/vials in 2018 from 3.2 million syringes/vials in 2017, and grew by 28% to 4.1 million syringes/vials in the nine months ended September 30, 2019 from 3.2 million syringes/vials in the nine months ended September 30, 2018. We expect our Prolongin to be the first enoxaparin approved based on Quality Consistency Evaluation (QCE) in China, further solidifying our competitive advantage to capture the fast growth of enoxaparin in the China market.

We are the largest provider of heparin API with a global market share of 40.7%, larger than the second and third market players combined, based on 2018 global revenue according to Frost &

BUSINESS

Sullivan. We also have exclusive access to over 50% of the traceable heparin raw materials in China and over 40% in the U.S. in 2018, which ensures sufficient supply of high quality heparin raw materials. With 90.8% of our revenue generated from markets outside PRC in 2018, we are continuously expanding our strong global footprint to additional overseas markets, such as Southeast Asia, Middle East and South America.

We have established a fully integrated business model covering the heparin industry value chain from supply of raw materials, manufacturing of APIs to the sales of enoxaparin finished doses. Based on such unique business model, we have developed our state-of-the-art supply chain management and world-class facilities with proprietary manufacturing technologies, rigorous quality control standards and large-scale manufacture capability. Through our integrated supply chain management, we have access to a significant portion of the traceable crude heparin globally, which ensures safety, reliability and stability for the supply of our heparin raw materials. Our manufacturing processes and facilities comply with the CGMP requirements in the EU, the U.S. and China, and follow rigorous manufacturing and quality control standards. We have accumulated extensive manufacturing expertise and know-how including our proprietary extraction, purification and virus and bacteria inactivation technologies, which we believe will further solidify our long-term competitiveness in the global enoxaparin market. We are one of the few China-based pharmaceutical companies which are able to produce commercialized biological drugs on a large scale. Our world-leading facilities enable us to efficiently manufacture biopharmaceutical products in large volumes while consistently ensure high quality. We believe our unique business model together with state-of-the-art supply chain management and world-class facilities serve as the cornerstones of our leading position in the global enoxaparin market.

Based on our profound understanding of immune response mechanisms, we have strategically constructed a robust portfolio of both exclusive development and commercial rights in Greater China for first-in-class clinical stage drug candidates and self-developed first-in-class drug candidate. These pipeline drugs are being developed to address the significant unmet medical demands in oncology, cardiovascular, inflammation and autoimmune areas. We place great importance in nurturing our partners and provide strong support to them in various areas including clinical development through our CDMO platform and equity investment. For example, Oregovomab, an immune-oncology antibody candidate being developed for first-line treatment of ovarian cancer in combination with chemotherapy, has shown a significant prolongation of median progression-free survival (median PFS 41.8 months vs. 12.2 months in patients treated by chemo-alone, $p=0.0027$) in a phase II trial. It also showed a significant improvement in overall survival (OS) ($p=0.0043$). We own 38.74% equity interest in the developer company of Oregovomab as well as its exclusive development and commercial rights in Greater China.

BUSINESS

As of the Latest Practicable Date, we have exclusive development and commercial rights in Greater China for five drug candidates, among which two are in phase III global clinical trials and two are in phase II global trials. We are also developing a self-discovered proprietary oncology drug candidate currently at preclinical stage. We believe we are able to leverage our manufacturing, marketing and distribution capabilities of enoxaparin and industry experience to successfully develop and commercialize our innovative drug pipeline. The following chart summarizes the development status of our pipeline drugs as of the Latest Practicable Date:

Drug Candidate	Target / Mechanism of Action	Indications	Partner Company	Hepalink Shareholding	Development and Commercial Rights Owned by (Regions)	IND	Ph1	Ph2	Ph3	MRCT ¹ Participated by Hepalink
Oregovomab	Immunological stimulation after binding to CA125 antigen	Primary late-stage ovarian cancer	OncoQuest	38.74%	OncoVent ² (Greater China)					☆
		Recurrent late-stage ovarian cancer (Oregovomab+Hiltonol)								☆
		Recurrent late-stage ovarian cancer (Oregovomab+PD-1 Inhibitor nivolumab)								☆
		Recurrent late-stage ovarian cancer (Oregovomab+PARP Inhibitor niraparib)								☆
mAb-AR20.5	Immunological stimulation after binding to MUC1 antigen	Pancreatic cancer								☆
AR-301	α-toxin released by Gram-positive staphylococcus aureus	Staphylococcus aureus pneumonia	Aridis	9.86%	Shenzhen Arimab ³ (Greater China)					★
AR-101	Gram-negative pseudomonas aeruginosa O11 serum	Pseudomonas aeruginosa pneumonia								☆
RVX-208	BD2 domain of BET family member	Type 2 diabetes with coronary heart disease	Resverlogix	38.80%	Hepalink (Greater China)					
		Chronic Kidney Disease								
		New Indication								☆
H1710	Heparanase (HPA)	Pancreatic cancer	Hepalink (In-house)	100%	Hepalink (Global)					

 Hepalink initiated the trials
 The companies Hepalink invested initiated the clinical trials
 The company Hepalink invested plans to initiate the clinical trials for new indication based on the ph3 clinical data of Type 2 diabetes with coronary heart disease
 Hepalink has initiated the China portion MRCT¹
 Hepalink plans to initiate the respective China portion MRCTs¹ once entered pivotal phase

¹ MRCT refers to multi-regional clinical trials, which involves more than one independent center in enrolling and following clinical trial participants. It is widely conducted by many global pharmaceutical companies to reduce the time lag of launching innovative drugs in different regions.
² We directly hold 54.00% equity interest in OncoVent and are entitled to additional economic interest through our investee companies which hold 40.00% of its equity interest in total.
³ We directly hold 51.00% equity interest in Shenzhen Arimab and are entitled to additional economic interest through our investee company which holds the remaining 49.00% of its equity interest.

We operate a fast-growing CDMO business through two platforms, Cytovance, a CDMO platform enabling the development and manufacture of recombinant pharmaceutical products and critical non-viral vectors and intermediates for gene therapy, and SPL, a CDMO platform enabling the development and manufacture of pharmaceutical products from natural sources, to capture the growth opportunities in the global biopharmaceutical sector. Our CDMO business ranks among the top three China-owned biologics CDMO operators based on 2018 revenue according to Frost & Sullivan. Our CDMO revenue grew by 66.8% from RMB325.6 million in 2017 to RMB543.2 million in 2018 and grew by 41.5% from RMB353.0 million for the first nine months in 2018 to RMB499.6 million for the first nine months in 2019. Our customer base ranges from multinational pharmaceutical giants to midsize, small and virtual biotech companies. With continuous investments in capabilities, capacity and innovation, the dual CDMO platform addresses diverse customer needs while leveraging over 45 years of combined experience of Cytovance and SPL in the development and manufacture of large molecule pharmaceutical products for innovative biologically based therapeutics. In addition to supporting a multitude of customer drug pipelines, our own product pipeline is aptly enabled and enhanced by the dual CDMO platform strategy. By addressing the capacity shortage and technological challenge in the CMC process, our CDMO platform empowers our customers to develop drugs from concept to commercial manufacturing stage and ensures CDMO capacities for the development of our own pipeline drugs. Benefiting from the global growth in the biopharmaceutical sector, our CDMO

BUSINESS

business has contributed to our rapid growth and diversified our revenue source. As of the Latest Practicable Date, we had 39 on-going projects and a backlog of US\$62.1 million, which represents the total amount of contracted service fees pending milestone delivery. The following table shows the status of our on-going projects as of the Latest Practicable Date:

Biologics development stage	Number of on-going projects
Pre-IND	
—Drug discovery	2
—Preclinical development	10
Clinical trial	
—Early-phase (phase I & II) clinical development	20
—Late-phase (phase III) clinical development	4
Commercial manufacturing	<u>3</u>
Total	<u><u>39</u></u>

Our revenue increased by 69.7%, from RMB2,828.2 million in 2017 to RMB4,799.8 million in 2018, and decreased by 5.3%, from RMB3,306.7 million for the nine months ended September 30, 2018 to RMB3,132.2 million for the nine months ended September 30, 2019. Our net profit increased by 156.1% from RMB240.9 million in 2017 to RMB617.0 million in 2018, and increased by 59.6% from RMB469.4 million for the nine months ended September 30, 2018 to RMB749.0 million for the nine months ended September 30, 2019.

Our Strengths

We believe the following strengths have contributed to our success and differentiated us from our competitors:

Strategic focus on attractive therapeutic areas with both commercialized drugs of significant growth potential and first-in-class pipeline drugs

We are founded and led by a group of seasoned polysaccharide-chemists with a strategic focus on heparin to address coagulation and thrombosis that cause life-threatening conditions. Through two decades of research, we have also accumulated profound understanding of the immune response mechanisms and engaged in the development of innovative drug candidates for fatal diseases with an immune system disorder axis. Our portfolio includes both commercialized drugs and first-in-class pipeline drugs, which provides us with stable cash flow as well as significant growth potential.

- Enoxaparin. Our own branded enoxaparin sodium injections (Inhixa, Neoparin and Prolongin) have been approved in 36 countries and sold in 15 countries globally with Neoparin targeting Poland, Inhixa targeting the EU market other than Poland and Prolongin targeting China and other emerging markets. We have also supplied enoxaparin sodium injection to our customers in 13 other countries. We had cumulative sales of enoxaparin sodium injections in the EU exceeding 100 million doses since 2016. Enoxaparin is the “gold standard” anticoagulant and antithrombotic drug with huge market demands and significant growth potential. According to Frost & Sullivan, the global market size of enoxaparin was US\$2,733.5 million in 2018, which is expected to increase

BUSINESS

to US\$5,670.0 million in 2024, and the global usage of enoxaparin exceeded 763.2 million syringes/vials in 2018, which is expected to reach 1,444.3 million syringes/vials in 2024.

- Six first-in-class drug candidates. Our drug candidates are being developed to treat diseases with a weak immune system axis (such as oncology and bacterial inflammation) and diseases with an overactive immune system axis (such as cardiovascular disease, non-infectious inflammation and autoimmune diseases). As of the Latest Practicable Date, we have obtained the clinical development and commercial rights of five of these drug candidates in the Greater China. Two of these drug candidates are in phase III clinical trials and two of them are in phase II clinical trials. We are also developing a self-discovered propriety oncology drug candidate currently at preclinical stage.

“Gold standard” anticoagulant and antithrombotic drug with outstanding safety profile

Our leading drugs, Inhixa, Neoparin and Prolongin (enoxaparin sodium injections), are the “gold standard” anticoagulant and antithrombotic drug for various indications, such as VTE and PE, with significant growth potential. Enoxaparin, as an anticoagulant and antithrombotic drug, has been vital in preventing and treating life-threatening conditions caused by coagulation and thrombosis, such as stroke, heart attack and PE. Compared with other general anticoagulant drugs, due to its glycosylated polysaccharide structure, enoxaparin cannot be synthesized *in vitro* at least in the short term, and is neither completely replaceable nor replicable.

Enoxaparin, a type of LMWH, is expected to gradually replace other LMWH drugs. Compared with other LMWH drugs, enoxaparin has wider range of approved indications, more comprehensive delivery routes, longer elimination half-life, higher bioavailability and better anti-Xa and anti-IIa activity ratios. Guidelines published by ACCF/AHA recommend the usage of enoxaparin over other anticoagulant and antithrombotic drugs for the treatment of myocardial infarction. The World Health Organization (WHO) incorporates enoxaparin in the list of essential medicines, highlighting its importance in the anticoagulant and antithrombotic areas and its application as a first option of standard antithrombotic therapy in routine practice in many settings.

Enoxaparin enjoys huge market demand and significant growth potential. According to Frost & Sullivan, the global usage of enoxaparin exceeded 763.2 million syringes/vials in 2018, and is expected to reach 1,444.3 million syringes/vials in 2024. Its usage in China was 41.9 million syringes/vials in 2018, and is expected to increase at a CAGR of 47.5% to 431.7 million syringes/vials in 2024.

We believe we will benefit from such significant market opportunities by virtue of the outstanding safety profile of our enoxaparin drugs. The outstanding safety profile of our enoxaparin products is demonstrated by its low pharmacovigilance (PV) rate, low batch-to-batch variation, high biological purity (anti-Xa and anti-IIa activity ratio) and high purity level. In 2019, among the 3,042 PV cases reported on the EMA PV system (EudraVigilance), only 139 cases, or 4.57%, were related to our enoxaparin drugs, while we sold 85.5 million syringes/vials of enoxaparin in the EU in 2019, accounting for 18.0% of the total enoxaparin doses sold in the EU in the same year. Our enoxaparin drugs also demonstrated lower batch-to-batch variation as compared to the originator brand drugs. Percentages of impurities, such as galacturonic acid and sulfate in our enoxaparin sodium product are lower than the originator brand or pharmacopeia standards.

BUSINESS

Fully integrated business model to enhance profitability

We have a fully integrated business model covering the heparin industry value chain from supply of raw materials, manufacturing of APIs to the sales of enoxaparin finished doses. Such unique business model together with state-of-the-art supply chain management, proprietary manufacturing technologies, rigorous quality control standards and large-scale manufacture capability serve as the cornerstones of our leading position in the global enoxaparin market and allow us to secure sufficient supply of high quality raw materials, improve cost efficiency and enhance profitability.

- *State-of-the-art supply chain management:* To ensure sufficient supply of the key heparin raw material, crude heparin, we have built our own crude heparin factories in China and the U.S. The state-of-the-art supply chain network guarantees us exclusive access to over 50% of the traceable heparin raw materials in China and over 40% in the U.S. by volume of the traceable heparin raw materials in 2018. Our state-of-the-art integrated supply chain management ensures safety, reliability, stability and quality for the supply of our heparin raw materials. Our outstanding supply chain management has helped us to establish our leading position in the global heparin industry during the Baxter Incident. In 2008, contamination in the heparin sodium API used in the heparin sodium injections sold by Baxter caused serious acute hypersensitivity reactions in patients. The FDA later confirmed that the heparin sodium API supplied by us did not cause any single event of severe allergic reaction, which made us one of the few major heparin sodium API suppliers unaffected by the Baxter Incident in the U.S. market.
- *Proprietary manufacturing technologies and rigorous quality control:* Our proprietary manufacturing technologies ensure the best-in-class quality of our products. Based on years of experience in manufacturing heparin products, we have developed leading manufacturing technologies and know-how, such as purification technology, virus and bacteria inactivation technology, structural integrity protection and activity release technology and directed compound separation technology. Our leading technologies enable us to effectively preserve the structural integrity and molecular activity to the highest degree while minimize the impurity level of our enoxaparin sodium API. The design of our manufacturing system is rooted in our pursuit for the best-in-class quality standards. Our manufacturing processes and facilities not only comply with the CGMP requirements in the EU, the U.S. and China, but also follow comprehensive and rigorous quality control standards which cover every step of the manufacturing process. Such high quality control standards ensure the outstanding safety profile of our products, which has been proven by our long-term relationships with leading pharmaceutical giants, such as Sanofi.
- *Scaled production capability:* We are one of the few China-based pharmaceutical companies which are able to produce commercialized biological drugs on a large scale. We have state-of-the-art manufacturing facilities in China and the U.S. As of the Latest Practicable Date, with respect to heparin sodium API, we have an annual production capacity of 10,000,000 mega in China and 3,000,000 mega in the U.S. With respect to enoxaparin sodium API, we have an annual production capacity of 33,350 kg in China. With respect to enoxaparin sodium injection, we have an annual production capacity of 240 million pre-filled syringes, and 80 million vials. Our large-scale manufacturing capability ensures us to meet the huge market demand and capture the significant growth potential of enoxaparin as well as achieve economics of scale.

BUSINESS

We believe our fully integrated business model differentiates us from our competitors and gives us competitive advantages. It ensures sufficient supply of high quality raw materials and enhances our risk resistance profile with respect to price fluctuations and shortage of raw materials. It also improves cost efficiency as it allows us to have better control of the costs on each step throughout the operations of our heparin business and gives us flexibility in making price adjustments for our products in order to enhance our sales. Our powerful supply chain management and cost control capabilities, together with our large-scale manufacturing capability will support our high-volume sales of enoxaparin to capture the huge market demand for enoxaparin globally and continue our growth in enoxaparin business.

Well positioned to be the global leader in the enoxaparin market with effective marketing strategies in the major markets worldwide

We keep abreast of the latest market developments and implement localized and differentiated marketing strategies in the three major enoxaparin markets, the EU, China and the U.S., based on various factors including market size, growth potential, competition and regulatory environment in those markets. We believe we are well positioned to become the leader in the global enoxaparin market by implementing such effective and diversified marketing strategies.

- EU: As the largest enoxaparin market globally, EU consumed 486.7 million syringes/vials of enoxaparin out of 763.2 million syringes/vials consumed globally in 2018, and total sales of enoxaparin in the EU (including both originator brand and biosimilar drugs) was US\$1,691.8 million in 2018 and is expected to reach US\$3,142.3 million in 2024, according to Frost & Sullivan. In the EU, as the first approved enoxaparin biosimilar drug, Inhixa has been commercialized in more than nine EU countries including the top six enoxaparin country markets in the EU with the largest market share in the UK and leading market positions in Italy and Austria. In addition, Neoparin has the largest market share in Poland by sales in 2019. Our total sales volume of enoxaparin in the EU reached 85.5 million syringes/vials in 2019, accounting for 18.0% of market share in the EU. As a biosimilar drug, prescription of enoxaparin is based on brand name. To promote our brand name and product awareness, we have established a dedicated in-house sales team in the EU. We also engage distributors and third party promoters to expand our distribution network in various EU countries. As a pioneer in the EU enoxaparin biosimilars market, we believe we have established a strong brand name among leading hospitals and medical professionals.
- China: China enjoys one of the most rapid growth rates for enoxaparin sales globally. Total sales of enoxaparin in China reached US\$260.6 million in 2018, representing a CAGR of 26.2% from 2014 to 2018, and is expected to reach US\$947.1 million by 2024 according to Frost & Sullivan. The per capita use of enoxaparin in China was 0.03 dose while the per capita use was 0.95 dose in the EU in 2018, indicating significant growth potential in China. To further regulate the enoxaparin market and strengthen quality control in China, the NMPA is expected to implement an approval regime for injectable pharmaceuticals based on QCE in 2020. We believe after the QCE approval regime becomes effective, enoxaparin products that pass the QCE will gradually replace the low quality LMWH in the market that cannot pass the QCE. To capture the fast growth of enoxaparin market in China, we plan to further promote our current enoxaparin brand Prolongin after it obtains QCE approval. We submitted application for QCE approval of Prolongin to the NMPA in April 2018 and we believe Prolongin will be the first QCE-approved enoxaparin in China.

BUSINESS

- U.S.: U.S. represents a significant enoxaparin market. According to Frost & Sullivan, total sales of enoxaparin in the U.S. is expected to increase from US\$464.6 million in 2018 to US\$931.7 million in 2024, representing a CAGR of 12.3%. In the U.S., as a generic drug, prescription of enoxaparin is based on the generic name. Large scale supply and manufacturing capability is key to capture the significant market demand in the U.S. To take advantage of this market opportunity. We have submitted an ANDA for our enoxaparin sodium injection, which is currently under review by the FDA. In the meantime, we have a supply arrangement with a multinational pharmaceutical company to be its major supplier of enoxaparin sodium injections once launched in the U.S..

A robust portfolio of first-in-class clinical stage drug candidates for the China market

We have obtained exclusive development and commercial rights in Greater China for five pipeline drugs, among which two are currently in phase III clinical trials and two are in phase II clinical trials. Below are our late clinical stage drug candidates:

- Oregovomab: Oregovomab, an anti-idiotypic murine monoclonal antibody, is an anti-CA125 immunotherapy drug candidate that is being developed by OncoQuest, in which we hold a 38.74% equity interest. It has completed a phase II clinical trial as a first-line treatment combined with chemotherapy in patients with advanced primary ovarian cancer. Phase II clinical trial have proven the safety and efficacy of Oregovomab in such combined treatment regime for advanced primary ovarian cancer patients. The combination of Oregovomab and chemotherapy leverages the effects of chemotherapy without additional toxicity. Phase II clinical results have shown a significant prolongation of median PFS, with a median PFS of 41.8 months, compared with 12.2 months in patients treated by chemotherapy alone ($p=0.0027$). It also showed a significant improvement in OS ($p=0.0043$). OncoQuest is currently in discussion with the FDA regarding a phase III trial plan. We plan to participate in the phase III MRCT of Oregovomab for such combined treatment. Oregovomab has Orphan Drug Designation from the FDA and EMA. Oregovomab is also being evaluated in a phase II clinical trial in combination with an investigational stage immune booster (poly ICLC / Hiltonol) for patients with advanced recurrent ovarian cancer, a phase Ib/IIa clinical trial in combination with PD-1 inhibitor (nivolumab) as a novel combinational immunotherapy treatment for patients with recurrent ovarian cancer, and a phase II clinical trial as a combined treatment with a PARP inhibitor (niraparib) for patients with recurrent ovarian cancer.
- AR-301 (Salvecin): AR-301 is a fully human monoclonal IgG1 antibody (mAb) that specifically targets *S. aureus* alpha-toxin. It is being developed by Aridis (NASDAQ: ARDS) in which we hold a 9.86% equity interest. It is currently being evaluated in a global phase III clinical study as an adjunctive therapy to standard of care antibiotics in patients diagnosed with ventilator associated pneumonia (VAP) caused by *S. aureus*. Results of a Phase I/II trial have shown that patients treated with AR-301 consistently demonstrated less time spent under mechanical ventilation and higher rates of *S. aureus* eradication as compared to those treated with antibiotics alone. AR-301 was granted Fast Track Designation by the FDA and Orphan Drug Designation by the EMA. We are conducting a phase III clinical trial in China as part of the global MRCT of AR-301.
- RVX-208 (Apabetalone): RVX-208 is an inhibitor of BET transcriptional regulators with selectivity for the second bromodomain. RVX-208 has completed phase III clinical trial

BUSINESS

(BETonMACE) in combination with standard of care to reduce major adverse cardiovascular events among high-risk cardiovascular disease patients with type 2 diabetes mellitus, recent acute coronary syndrome, and low levels of high-density lipoprotein (HDL). It is being developed by Resverlogix (TSE: RVX) in which we held a 38.80% equity interest as of the Latest Practicable Date.

We believe we are able to leverage our industry experience and proven execution capabilities to develop and commercialize these late-stage product candidates in the China market.

A fast-growing CDMO business focusing on a vast spectrum of recombinant and naturally derived large molecule and gene therapy products

We operate a rapidly-growing CDMO business to capture the global growth opportunities in the biopharmaceutical sector and support the clinical development of our pipeline drugs. Our CDMO business ranked among the top three China-owned biologics CDMO operators based on 2018 revenue according to Frost & Sullivan. We offer comprehensive, integrated and highly customizable end-to-end CMC services, including R&D services, manufacturing services, quality assurance, and program management in our state-of-the-art laboratories and CGMP-compliant manufacturing facilities. Through combining the capabilities of our two platforms, Cytovance and SPL, our CDMO business enables the development and manufacture of a wide range of products including naturally derived and recombinant large molecule products and critical non-viral vectors and intermediates for gene therapy, which makes us distinct within the global CDMO industry.

Cytovance is a biopharmaceutical contract manufacturing company specializing in the development and manufacture of recombinant biologic pharmaceuticals from mammalian cell culture and microbial fermentation, and non-viral vectors and intermediates for gene therapy. Cytovance entered the gene therapy sector by developing an innovative platform in October 2019 for critical reagent grade pDNA manufacturing, in order to meet the huge market demand for high-quality pDNA. Cytovance has enabled successful clinical and company milestones for dozens of customers through its CMC services. As a testament to value created by our CDMO platform, several of Cytovance’s customers were acquired by large pharmaceutical companies, such as Synageva BioPharma Corp. which was purchased by Alexion Pharmaceuticals, Inc. in 2015, Selexys Pharmaceuticals Corporation which was purchased by Novartis International AG in 2016, ARMO Biosciences, Inc. which was purchased by Eli Lilly and Company in 2018 and Synthorx Inc which was purchased by Sanofi in 2019.

SPL offers a broad spectrum of capabilities in the extraction, isolation and purification of naturally derived pharmaceuticals and extensive expertise in regulatory compliance. Moreover, SPL is able to provide services at scales ranging from laboratory development to CGMP suite production and further to metric-ton, full-scale commercial production.

The breadth of our CDMO services and our on-going innovation to focus on unmet market demands allow us to capitalize on the opportunities offered by different segments of the global biologics outsourcing services market. Our CDMO services address the capacity shortage and technological challenge in the CMC process during clinical development, which empower our customers to develop drugs from concept to commercial manufacturing stage and also help to accelerate the development of our pipeline drugs. Our CDMO business has a global and diversified customer base, consisting of leading global pharmaceutical companies and small- to mid-sized

BUSINESS

biotechnology companies as well as start-up companies. We enjoy a high level of customer loyalty and industry referrals. We provided services to 49, 53 and 43 customers in the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, respectively, including five out of the ten largest pharmaceutical companies in the world.

As of the Latest Practicable Date, we had 39 on-going projects including 12 pre-IND projects, 24 clinical trial projects and 3 commercial manufacturing projects with a total backlog of US\$62.1 million, which represents the total amount of service fee for services that we have contracted to perform but have not performed yet. During the Track Record Period, our CDMO services enabled approximately 20 regulatory filing milestones, including INDs, NDAs, BLAs or amendments.

Benefiting from the global growth in the biopharmaceutical sector, our CDMO business experienced rapid growth during the Track Record Period. Revenue from our CDMO business increased from RMB324.3 million in 2017 to RMB548.5 million in 2018, and increased from RMB356.5 million for the nine months ended September 30, 2018 to RMB503.2 million for the nine months ended September 30, 2019. Our CDMO business has contributed to our rapid growth and diversified our revenue sources.

Seasoned polysaccharide-chemists founders and experienced management team with strategic insight and proven ability to lead our success

Our founders are seasoned biochemists with solid scientific background as well as strategic insight. We are led by our founder and chairman of our Board, Mr. Li, who has 27 years of experience in the biopharmaceutical industry. Mr. Li has led the development of our heparin and enoxaparin products and played an instrumental role in our research and development efforts and our overall business growth. Our co-founder and deputy general manager, Ms. Li, and co-founder and general manager, Mr. Shan, have also made significant contributions to the success of our Company. Ms. Li has 27 years and Mr. Shan has 26 years of experience in the biopharmaceutical industry. Since their founding of the Company in 1998, they have worked diligently and passionately to achieve their shared vision to provide high-quality and innovative drugs for treatment of diseases with high mortality to benefit patients globally. With decades of scientific research and industry experience of heparin, we believe our founders are able to replicate our success in the heparin industry to our other businesses and guide us to become a leading pharmaceutical company globally.

Led by our founders, we have assembled a stable senior management team with extensive industry expertise, innovative vision and strong execution capabilities. Members of our senior management team on average have nearly 20 years of experience in the biopharmaceutical industry. Many of them have worked with leading global biopharmaceutical companies. They bring extensive industry experience and in-depth knowledge on the intricacies of managing a biopharmaceutical company. With their exceptional experience in global operations and acquisitions, excellent track record and strong execution capabilities, we believe our management team will continuously deepen our competitive edge and strengthen our integrated global operations and consistently strive to achieve our mission to become a global leader.

BUSINESS

Our Strategies

To achieve our goal to become a global leading pharmaceutical company, we intend to pursue the following strategies:

Continue to expand our market share of enoxaparin to become the leader in the global heparin industry

According to Frost & Sullivan, the global enoxaparin market is expected to grow to US\$5,670.0 million in 2024. We aim to achieve significant market share in the global enoxaparin market by deepening penetration in our existing markets as well as expanding into new markets.

- **EU:** We are committed to continuing to increase our sales of enoxaparin in the EU market by implementing differentiated market strategies in various EU countries based on local market conditions and leveraging our experienced in-house sales team supported by our distributors and third-party promoters. As the pioneer of enoxaparin biosimilar in the EU, we plan to further increase our penetration in the major EU countries where we currently have sales and increase our sales to pharmacies, which generally have a higher profit margin than hospitals. In addition, we are considering suitable opportunities to launch our enoxaparin drugs in other European countries, such as Switzerland, primarily by enhancing physician’s awareness through our increased academic marketing efforts and expanding our sales and distribution network.
- **China:** We plan to further promote our Prolongin as the first QCE-approved enoxaparin in China upon NMPA’s approval and cultivate the PRC enoxaparin market.
- **U.S.:** In addition to our supply arrangement with a multinational pharmaceutical company to be its major supplier of enoxaparin sodium injections in the U.S., we are also developing our own generic enoxaparin sodium injection for which we have submitted an ANDA, which is currently under review by the FDA.
- **Other markets:** We aim to expand our sales of enoxaparin in Canada and the emerging markets, such as Southeast Asia, Latin America and Middle East. As of the Latest Practicable Date, our enoxaparin product has received marketing approvals in over 20 countries. Our distributors and we are also in the process of applying for marketing approval in 16 other countries. We believe we are able to become a leader in these markets by leveraging our high product quality, manufacturing and sales experience, customer base and sales network with local agents and pharmaceutical companies.

We will continue to solidify our leadership position in heparin sodium API, which serves as an important entry barrier for the global enoxaparin market, and maintain our position as the key manufacturer and supplier of heparin sodium API for well-known pharmaceutical companies, such as Sanofi. We plan to further optimize our supply chain management and enhance our quality control of the raw material of heparin API. We plan to expand the production capacity of crude heparin of our two factories in China to reduce our purchase of raw materials from third parties and increase our access to the traceable crude heparin globally. We will continue to invest in the research and development of manufacturing technologies and quality control system to further enhance our competitiveness and distinguish us from our peers.

BUSINESS

Maximize the commercial value of our first-in-class pipeline drugs in China by leveraging our local insight and vast experience in global operations

We have developed a clear road map for the commercialization of our first-in-class pipeline drugs in China to maximize their commercial value. We have established an extensive sales and distribution network and teams in China for our heparin business and we believe we can leverage these resources in China to build specialized in-house sales teams and a distribution channel to hospitals and physicians for the academic marketing of our pipeline drugs. Through years of operations in China and globally, we have accumulated both local insight in China and vast experience in global operations. We believe we are able to leverage our successful experience in the heparin industry and our local insight in China to successfully launch our drug candidates and maximize their commercial value in China.

Further expand and develop our CDMO business and build a world-leading CDMO platform

We plan to further expand and develop our CDMO business to build a world-leading CDMO platform to capture the global growth opportunities in the biopharmaceutical sector and serve as the incubator for our pipeline drugs, by enhancing our production capacity, expanding our customer base and improving our research and development capabilities.

To enhance Cytovance’s drug discovery, development and manufacture capabilities, we intend to double its production capacity of both microbial fermentation and mammalian cell culture. Moreover, we plan to expand rapidly into the gene therapy sector by increasing Cytovance’s current pDNA manufacturing capacity and developing innovative manufacturing platforms for viral vectors, which will differentiate Cytovance from other CDMO service providers with the capability to manufacture both plasmids and viral vectors. We believe the significant unmet market demands for both plasmids and viral vectors will drive the growth of Cytovance. We also plan to enhance Cytovance’s discovery and cell line development capabilities, protein analytics and materials testing services, and establish final dose manufacturing capabilities. Moreover, we plan to further enhance SPL’s development and manufacturing services for large molecule pharmaceutical products extracted from a broader range of natural sources.

To increase our market share in the CDMO industry, we aim to deepen our collaborations with existing clients, such as leading multinational pharmaceutical companies, as well as expand our customer base and promote our CDMO services to new customers in order to secure more projects. Advanced technologies are crucial to become a world-leading CDMO platform. We will continue to invest in innovative technologies to stay at the forefront of the industry. This will enable us to provide the most efficient and effective CDMO solutions to our clients and accelerate their drug development process.

Expand our business and strengthen our core competencies through acquisitions and strategic investments

We intend to expand our business and strengthen our core competencies through selective acquisitions of, or strategic investments in, pharmaceutical or biotech companies. We are primarily interested in companies with robust product portfolios, strong R&D and sales and marketing capabilities that are complementary to ours. We will continue to identify suitable targets leveraging on our scientific insights and extensive industry experience. We take a market-driven approach in assessing potential acquisition targets. We primarily focus on the market potential of a target’s products and pipeline and potential synergies with our existing product pipeline.

BUSINESS

We believe that our strategic vision, vast industry experience and leading CDMO capabilities will make us a desirable acquirer and partner. Our strong business execution capabilities will help us effectively integrate the acquired businesses into our existing platform and achieve synergies with our R&D, manufacturing, sales and marketing capabilities.

Furthermore, we will selectively pursue opportunities to in-license international blockbuster drugs, in particular those targeting therapeutic areas or conditions with significant unmet clinical demands, such as oncology and cardiovascular diseases, as well as those that fall into our main therapeutic areas.

Develop our Pingshan Industrial Park into a world-class manufacture base for pharmaceutical products

Our Pingshan Industrial Park is located within the National Biopharmaceutical Industrial Base in Pingshan, Shenzhen, China, with a gross floor area of over 200,000 sq.m. We have completed the construction and process validation of part of our facilities and product lines in Pingshan Industrial Park, and we are committed to developing our Pingshan Industrial Park into a world-class manufacturing base for pharmaceutical products. We have established 24,000kg annual production capacity of enoxaparin sodium API, and 12,000,000 mega annual production capacity of heparin sodium API. We plan to further expand our production capacity in Pingshan Industrial Park, including the production capacity of pre-filled syringes of enoxaparin sodium injection.

We also plan to make Pingshan Industrial Park as the manufacturing base for our innovative drug candidates in the future. With its leading production design and CGMP-compliant manufacturing system and facilities, we believe it can swiftly and seamlessly undertake the production of our new drug candidates to prepare for their commercialization in the near future.

OUR BUSINESS

We are a global pharmaceutical company with business spanning the manufacture and sale of pharmaceutical products, development of innovative drugs and CDMO services. Our sales of pharmaceutical products consist of (i) finished dose pharmaceutical products which include heparin sodium injection and enoxaparin sodium injection, (ii) API products including heparin sodium API and enoxaparin sodium API and (iii) other products mainly including pancreatin API. We have obtained exclusive development and commercial rights in Greater China for clinical stage innovative drug candidates which are being developed for the treatment of diseases with an immune system axis. We are also developing a self-discovered proprietary drug candidate currently at preclinical stage. We operate a CDMO business that provides R&D, manufacturing, quality management and program management services, through our wholly-owned subsidiary Cytovance, which specializes in the development and manufacture of recombinant pharmaceutical products and critical non-viral vectors and intermediates for gene therapy, and through our wholly owned subsidiary, SPL, which provides services in the development and manufacture of naturally derived pharmaceutical products.

BUSINESS

The following table sets forth a breakdown of our revenue by our products and services during the Track Record Period.

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue
Sale of Goods								
Finished dose pharmaceutical products	381,197	13.5	1,045,643	21.8	605,142	18.3	720,891	23.0
API	1,846,129	65.3	2,752,386	57.3	2,003,884	60.1	1,690,020	54.0
Others	217,124	7.7	385,403	8.0	310,762	9.4	193,398	6.2
Subtotal	<u>2,444,450</u>	<u>86.4</u>	<u>4,183,432</u>	<u>87.2</u>	<u>2,919,788</u>	<u>88.3</u>	<u>2,604,309</u>	<u>83.1</u>
CDMO services	324,308	11.5	548,469	11.4	356,542	10.8	503,161	16.1
Others	59,467	2.1	67,906	1.4	30,418	0.9	24,701	0.8
Total	<u>2,828,225</u>	<u>100.0</u>	<u>4,799,807</u>	<u>100.0</u>	<u>3,306,748</u>	<u>100.0</u>	<u>3,132,171</u>	<u>100.0</u>

OUR PHARMACEUTICAL PRODUCTS

The sales of our pharmaceutical products accounted for 86.4%, 87.2%, and 83.1% of our revenue in 2017, 2018, and the nine months ended September 30, 2019, respectively. We focus primarily on the anticoagulant and antithrombotic finished dose pharmaceutical products, including enoxaparin sodium injection and heparin sodium injection and their relevant APIs. The sales of our finished dose pharmaceuticals accounted for 13.5%, 21.8%, and 23.0% of our revenue in 2017, 2018 and the nine months ended September 30, 2019, respectively, and the sales of our API products accounted for 65.3%, 57.3%, and 54.0% of our revenue in the respective periods.

BUSINESS

The following table sets forth selective information relating to our products as of the Latest Practicable Date:

PRODUCT TYPE	PRODUCTS	APPROVAL FOR SALES IN CHINA	APPROVAL FOR SALES IN THE EU	APPROVAL FOR SALES IN THE U.S.	APPROVAL FOR SALES IN OTHER MAJOR COUNTRIES*	APPLICATION OF APPROVAL FOR SALES IN OTHER MAJOR COUNTRIES*
FINISHED DOSE PHARMACEUTICAL PRODUCTS	Enoxaparin sodium injection	Prolongin— approved by the NMPA for five strengths in 2005	Inhixa— approved by the EMA in 2016 for five strengths and in 2018 for multi-dose vials and high strengths Neoparin— approved in Poland in 2016 for five strengths and in 2018 for multi-dose vials and high strengths	Filed an ANDA under the FDA’s review for enoxaparin sodium injection for seven strengths	Brazil, Colombia, Pakistan, Chile, Bolivia, Vietnam, Ecuador, Paraguay, Myanmar, Madagascar, Jordan, Sri Lanka, Philippines, Nicaragua, United Arab Emirates	Canada, Saudi Arabia, Singapore, Malaysia, Switzerland, Israel, Montenegro, El Salvador, Costa Rica, Panama, Uzbekistan, Honduras
	Heparin sodium injection	—	—	Four ANDAs approved for nine respective strengths by FDA	—	—
	Heparin sodium API	Approved by the NMPA in 2002	Approved by the EDQM in 2008 and renewed in 2013	Authorized supplier of heparin sodium API for the manufacture of several heparin products	Authorized supplier in Turkey, India, Italy, Brazil, South Korea, Mexico, Canada	Authorized supplier in Russia
	Enoxaparin sodium API	Approved by the NMPA in 2005	—	Filed DMF and under the FDA’s review as the manufacturer referenced in a customer’s ANDA for enoxaparin sodium injection Filed DMF and under the FDA’s review of our ANDA for enoxaparin sodium injection for seven strengths	Authorized supplier in Turkey, Brazil, Morocco, Uruguay, South Korea, Bangladesh, Paraguay, Colombia, India, Peru	Authorized supplier in Vietnam, Algeria, Russia, Saudi Arabia, Mexico, Thailand, Malaysia, Jordan

* Marketing approvals of our products in these countries are held by third parties.

Our Finished Dose Pharmaceutical Products

Enoxaparin Sodium Injection

Our finished dose enoxaparin product, enoxaparin sodium injection, a sterile solution of enoxaparin sodium in water for injection, is an injectable anticoagulant and antithrombotic drug that helps prevent blood clots in patients. Our finished dose enoxaparin product is available as solution for injection in both pre-filled syringes and vials. Enoxaparin increases the effect of antithrombin III, a natural substance that controls the blood’s clotting factors and helps prevent blood from clotting inside

BUSINESS

the body, which helps to stop the formation of new blood clots and control existing ones. Our enoxaparin product has been approved for marketing in the EU and China for (i) prevention of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery, (ii) prevention of venous thromboembolic disease in medical patients with an acute illness and reduced mobility at increased risk of venous thromboembolism, (iii) treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery, (iv) prevention of thrombus formation in extra corporeal circulation during haemodialysis, and (v) treatment of acute coronary syndrome, including unstable angina and certain types of myocardial infarction.

Approved by the EMA, the NMPA and relevant governmental authorities, our enoxaparin product can be administered through all three injection routes, including subcutaneous injection, intravenous (bolus) injection and arterial line injection. In the comparison study with its reference drug Clexane, the fluctuation range of several features of our enoxaparin sodium API, including molecular distribution and molecular weight, the average degree of polymerization, the amount of disaccharide after enzymolysis fall within the range of Clexane, which indicates the high similarity between our enoxaparin product and the reference drug, the outstanding safety profile of our enoxaparin product and the stability of our manufacturing technologies. The post-market safety report retrieved from EndraVigilance that collects incidence of adverse events using enoxaparin sodium injections in 2019 also shows the safety of our enoxaparin sodium injection, since the adverse events after the injection of our enoxaparin product in the EU is lower than our competitors. The number of adverse events using our product accounted for approximately 4.57% of all the adverse events after using enoxaparin sodium injections in the EU during such period, while our market share in the EU was 18.0% in 2019 by sales volume.

We are one of the few companies with integrated manufacturing process and manufacturing facilities of enoxaparin sodium injection that are in compliance with the EU, the U.S. and Chinese CGMP standards and have passed multiple inspections by the EMA, the FDA, the NMPA and other relevant governmental authorities. During the Track Record Period, our production of enoxaparin sodium injection was primarily conducted at Techdow Nanshan, which passed the inspection of the EMA in 2015, 2016, 2018 and 2019, the inspection of the FDA in 2018 and 2019 and the inspection of the NMPA in 2011 and 2016. During the Track Record Period, a small portion of our finished dose enoxaparin product was also produced by our OEM, the manufacturing process and facility of which are also in compliance with the EU CGMP requirements.

During the Track Record Period, we sold our enoxaparin finished dose products to over 20 countries either under our own brands or to other pharmaceutical companies for their resale under their own brands. In the EU, our enoxaparin sodium injection products were sold in nine countries primarily to distributors and wholesalers for their sales to hospitals and pharmacies in the EU. In China, we sold our enoxaparin sodium injection to distributors for their further distribution to hospitals. Revenue generated from the sales of our enoxaparin finished dose products increased from RMB311.2 million in 2017 to RMB981.9 million in 2018 and further from RMB541.4 million for the nine months ended September 30, 2018 to RMB720.9 million for the nine months ended September 30, 2019, accounted for 11.0%, 20.5%, 16.4% and 23.0% of our total revenue during the respective periods.

EU

Our enoxaparin product is currently marketed under our brand names, Inhixa and Neoparin. Inhixa has been approved by the EMA through the Centralized Authorization Procedure which allows

BUSINESS

it to be sold in all the EU countries without further approval, and Neoparin has been approved for marketing and sales in Poland.

- **Inhixa**

We received the marketing authorization from the EMA for Inhixa in September 2016 for five strengths ranging from 2,000 IU (20 mg)/ 0.2 mL to 10,000 IU (100 mg)/1 mL, based on the consistency evaluation of Inhixa as compared to Clexane in terms of structure, purity and biological activity in a PK/PD study. We also received the marketing authorization from the EMA for Inhixa in multi-dose vials and high-strength pre-filled syringes in September 2018. Inhixa is covered by the national healthcare programs of eight EU countries. As of the Latest Practicable Date, Inhixa was covered by the national healthcare programs in eight EU countries where it had been sold.

- **Neoparin**

Neoparin was approved by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Poland in February 2016 for five strengths, primarily based on a randomized, multicenter, parallel, open label clinical study comparing Neoparin with Clexane for the prevention of venous thromboembolism in patients undergoing knee surgery with high venous thromboembolism risk, which proved the safety and effectiveness of Neoparin and its similarity to Clexane. Neoparin in multi-dose vials and high-strength pre-filled syringes were approved in January 2018. SciencePharma holds the approval for sales in Poland for Neoparin. We granted SciencePharma a license to use trademark, designs and domains related to Neoparin for the purpose of its registration and sales.

China

- **Prolongin**

Our enoxaparin sodium injection, Prolongin, is the first generic enoxaparin sodium injection approved by the NMPA in China. We received the NMPA approval of our enoxaparin product for five strengths in 2005, which was renewed in 2015. Enoxaparin sodium injection is included as a category II drug in the National Medical Insurance Catalog. The CDE has completed technological evaluation for purpose of the QCE approval for injection doses to be implemented by the NMPA. For details, see “Regulatory Environment — Laws and Regulations Related to Our Business in the PRC — Regulations on Drug Research and Development & Registration Services.” We expect our enoxaparin sodium injection to be the first enoxaparin sodium injection approved by the NMPA based on QCE once the QCE approval regime for injection doses becomes effective.

U.S.

We have entered into a supply agreement with a multinational pharmaceutical company to be its major supplier of enoxaparin sodium injections in the U.S.. We are also developing our own generic enoxaparin sodium injection products for which we have submitted an ANDA, which is currently under review by the FDA based on the active ingredient sameness as the originator brand name drug, Lovenox. When we obtain the ANDA for our own branded enoxaparin sodium injection products in the U.S., we plan to collaborate with a world-leading pharmaceutical distributor, to mainly market and sell our products to pharmacies in the U.S.

Other Markets

During the Track Record Period, we also supplied enoxaparin sodium injections for pharmaceutical companies in the emerging market, including South America and Southeast Asia.

BUSINESS

According to Frost & Sullivan, we are the fourth largest supplier of enoxaparin finished doses globally accounting for 5.4% of the global market share by revenue in 2018, and we are the second largest supplier of enoxaparin finished doses in China accounting for 11.3% of the market share in China by revenue in 2018. We also have a leading market share in the EU, with the largest market share in the UK and Poland and leading market positions in Italy and Austria accounting for 70.9%, 52.5%, 33.1% and 19.1% of the market shares in those countries, respectively. Enoxaparin finished doses have significant growth potential. As enoxaparin sodium is expected to replace other LWMH preparations, the global usage of enoxaparin sodium will continue to grow from 763.2 million pre-filled syringes/vials in 2018 to 1,444.3 million pre-filled syringes/vials in 2024 according to Frost & Sullivan.

Heparin Sodium Injection

Our heparin sodium injection is a sterile solution of heparin sodium in water for injection, standardized for anticoagulant activity. It is to be administered by intravenous or deep subcutaneous routes. Heparin inhibits reactions that lead to the clotting of blood and the formation of fibrin clots both *in vitro* and *in vivo*, and it also prevents the formation of a stable fibrin clot by inhibiting the activation of the fibrin stabilizing factor. The approved indications of heparin sodium injection are (i) anticoagulant therapy in prophylaxis and treatment of venous thrombosis and its extension, (ii) low-dose regimen for prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing major abdominothoracic surgery or who, for other reasons, are at risk of developing thromboembolic disease; (iii) prophylaxis and treatment of pulmonary embolism, (iv) atrial fibrillation with embolization; treatment of acute and chronic consumptive coagulopathies (disseminated intravascular coagulation), (iv) prevention of clotting in arterial and cardiac surgery, (v) prophylaxis and treatment of peripheral arterial embolism and (vi) application as an anticoagulant in blood transfusions, extracorporeal circulation, and dialysis procedures.

We received four ANDAs for generic heparin sodium injection in 2014 for nine strengths in single or multiple dose vials. Before the disposal of our equity interests in Hepatunn in June 2018, we generated revenue from its sales of heparin sodium injection in China, which accounted for 2.5% and 1.3% of our total revenue in 2017 and 2018, respectively. Moreover, we entered into a collaboration agreement in 2010 with a world-leading pharmaceutical distributor, under which we granted such distributor with the exclusive distribution right of our generic heparin sodium injection in the U.S. During the Track Record Period, such distributor engaged third-party manufacturers to produce heparin sodium injection with the API we supplied. We plan to change the authorized manufacturer referenced in our ANDAs to Techdow Nanshan.

Primarily driven by the increase in the price of crude heparin, the market size of heparin is projected to grow from US\$573.9 million in 2018 to US\$691.8 million by 2024 at a CAGR of 3.2%, according to Frost & Sullivan. The heparin market is relatively scattered and less concentrated. There are many small market players, the profit margins of which are comparatively low.

Our API Products

Heparin sodium API

Heparin sodium is the sodium salt of sulfated glycosaminoglycans present as a mixture of heterogeneous molecules varying in molecular weights that retains a combination of activities against different factors of the blood clotting cascade. Our heparin sodium API product consists of heparin

BUSINESS

sodium purified from crude heparin, which is separated from the mucosa of porcine small intestines. Our heparin sodium API product is primarily used for the production of heparin sodium preparations and LMWH API.

As of the Latest Practicable Date, our heparin sodium API product was one of the few heparin sodium API products which received NMPA approval, EDQM approval and passed the FDA review. We commenced sales of our heparin sodium API product in the EU in 2000, in the U.S. in 2003 and in China in 2010. Moreover, we are one of the few companies with an integrated manufacturing system compliant with the U.S., EU and Chinese CGMP standards and has passed multiple inspections by the FDA, EMA, NMPA and other relevant governmental authorities. We participated in the revision of the USP heparin sodium standards in 2009, which was primarily in response to the contamination of heparin sodium API used in the Baxter Incident.

Our heparin sodium API was approved by the NMPA in 2002 and by the EDQM in 2008, and we have been authorized by the FDA as the heparin sodium API supplier for several finished dose heparin products. Moreover, our heparin sodium API has received marketing approvals in Canada and India. Our heparin sodium API is produced at our facility in Nanshan, Shenzhen, China (the “**Hepalink Nanshan**”) which complies with the U.S. CGMP requirements, and passed five FDA inspections in 2005, 2008, 2011, 2013, and 2016, including an inspection following the Baxter Incident, where the FDA did not find any deficiencies. As a result, our heparin sodium API was used as a reference for requirements certified by BfArm after its inspections in 2006, 2009, 2012, 2014 and 2017, and is in compliance with Chinese CGMP requirements with certificates issued by NMPA after its inspections in 2003, 2008, 2012 and 2017. Our heparin sodium API is also produced at our manufacturing facility in Wisconsin, the U.S., which is in compliance with the U.S. CGMP requirements and has passed multiple inspections by the FDA. Our heparin sodium API business in the U.S. is operated by our wholly-owned subsidiary, SPL, based in the U.S.

Our proprietary technologies in the separation and purification of heparin sodium API allow us to maximize the yield of highly charged, high molecular weight heparin chains present in the starting material without affecting the material by degradation, such as depolymerization and/or desulfation caused by the applied process conditions. As a result, we are able to maintain a high yield of the anti-factor IIa activity of our heparin sodium API. Since we are able to effectively remove impurities, such as lipids, peptides, protein and nuclear impurities, viruses, bacterial endotoxins, related glycosaminoglycans and other neutral and positively charged impurities, our heparin sodium API contains much less impurities per unit, compared with the standards stipulated per CHP, USP and EP. Our product’s high purity and complete structure also led to an anti-factor IIa potency of not less than 200 IU/mg in 80% batches during the Track Record Period, higher than the 180 IU/mg minimum requirement stipulated per USP, EP and CHP. Specifically, our proprietary technologies include technology of impurities and components separation, technology of virus and bacteria inactivation, technology of genetic integrity protection, technology of the release of active substances and technology of directional components separation, which are protected as our know-how and trade secrets.

We have established an integrated supply chain to secure high quality crude heparin for the manufacturing of our heparin sodium API. Our supply is comprised of crude heparin produced by Independent Third Parties and our wholly-owned subsidiaries, Chengdu Sunrace and Shandong Ruisheng. We require that the crude heparin we purchase or produce are processed from porcine small intestines that can be traced to its supplier. As of the Latest Practicable Date, through our own subsidiaries in

BUSINESS

China and the U.S. and supply network, we had exclusive supply for over 50% of the traceable crude heparin in China and over 40% in the U.S. by volume of the traceable heparin raw material in 2018.

During the Track Record Period, all of our heparin sodium API products were produced in our facilities in Hepalink Nanshan and SPL, and our heparin sodium API products were sold to over 15 countries and regions. We are able to provide customized heparin sodium API according to our customers’ specifications. Our customers remained relatively stable during the Track Record Period. Revenue generated from the sales of our heparin sodium API increased from RMB1,674.7 million in 2017 to RMB2,522.4 million in 2018 and due to the impact by African swine fever since late 2018, our revenue generated from the sales of heparin sodium API decreased from RMB1,823.4 million for the nine months ended September 30, 2018 to RMB1,458.3 million for the nine months ended September 30, 2019, accounted for 59.2%, 52.6%, 55.1% and 46.6% of our total revenue for the respective periods.

As of the Latest Practicable Date, there were four major suppliers of heparin sodium API based in China and six major suppliers globally, according to Frost & Sullivan. According to Frost & Sullivan, we are the largest heparin sodium API supplier in the global market and our heparin sodium API product had a market share of 40.7% of the global heparin sodium API supply market by revenue in 2018. The global sales revenue of heparin sodium API reached US\$1,176.1 million in 2018, which is expected to increase to US\$3,824.5 million at a CAGR of 21.7%, according to Frost & Sullivan. We believe our state-of-the-art supply chain management, rigorous quality control and manufacturing standards and proprietary manufacture technologies serve as the cornerstones of our leading position in the global heparin sodium API market, differentiate us from our competitors and strengthen our competitive advantages.

Enoxaparin sodium API

Our enoxaparin sodium API is the sodium salt of depolymerized heparin, obtained by alkaline depolymerization of heparin benzyl ester, by chemically breaking up the larger heparin chains into smaller fragments. Heparin sodium API is the primary raw material for our enoxaparin sodium API. Enoxaparin sodium API is used for the production of finished dose enoxaparin sodium pharmaceutical products.

As of the Latest Practicable Date, our enoxaparin sodium API product was one of the few enoxaparin sodium API approved by the NMPA and other regulatory authorities and qualified for sales in certain countries in Europe, South America, Asia and Africa. Moreover, we are one of the few companies with an integrated manufacturing process in compliance with U.S., EU and Chinese CGMP standards which has passed multiple inspections by the FDA, NMPA and EMA.

Our enoxaparin sodium API was approved by NMPA in 2005. We are currently under the FDA review as the API supplier referenced in a customer’s and Techdow’s enoxaparin ANDA applications. Our enoxaparin sodium API is produced at Techdow’s facility in Nanshan, Shenzhen, China (the “**Techdow Nanshan**”) in compliance with the EU, Chinese, Brazilian and Colombian CGMP requirements, with the relevant certificate issued by the EMA in 2015 and 2018, NMPA in 2015, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Product of Poland in 2013 and 2018, and ANVISA in 2011. Our production of enoxaparin sodium API at Techdow Nanshan is also in compliance with the U.S. CGMP standards, and passed the inspections by the FDA in 2012, 2015, 2018 and 2019. Moreover, our manufacturing process and facilities of enoxaparin sodium API in

BUSINESS

Pingshan Industrial Park are in compliance with the U.S, EU and China CGMP requirements and passed the EMA inspection in 2019, which will further increase our production capacity.

The high quality of our heparin sodium API and our proprietary technologies in the chemical process of the depolymerization of heparin benzyl ester allow us to maximize the yield of enoxaparin sodium API and ensure the stableness and completeness of its complex chemical features. We developed our proprietary technologies for manufacturing our enoxaparin sodium API which include directed cleavage and structural recombination techniques, targeted component and sequence selective separation techniques, and precise control techniques for purification and impurity removal of synthetic product, and are protected as our know-how and trade secrets. Our design of the manufacturing process and parameters and the technology know-how we apply in the process ensure that the structural integrity and molecular activity of our enoxaparin sodium API is highly consistent with the originator and the impurities of our enoxaparin sodium API are below or at the same level as the originator. In addition, we have established a comprehensive quality management system that guide our operations through our supply chain. We have set stringent quality standards on our enoxaparin sodium API product, which specifies a narrower range of molecular weight, a more stable molecular distribution and a more strict control of impurity than approved standards.

As a result of our proprietary production technologies, integrated supply chain and comprehensive quality management system, our enoxaparin sodium API is able to achieve a higher product quality. Potency of the anti-factor Xa activity of and the impurities contained in our enoxaparin sodium API conform with the respective requirement under the CHP, USP and EP and the potency tested in the API of our reference drug. Our stable manufacturing process also ensures less fluctuation in the product quality among each batch of enoxaparin sodium API we produce.

During the Track Record Period, all of our enoxaparin sodium API products were produced at Techdow Nanshan, which were sold to our distributors and manufacturers of finished dose enoxaparin products in over 10 countries, primarily in the Middle East, Europe, South America and Asia, for the production of enoxaparin sodium injections. Revenue generated from the sales of our enoxaparin sodium API increased from RMB171.4 million in 2017 to RMB230.0 million in 2018 and further from RMB180.5 million for the nine months ended September 30, 2018 to RMB231.7 million for the nine months ended September 30, 2019, accounted for 6.1%, 4.8%, 5.5% and 7.4% of our total revenue for the respective periods.

OUR INNOVATIVE DRUG BUSINESS

Based on our profound understanding of immune response mechanisms, we have engaged in the investment in and development of first-in-class drug candidates that address the significant unmet clinical demands for fatal diseases with an immune system disorder axis. We have strategically invested in a number of biotech companies with first-in-class drug candidates in our focused therapeutic areas and have obtained from them exclusive development and commercial rights of certain drug candidates in the Greater China, including two drug candidates in phase III clinical trials, two drug candidates in phase II clinical trials, and one drug candidate in phase I clinical trial, as of the Latest Practical Date. We are also developing a self-discovered proprietary oncology drug candidate currently at preclinical stage.

For the drug candidates of which we own exclusive development and commercial rights in Greater China, we plan to join the respective MRCTs by opening clinical sites in China, such as phase

BUSINESS

III trial for Oregovomab and AR-301. The trial for AR-301 has been approved by the NMPA. Data from MRCTs can be submitted to multiple regulatory agencies in International Conference on Harmonization (ICH) and non-ICH countries. Our participation in the MRCTs can reduce the time lag of launching our respective drug candidates in China.

The following chart summarizes the development status of our innovative drug candidates as of the Latest Practicable Date:

Drug Candidate	Target / Mechanism of Action	Indications	Partner Company	Hepalink Shareholding	Development and Commercial Rights Owned by (Regions)	IND	Ph1	Ph2	Ph3	MRCT ¹ Participated by Hepalink
Oregovomab	Immunological stimulation after binding to CA125 antigen	Primary late-stage ovarian cancer	OncoQuest	38.74%	OncoVent ² (Greater China)	[Progress bar: IND to Ph2]				☆
		Recurrent late-stage ovarian cancer (Oregovomab+Hiltonol)				[Progress bar: IND to Ph1]				☆
		Recurrent late-stage ovarian cancer (Oregovomab+PD-1 Inhibitor nivolumab)				[Progress bar: IND to Ph2]				☆
		Recurrent late-stage ovarian cancer (Oregovomab+PARP Inhibitor niraparib)				[Progress bar: IND to Ph2]				☆
mAb-AR20.5	Immunological stimulation after binding to MUC1 antigen	Pancreatic cancer				[Progress bar: IND to Ph1]				☆
AR-301	α-toxin released by Gram-positive staphylococcus aureus	Staphylococcus aureus pneumonia	Aridis	9.86%	Shenzhen Arimab ³ (Greater China)	[Progress bar: IND to Ph3]				★
AR-101	Gram-negative pseudomonas aeruginosa O11 serum	Pseudomonas aeruginosa pneumonia				[Progress bar: IND to Ph2]				☆
RVX-208	BD2 domain of BET family member	Type 2 diabetes with coronary heart disease	Resverlogix	38.80%	Hepalink (Greater China)	[Progress bar: IND to Ph3]				
		Chronic Kidney Disease				[Progress bar: IND to Ph2]				
H1710	Heparanase (HPA)	Pancreatic cancer	Hepalink (In-house)	100%	Hepalink (Global)	[Progress bar: IND to Ph1]				
		New Indication				[Dashed progress bar: IND to Ph2]				☆

▶ Hepalink initiated the trials
▶ The companies Hepalink invested initiated the clinical trials
- - - The company Hepalink invested plans to initiate the clinical trials for new indication based on the ph3 clinical data of Type 2 diabetes with coronary heart disease
★ Hepalink has initiated the China portion MRCT¹
☆ Hepalink plans to initiate the respective China portion MRCTs¹ once entered pivotal phase

¹ MRCT refers to multi-regional clinical trials, which involves more than one independent center in enrolling and following clinical trial participants. It is widely conducted by many global pharmaceutical companies to reduce the time lag of launching innovative drugs in different regions.
² We directly hold 54.00% equity interest in OncoVent and are entitled to additional economic interest through our investee companies which hold 40.00% of its equity interest in total.
³ We directly hold 51.00% equity interest in Shenzhen Arimab and are entitled to additional economic interest through our investee company which holds the remaining 49.00% of its equity interest.

In addition, our portfolio companies are also developing a number of innovative drugs with significant growth potential. As of the Latest Practicable Date, we held 47.02% equity interest in HighTide and 8.60% equity interest in Kymab.

Based on public information, HighTide is a global clinical-stage biopharmaceutical company focused on discovering and developing novel drugs to treat chronic liver diseases, gastrointestinal diseases and metabolic disorders with high unmet needs. Its leading drug candidate, HTD1801, is a first-in-class oral small molecule drug candidate, currently in Phase II trials for the treatment of nonalcoholic steatohepatitis (NASH) and primary sclerosing cholangitis (PSC). The FDA has granted HTD1801 Fast Track Designation in both diseases.

Based on public information, Kymab, based in Cambridge, the UK, is a clinical stage biopharmaceutical company focused on the discovery and development of fully human monoclonal antibody drugs using its proprietary antibody platforms (IntelliSelect[®]) which contain the entire repertoire of human antibodies. Kymab’s platform has been designed to maximise the diversity of human antibodies produced in response to immunisation with antigens. According to public source, Kymab is using its platforms for a number of internal drug discovery programmes and in partnership with pharmaceutical companies. It has a broad pipeline of therapeutic antibody programmes, with four drug candidates for immune-oncology therapy with significant growth potential.

BUSINESS

Oregovomab

Oregovomab is an investigational first-in-class anti-CA125 immunotherapy intended to treat advanced ovarian cancer, including first-line treatment of primary advanced ovarian cancer and recurrent advanced ovarian cancer. Oregovomab is a high affinity murine monoclonal antibody specific for CA125 to induce therapeutic immunity directed against the tumor. OncoVent, a joint venture established by OncoQuest and us, in which we hold 54.0% equity interest, obtained exclusive rights to develop and commercialize Oregovomab in Greater China from OncoQuest, in which we hold 38.74% equity interest. We are entitled to additional economic interest in OncoVent through our investee companies which hold 40.00% of its equity interest in total. Oregovomab has been granted Orphan Drug Designation by the FDA and EMA for its indication in treating primary advanced ovarian cancer, for which, OncoQuest has completed a phase II clinical trial using Oregovomab as first-line therapy combined with first-line chemotherapy. Oregovomab is also undergoing three global clinical trials to evaluate Oregovomab combined with PARP inhibitor or immunotherapy for treating patients with recurrent advanced ovarian cancer. We acquired the exclusive development and commercial right of Oregovomab in Greater China in September 2016.

Market Opportunity and Competition

There is significant market potential for the treatment of ovarian cancer in China. According to Frost & Sullivan, the incidence of ovarian cancer in China increased from 51.0 thousand in 2014 to 54.1 thousand in 2018, representing a CAGR of 1.5%, which is expected to reach 66.9 thousand by 2028 at a CAGR of 2.2%, and 74.0 thousand by 2035 at a CAGR of 1.4%.

There are three main treatment options for ovarian cancer, including chemotherapy, surgery and hormone therapy. The most adopted first-line treatment for primary ovarian cancer is chemotherapy with carboplatin, docetaxel or paclitaxel, but its effects are not typically long-lasting. More than 80% of ovarian cancer patients treated with chemotherapy experience recurrent disease, and more than 50% of these patients die from the disease in less than five years post-diagnosis. Options of targeted therapy are also limited. Clinical results have shown that bevacizumab has limited efficacy delaying the progression of ovarian cancer. Moreover, PARP inhibitor olaparib is approved as first-line maintenance therapy for patients with deleterious BRCA mutations after response to first-line chemotherapy. Only around 10-15% patients with ovarian cancer had BRCA mutations, leaving the rest of patients in urgent need of new first-line treatment.

BUSINESS

As of the Latest Practicable Date, according to Frost & Sullivan, there was no approved or commercialized immunotherapy or anti-CA125 monoclonal antibody treatment for ovarian cancer globally, and there were three anti-CA125 antibody candidates under clinical development, as shown in the table below:

Global Pipelines of Anti-CA125 Antibody Treatment for Ovarian Cancer ¹			
Pipeline	Indication	Company	Status
Oregovomab/OvaRex®	• Ovarian Neoplasms	OncoQuest Inc. ²	Phase II
DMUC4064A	• Pancreatic Neoplasms • Ovarian Neoplasms	Genentech, Inc.	Phase I
Sofituzumab vedotin	• Pancreatic Neoplasms • Ovarian Neoplasms	Genentech, Inc.	Phase I

1. Pre-clinical pipelines are excluded.

2. OncoVent as the exclusive rights to develop and commercialize the drug candidate in Greater China. We directly hold 54.00% equity interest in OncoVent and are entitled to additional economic interest through our investee companies which hold 40.00% of its equity interest in total. We also holds 38.74% of equity interest in OncoQuest.

Source: Frost & Sullivan Report

Oregovomab is being developed as an immunotherapy for ovarian cancer. Using murine mAb, Oregovomab has a novel immunotherapeutic mechanism of action which, in combination with immunomodulating effects of the standard of care chemotherapy, has generated promising evidence. It has demonstrated to prolong life and cause a beneficial immune response which substantially improves standard of care chemotherapy. It does not increase toxicity while having an acceptable and manageable safety profile. The cumulative amount of antibody used is also lower compared to current therapy, with treatment effect achieved with only four infusions. Oregovomab has the potential to be a first-line treatment option for ovarian cancer.

Please refer to the section headed “Industry Overview—Innovative Drug Market—Ovarian Cancer” for more industry related details.

Mechanism of Action

Oregovomab is a murine monoclonal antibody IgG1 specific for tumor-associated antigen CA125. CA125 is a surface mucin-like glycoprotein antigen that is expressed on more than 95% of all nonmucinous stage III/IV epithelial ovarian carcinomas and occurs at elevated levels in the serum of patients with ovarian cancer. Increased CA125 serum levels have also been observed patients with a variety of malignancies (carcinomas of the pancreas, lung, colon, and other gastrointestinal tumors).

Oregovomab has a unique mechanism of action based on immunological stimulation following its binding to CA125. The non-human antibody, murine mAb, in combination with chemotherapy, upon binding to tumor antigen CA125 in patient, will trigger initial human anti-mouse (HAMA) response, which through antigen presentation will stimulate antigen CA125 specific T cells. Current evidence supports that this binding *in vivo* renders the target antigen CA125 more immunogenic or “neoantigen-like” through altered and enhanced recognition, antigen processing and presentation to specific T cells. This induces antigen-antibody uptake and processing using the immunoglobulin Fcγ binding via the mannose receptor, FcγR1, and CCR5, a binding pattern in the human unique to murine IgG1 resulting in cross presentation of CA125 peptides and initiation of local specific immune responses with an IFN-γ signature. These properties initiate demonstrable humoral and cellular responses in patients with CA125-positive cancer that are otherwise in a state of relative immune

BUSINESS

tolerance to their disease, and thus unlikely to mount clinically relevant anti-tumor immune responses. Due to transient changes in relative immune tolerance associated with chemotherapy, clinical activity is particularly enhanced when Oregovomab is given in combination with selected chemotherapeutic agents in a specific schedule in patients with Stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer in the first-line setting.

This application of monoclonal antibody indirect immunization is different from classical active immunization that induces protective immunity, or passive immunization that directly targets disease using mechanisms such as antibody-dependent cell-mediated cytotoxicity (ADCC). Indirect immunization involves transient repeated exposure to a lower dose of specific antibody, avoiding gross antibody excess, and allows immune stimulatory antigen processing in the tumor microenvironment and additional systemic sites. Induced cellular immunity targeting tumor antigen is believed to be the primary mechanism of indirect treatment effect.

Summary of Clinical Trial Data

Overview

OncoQuest completed a phase II clinical trial to evaluate the safety and efficacy of Oregovomab as a first-line therapy combined with SOC chemotherapy for treating primary advanced ovarian cancer in February 2019. The trial results have demonstrated that the simultaneous application of Oregovomab and chemotherapy enhances the effects of chemotherapy without additional toxicity.

Trial Design

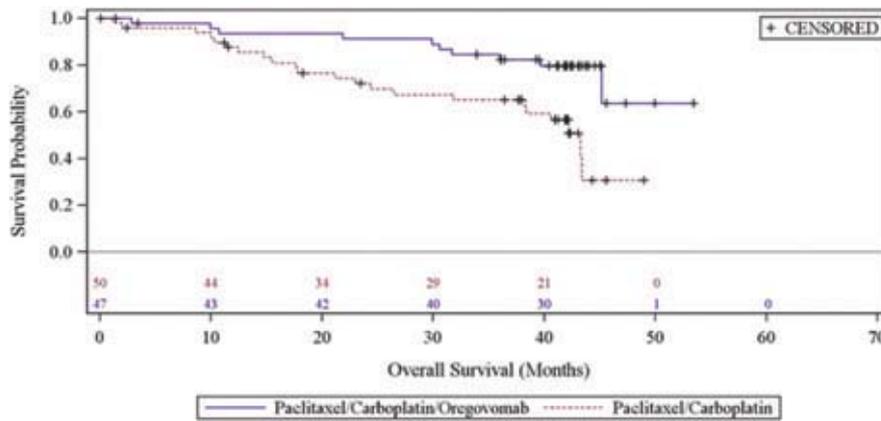
The trial was conducted at 13 centers in Italy and the US, and was a randomized controlled study to evaluate safety and efficacy of first-line chemoimmunotherapy (carboplatin-paclitaxel and Oregovomab) versus chemotherapy SOC (carboplatin and paclitaxel) in this patient population. A 36-month follow-up period was required after the treatment, and a total of 97 patients with newly diagnosed metastatic advanced stage ovarian cancer were enrolled in the study, with 95 patients available for safety assessment. 47 patients were treated with chemotherapy plus Oregovomab and 50 patients were treated with chemotherapy alone. The efficacy endpoints include PFS and OS. The safety endpoint is incidence rate of adverse events.

Efficacy Data

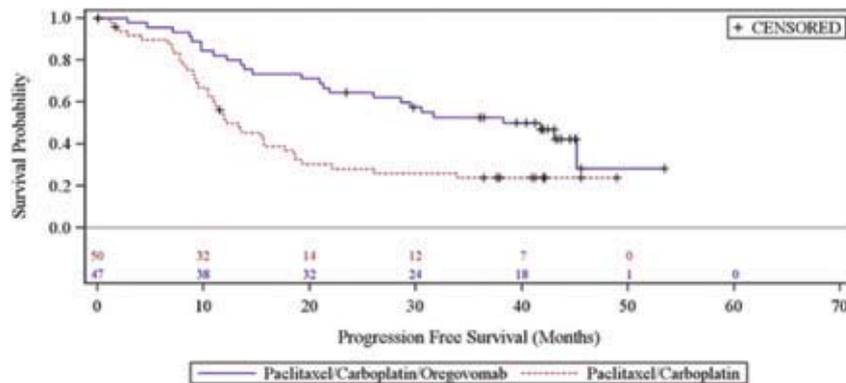
Subjects treated with chemoimmunotherapy had a clinically significant improved OS. There were ten mortality cases among patients treated with chemotherapy plus Oregovomab, lower than the 22 mortality cases among patients treated with chemotherapy alone, $p=0.0043$.

The study included a cohort in which we demonstrated that adding Oregovomab to SOC resulted in increased patient numbers with amplified CA125-specific CD8⁺ T lymphocytes/ml peripheral blood counts, which might explain the improved therapeutic effect of combined treatment of chemotherapy plus Oregovomab over chemotherapy alone. The diagram below illustrates the Kaplan-Meier curve of OS by treatment group.

BUSINESS



The clinical result of phase II shows that subjects treated with chemoimmunotherapy had a clinically significant improvement in PFS, with a median PFS of 41.8 months, compared to subjects treated with chemotherapy alone, with a median PFS of 12.2 months, $p=0.0027$. The diagram below illustrates the Kaplan-Meier curve of PFS by treatment group.



Source: Brewer et al., 2020 Front-line chemo-immunotherapy with carboplatin-paclitaxel using Oregovomab indirect immunization in advanced ovarian cancer: A randomized phase II study

Safety Data

Safety analysis carried out in 95 patients showed no significant difference on the incidents of adverse events, related adverse events and serious adverse events between the two groups, as indicated in the table below:

	Patients treated with chemoimmunotherapy (N=46)	Patients treated with chemotherapy (N=49)
At least 1 Treatment Emergent Adverse Event (TEAE)	38 (82.6%)	40 (81.6%)
At least 1 related TEAE	8 (17.4%)	9 (18.4%)
At least 1 TEAE with grade ≥ 3	10 (21.7%)	8 (16.3%)
At least 1 related TEAE with grade ≥ 3	0 (0.0%)	0 (0.0%)
At least 1 serious TEAE	24 (52.2%)	28 (57.1%)
At least 1 related serious TEAE	2 (4.4%)	4 (8.2%)
At least 1 TEAE leading to study withdrawal	3 (6.5%)	1 (2.0%)
At least 1 TEAE leading to death	1 (2.2%)	1 (2.0%)

Source: Brewer et al., 2020 Front-line chemo-immunotherapy with carboplatin-paclitaxel using Oregovomab indirect immunization in advanced ovarian cancer: A randomized phase II study

BUSINESS

Clinical Development Plan

Based on the clinical data of global Phase II study, a global phase III pivotal trial will start in 2020. This is a phase 3 double-blind, placebo-controlled, multi-center study to compare the safety and efficacy of Oregovomab versus placebo, administered in combination with specific cycles of a standard six-cycle chemotherapy regimen (paclitaxel—carboplatin), for the treatment of subjects with newly diagnosed advanced ovarian cancer who have undergone optimal debulking surgery. The study is expected to enroll over 500 patients with newly diagnosed, advanced ovarian cancer globally. We plan to join the phase III trial under MRCT by initiating clinical trial in China.

OncoQuest is conducting three other trials evaluating the efficacy of Oregovomab in patients with recurrent ovarian cancer, including a phase II clinical trial that tests the combination of Oregovomab and an investigational stage immune booster Hiltonol, a phase Ib/IIa clinical trial that tests the combination of Oregovomab with a PD-1 checkpoint inhibitor nivolumab, and a phase II clinical trial that tests the combination treatment of Oregovomab with a PARP inhibitor niraparib.

mAb-AR20.5

mAb-AR20.5 is a first-in-class immunotherapeutic drug that is being developed by OncoQuest and OncoVent for pancreatic cancer. mAb-AR20.5 is an activated murine monoclonal antibody IgG1 binding with high affinity to the MUC1 antigen. OncoVent acquired the exclusive rights to develop and commercialize mAb-AR20.5 in Greater China in September 2016.

Market opportunity and competition

According to Frost & Sullivan, the incidence of pancreatic cancer in China grew from 91.9 thousand in 2014 to 104.9 thousand in 2018, representing a CAGR of 3.4%, which is expected to increase to 143.6 thousand by 2028 at a CAGR of 3.2%, and to 174.5 thousand by 2035 at a CAGR of 2.8%.

The conventional therapeutic options for pancreatic cancer include surgery, radiotherapy, chemotherapy and interventional therapy. Most of the patients taking certain first-line drugs, such as gemcitabine, have been found to develop drug resistance. The options of targeted therapy are also limited. Certain targeted therapies have been applied in combination with gemcitabine, nevertheless none of which has shown clinically significant improvement in efficacy. Recently, PARP inhibitor olaparib has been approved in the U.S. as a first-line maintenance treatment of germline BRCA-mutated metastatic pancreatic cancer. However, treatment using olaparib increased the PFS of the patients with BRCA mutation by 3.6 months, and no survival benefit was found in patients treated with olaparib. There has been limited success in the use of immunotherapy in treating pancreatic cancer. Single-agent anti-CTLA-4 ipilimumab was evaluated in a phase II study in patients with advanced pancreatic cancer in 27 patients and showed a delayed response in one patient only, indicating that single-agent ipilimumab was not an effective therapy in advanced pancreatic cancer. Moreover, in a phase I trial of anti-PD-L1 therapy, no patients with pancreatic cancer showed a clinical response. This creates huge unmet medical need for an immunotherapy with novel mechanism of action.

Studies have shown that MUC1 overexpression is associated with tumor progression, invasion and metastasis of pancreatic cancer, and its expression is closely related to the drug resistance. mAb-AR20.5 stimulates or re-activates tumor antigen MUC1-specific T cells, is expected to become a promising treatment method for pancreatic cancer.

BUSINESS

As of the Latest Practicable Date, according to Frost & Sullivan, there was no approved or commercialized immunotherapy or anti-MUC1 antibody treatment for pancreatic cancer globally. As of the Latest Practicable Date, there were three anti-MUC1 antibody candidates under clinical development, as shown in the table below:

Global Pipelines of Anti-MUC1 Antibody Treatment for Pancreatic Cancer ¹			
Pipeline	Indication	Company	Status
ETBX-061	Metastatic Pancreatic Cancer	Etubics Corporation	Phase II
Anti-CD3-MUC1 Bispecific Antibody	Advanced Pancreatic Cancer	Benhealth Biopharmaceutical	Phase II
AR20.5	Pancreatic Cancer	OncoQuest ²	Phase I

1. Preclinical pipelines are excluded.

2. OncoVent has the exclusive rights to develop and commercialize the drug candidate in Greater China. We directly hold 54.00% equity interest in OncoVent and are entitled to additional economic interest through our investee companies which hold 40.00% of its equity interest in total. We also holds 38.74% of equity interest in OncoQuest.

Source: Frost & Sullivan Report

Please refer to the section headed “Industry Overview—Innovative Drug Market—Pancreatic Cancer” for more industry related details.

Mechanism of Action

mAb-AR20.5 is an activated murine monoclonal antibody IgG1 binding with high affinity to the MUC1 antigen intended for treatment of pancreatic cancer and MUC1 expressing tumors. The MUC1 is aberrantly glycosylated and overexpressed in a variety of epithelial cancers, and plays a crucial role in progression of the disease. The extracellular domain of MUC1 can serve as a ligand for stromal and endothelial cell adhesion receptors, and the cytoplasmic domain engages in several interactions that can result in increased migration and invasion, as well as survival. mAb-AR20.5 binds with high affinity to MUC1, which shed off from tumor cell when patients receive radiotherapy or chemotherapy, recognizing the tandem repeat peptide sequence DTRPAP of MUC1 extracellular domain.

The mechanism of action of mAb-AR20.5 includes the generation of MUC1-specific immune responses through complex formation of the murine antibody with MUC1 in circulation and/or on MUC1-expressing tumor cells. Dendritic cells that acquire antigenic substances through receptor-mediated endocytosis (FcR, C-type lectins, complement receptors) as compared with macropinocytosis show facilitated uptake and T-cell activation. A “neoantigen –like” immune complex form, taken up by such receptors, have been shown to induce CD4+ and CD8+ T-cell responses. Current evidence shows a stronger CD4+ and CD8+ T-cell induction with dendritic cells pulsed *ex vivo* with MUC1-antibody complexes compared with dendritic cells pulsed with MUC1 alone. Engagement of the activating Fc receptors (CD16, CD64) also induced dendritic cell maturation. The results suggest that effective immunotherapy may be generated in immune complex form. Intravenously administered low-dose antibodies mAb-AR20.5 can target circulating antigen MUC1 and form immune complex *in vivo* that are taken up by antigen-presenting cells and thereby promote a more effective presentation of the antigen to the immune system.

BUSINESS

Summary of Clinical Trial Data

Overview

A phase I clinical trial was completed in 2004 to evaluate the safety and immunology of mAb-AR20.5 in patients with metastatic cancer at 1, 2 and 4-mg doses. The clinical results demonstrated the bioactivity of mAb-AR20.5 along with a favorable safety profile.

Trial Design

The phase I clinical trial enrolled 17 patients with MUC1-positive cancers, who received intravenous infusions of the antibody over 30 min on weeks 1, 3, 5, 9, 13 and 17 of treatment. Patients received either a 1-, 2- or 4-mg dose of mAb-AR20.5. The principal objectives of this study were to: (i) characterize the toxicities of mAb-AR20.5 administered as a 30-min intravenous infusion on weeks 1, 3, 5, 9, 13 and 17 in patients with advanced solid malignancies at 1-, 2- and 4-mg doses; (ii) determine the most immunogenic dose with acceptable toxicity and recommend a safe starting dose on this schedule for phase II studies; (iii) characterize the humoral and cellular immunological responses induced by mAb-AR20.5; and (iv) seek preliminary evidence of antitumor activity.

Efficacy Data

Overall, five of 15 evaluable patients developed human anti-mouse antibodies (HAMA), five developed anti-idiotypic antibodies and seven developed anti-MUC1 antibodies. Immune responses were most prominent in the 2-mg dose cohort for all parameters tested, and treatment-emergent MUC1-specific T-cell responses were detected in five of 10 evaluable patients treated with mAb-AR20.5. 2-mg dose cohort and 4-mg dose cohort generate MUC1 specific T cell response. There were no objective antitumour responses.

Safety Data

Clinical results show that mAb-AR20.5 was well tolerated at all of the dose levels tested did not induce hypersensitivity reactions, with minimal toxicity being observed during this study. None of the patients discontinued the study due to adverse events, and there was no dose-limiting toxicity. Five patients were reported as having infusion-related adverse events. The majority of reported events were classified as NCI CTC grade 1 or 2. Most adverse events appeared to be transient, non-clinically significant and resolved without medical intervention.

Summary of PreClinical Data

A preclinical study was completed in 2016, which investigated the anti-tumor effect of mAb-AR20.5 in combination with anti-PD-L1 and Poly (I:C) in murine models of pancreatic adenocarcinoma using human MUC1 expressing transgenic (hMUC1.Tg) mice, which are immunologically tolerant to MUC1. The therapeutic combination of mAb-AR20.5+anti-PD-L1+Poly (I:C) induced rejection or significant inhibition of tumor growth for two different MUC1 expressing pancreatic tumor cell lines, which was accompanied by persistent MUC1 specific memory immune response, which could be adoptively transferred to other mice and shown to protect against subsequent tumor challenge.

Together, these data support the hypothesis that targeting checkpoint induced immunosuppression (anti-PD-L1) together with the use of toll-like receptor 3 agonist as an adjuvant

BUSINESS

(poly (I:C)) enhances the capacity of mAb-AR20.5 to induce specific cell mediated immune responses to MUC1, which in turn provide long lasting anti-tumor response against pancreatic tumors. The study provides a proof of principle that an effective and long-lasting anti-tumor cellular immunity can be achieved in pancreatic tumor-bearing hosts against their own antigen (MUC1), which can be further potentiated using a vaccine adjuvant and an immune checkpoint inhibitor. The results support the rapid translation of this strategy into clinical trials for pancreatic cancer patients.

Clinical Development Plan

OncoVent is in the process of preparing for phase Ib/II clinical trial to assess the safety and efficacy of using combined treatment of mAb-AR20.5 and chemotherapy (FOLIRINOX) for pancreatic cancer.

AR – 301

AR-301 is a first-in-class fully human monoclonal IgG1 antibody (mAb), being developed for the treatment of patients with severe ventilator-associated pneumonia (VAP) or hospital-acquired pneumonia (HAP) caused by *Staphylococcus aureus* (*S. aureus*). AR-301’s mode of action is independent of the antibiotic resistance profile of *S. aureus* and it is active against infections caused by both methicillin-resistant staphylococcus aureus (MRSA) and methicillin-sensitive staphylococcus aureus (MSSA). AR-301 is being developed by Aridis in which we hold 9.86% equity interest. Shenzhen Arimab, a joint venture company formed by Aridis and us, in which hold 51% equity interest, acquired the exclusive development and commercial rights of AR-301 in Greater China in February 2018. We are entitled to additional economic interest in Shenzhen Arimab through our investee company which holds the remaining 49.00% of its equity interest. AR-301 has been granted Fast Track Designation by the FDA and Orphan Drug Designation by the EMA.

Market opportunity and competition

There is significant market potential for the treatment of VAP and HAP caused by *S. aureus* in China. According to Frost & Sullivan, the incidence of VAP and HAP caused by *S. aureus* in China increased from 326.3 thousand in 2014 to 411.1 thousand in 2018, representing a CAGR of 5.9%, which is expected to reach 571.8 thousand by 2028 at a CAGR of 3.4%, and 657.7 thousand by 2035 at a CAGR of 2.0%.

Anti-infection therapy of VAP and HAP includes initial empiric antibiotic therapy with monotherapy or combined antibiotic therapy, that evolves into pathogen-specific antibiotic therapy. MRSA is one of the most common drug-resistant pathogens in VAP and HAP. Glycopeptides and linezolid are two antibiotics commonly used for MRSA-specific infections, and development of further drug resistance is a major concern.

Anti-infective mAbs is a new class of anti-infective drugs that has the potential to become the standard of care treatment for VAP and HAP due to its superior safety profile, a remarkably long plasma half-life period, and a low possibility of drug resistance.

According to Frost & Sullivan, as of the Latest Practicable Date, there was no approved or commercialized drug and only one drug candidate at clinical stage with similar mechanism as AR-301

BUSINESS

that specifically neutralizes the pathogenic effects brought about by *S. aureus* toxins, as shown in the table below:

Global Pipelines Targeting Staphylococcus Aureus α Toxin ¹			
Pipeline	Indication	Company	Status
AR-301	<ul style="list-style-type: none"> Ventilator-Associated Infection 	Aridis Pharmaceuticals ¹	Phase III
MEDI-4893	<ul style="list-style-type: none"> Staphylococcus Aureus Pneumonia 	MedImmune LLC	Phase II

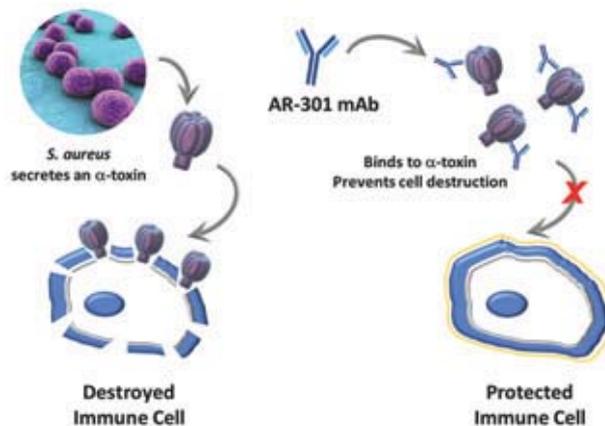
1. Preclinical pipelines are excluded.
 2. Shenzhen Arimab has the exclusive rights to develop and commercialize the drug candidate in Greater China. We directly hold 51.00% equity interest in Shenzhen Arimab and are entitled to additional economic interest through our investee company which holds the remaining 49.00% of its equity interest. We also holds 9.86% of equity interest in Aridis.

Source: Frost & Sullivan Report

Please refer to the sub-section headed “Industry Overview—Innovative Drug Market—VAP and HAP Caused by *Staphylococcus Aureus*” for more details.

Mechanism of Action

AR-301 specifically targets *S. aureus* alpha-toxin, an important virulence factor that is secreted by both MRSA and MSSA. AR-301 binds to alphatoxin with high affinity and prevents its assembly into an active complex, which prevents alphatoxin-mediated breakdown of cell membranes, or cell lysis of erythrocytes, human lung cells and immune cells such as lymphocytes. This prevention of killing of host cells, in turn, may protect the patient from further progression of pneumonia disease and systemic spread of infections caused by *S. aureus*. During infection and active proliferation, *S. aureus* is metabolically more virulent, geared toward higher toxin production than during a more sessile colonization stage. In contrast to other programs targeting *S. aureus* colonization, AR-301 targets the active, disease enhancing infection stage. We believe that this mechanism of action complements the bacterial killing properties of multiple conventional antibiotics, essentially neutralizing the bacterial toxins left behind following antibiotic-mediated killing. Additional indications for AR-301 may include other *S. aureus* infections, particularly surgical site infections, blood stream infections (bacteremia and/or endocarditis), septic arthritis and osteomyelitis, skin and soft tissue infections and non-healing wounds such as diabetic ulcers.



Source: prospectus of Aridis dated August 13, 2018

BUSINESS

Summary of Clinical Trial Data

Overview

A double-blind, placebo-controlled, active comparator, ascending dose phase I/II clinical trial of AR-301 was completed in September 2016 to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and explore efficacy of a single intravenous administration of AR-301 plus SOC antibiotics in patients with severe VAP caused by *S. aureus*. The phase I/II clinical results showed that patients treated with AR-301 spent less time on mechanical ventilation and there was a trend toward higher and faster eradication rates of *S. aureus* compared with the placebo group treated with SOC antibiotics alone.

Trial Design

The phase I/II clinical trial included 13 sites located across Belgium, France, Spain, the United Kingdom, and the U.S. and was designed primarily to address the safety and pharmacokinetics of AR-301. 48 patients were enrolled in the study. Six patients enrolled in the first cohort (1 mg/kg AR-301 plus SOC), eight in the second cohort (3 mg/kg AR-301 plus SOC), ten in the third cohort (10 mg/kg AR-301 plus SOC) and eight in the fourth cohort (20 mg/kg AR-301 plus SOC). An additional 16 patients received placebo plus SOC as a blind control.

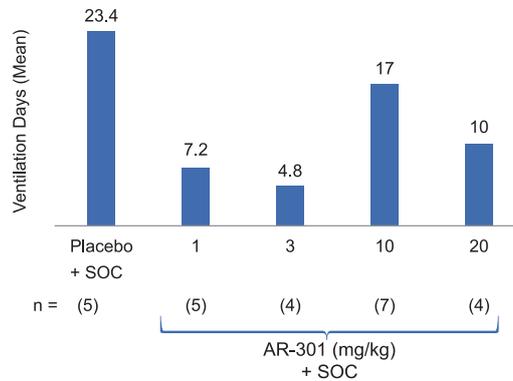
Efficacy Data

Multiple efficacy endpoints of clinical improvement were evaluated, including time to extubation, ventilation time and microbiological outcomes. In exploratory analysis of the VAP subgroup of 25 patients, numeric clinical improvement of antibody treated patients over placebo were observed in time to extubation. The clinical results suggest that the addition of AR-301 to SOC treatment may increase the rate of microbiological eradication, and may reduce time to eradication, time on mechanical ventilation and overall duration of hospital stay.

Time intubated to day 28 showed a decrease in the length of time patients who were treated with AR-301 plus SOC remained intubated as compared to those receiving placebo and SOC. When the subset of 25 patients with VAP was assessed, ventilation time was reduced numerically for patients in all four active dose groups receiving AR-301 plus SOC compared to those receiving placebo plus SOC. The lack of dose response could be attributed to high variability associated with a small sample size, and/or to the high level of circulating AR-301 mAb as compared to alphatoxin load in infected patients, as even at the lowest dose administered (i.e. one mg/kg), it is estimated that there is more than ten-fold mAbs than the predicted alphatoxin load.

BUSINESS

**Observed Ventilation days in VAP patients
(n =25, microbiologically confirmed VAP,
intent to treat population)**



Source: Francois et al., 2018 Safety and tolerability of a single administration of AR-301, a human monoclonal antibody, in ICU patients with severe pneumonia caused by *Staphylococcus aureus*: first-in-human trial

With respect to the microbiological outcomes in the overall study population, eradication or presumed eradication (cured of pneumonia) was observed in 25 (80.6%) of 31 patients treated with AR-301 plus SOC and ten (62.5%) of 16 subjects treated with placebo plus SOC. The mean time to eradication of *S. aureus* bacteria (Day to eradicate) also trended shorter in AR-301 treated cohorts as compared to the placebo cohort.

Details of microbiological outcome by treatment cohort are illustrated below.

	Placebo (Placebo + SOC) SOL	Cohort 1 (AR-301 1 mg/kg + SOC) n = 6	Cohort 2 (AR-301 3 mg/kg + SOC) n = 8	Cohort 3 (AR-301 10 mg/kg + SOC) n = 9	Cohort 4 (AR-301 20 mg/kg + SOC) n = 8	All treated n = 31
Eradicated	7 (43.8%)	1 (16.7%)	5 (62.5%)	4 (44.4%)	4 (50.0%)	14 (45.2%)
Day to eradicate	10.9±4.4	8.0	9.4±3.1	9.8±3.5	8.8±1.0	9.2±2.5
Presumed eradicated	3 (18.8%)	4 (66.7%)	2 (25.0%)	3 (33.3%)	2 (25.0%)	11 (35.5%)
Eradicated or presumed eradicated . . .	62.5%	83.3%	87.5%	77.8%	75.0%	80.6%

Source: Francois et al., 2018 Safety and tolerability of a single administration of AR-301, a human monoclonal antibody, in ICU patients with severe pneumonia caused by *Staphylococcus aureus*: first-in-human trial

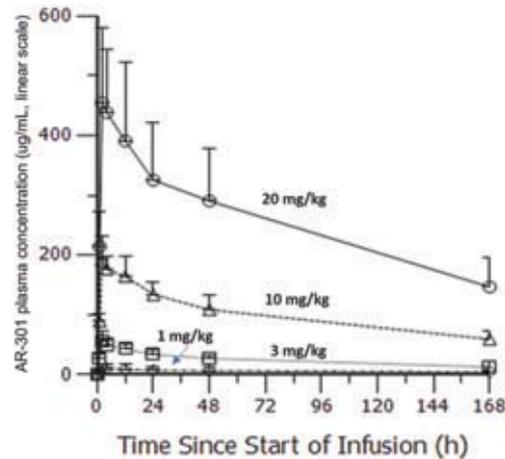
When clinical cure was assessed based on the sole judgment of the investigator, there was no statistically significant difference between the groups, and the overall cure rate was high compared to historic published references. Over the first 28 days of the study, the length of stay in the ICU and in the hospital both showed a modest decrease in the AR-301 plus SOC groups as compared to placebo plus SOC-treated subjects, however, this difference did not reach statistical significance.

Safety Data

Data from the Phase I/II clinical trial suggests that AR-301 was well tolerated as adjunctive treatment for severe pneumonia caused by *S. aureus* when used as directed and in addition to antibiotics. Few AEs, with an incidence rate of 2.3% were considered treatment-related by the investigators. None of the SAEs were deemed related to AR-301 treatment. Immunogenicity was observed in one subject, with no related adverse event. No significant difference in mortality was observed between groups. There were six deaths in the trial, none of which were deemed related to AR-301. The pharmacokinetic, or PK, profile of AR-301 is consistent with that of a human IgG1mAb,

BUSINESS

with a plasma half-life of 23 to 31 days, and supports a single-dose administration for the pneumonia indication, as illustrated in the diagram below.



Source: Francois et al., 2018 Safety and tolerability of a single administration of AR-301, a human monoclonal antibody, in ICU patients with severe pneumonia caused by *Staphylococcus aureus*: first-in-human trial

Clinical Development Plan

A global phase III randomized, double-blind, placebo-controlled clinical trial is currently ongoing, which compares the treatment with active comparator AR-301 (20 mg/kg) plus SOC to treatment with placebo plus SOC. The trial started in May 2019 and targets to enroll approximately 240 patients in over 15 countries. We will join the phase III trial under MRCT by undertaking clinical trial in China, and received the NMPA approval for such trial in July 2019.

AR—101

AR-101 is a first-in class human IgM monoclonal antibody targeting lipopolysaccharide (LPS) on the surface of *P. aeruginosa* serotype O11, being developed by Aridis for treatment of patients with severe VAP or HAP caused by *Pseudomonas aeruginosa* (*P. aeruginosa*). Shenzhen Arimab acquired the exclusive rights to develop and commercialize AR-101 in Greater China in February 2018. It has been granted an Orphan Drug Designation from the FDA and EMA.

Market opportunity and competition

There is significant market potential for the treatment of HAP and VAP caused by *P. aeruginosa* in China. According to Frost & Sullivan, the incidence of HAP and VAP caused by *P. aeruginosa* in China grew from 446.3 thousand in 2014 to 558.2 thousand in 2018, representing a CAGR of 5.8%, which is expected to increase to 823.2 thousand by 2028 at a CAGR of 4.0%, and to 948.3 thousand by 2035 at a CAGR of 2.0%.

P. aeruginosa is a common pathogenic bacteria of HAP and VAP, which can be treated by specific antibiotics such as cephalosporin, carbapenem, β -lactamase inhibitors, aminoglycosides and polymyxin. However, anti-microbial resistance in major pathogens of HAP and VAP, such as *P. aeruginosa*, may ultimately result in treatment failure. Anti-infective mAbs is a new class of anti-infective drugs that may become the standard of care treatment for HAP and VAP caused by *P. aeruginosa* due to its superior safety profile and a lower possibility of drug resistance.

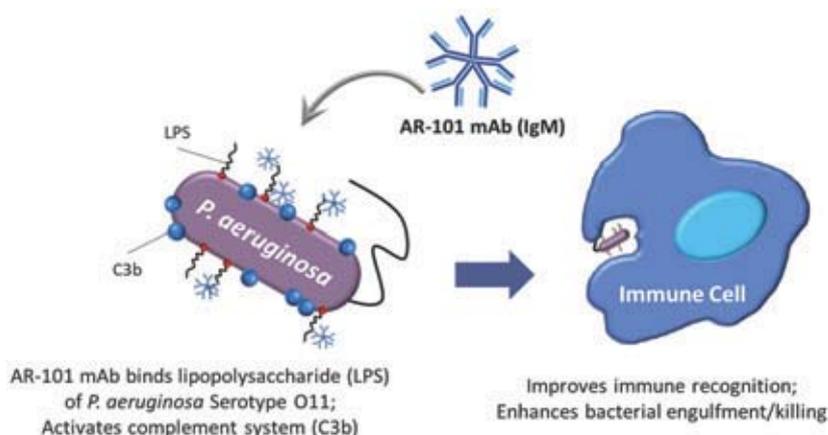
BUSINESS

According to Frost & Sullivan, as of the Latest Practicable Date, there was no approved or commercialized drug or drug candidate at clinical stage with similar mechanism as AR-101 that is effective against multidrug resistant LPS serotype O11 *P. aureus* clinical isolates.

Please refer to the sub-section headed “Industry Overview—Innovative Drug Market—HAP and VAP Caused by *Pseudomonas aeruginosa*” for more details.

Mechanism of Action

AR-101 targets against *P. aeruginosa* lipopolysaccharide serotype O11. Binding of AR-101 to *P. aeruginosa* pneumonia bacteria facilitates human complement binding and improves immune recognition and destruction by circulating human phagocytes. AR-101’s mechanism of action is distinct from mechanisms of antibiotic resistance, and is effective against multidrug resistant LPS serotype O11 *P. aeruginosa* clinical isolates. Upon binding, AR-101 mediates the deposition of the human complement to the surface of *P. aeruginosa* bacteria. This antibody-complement complex leads to improved recognition by the host immune cells, which results in engulfment and killing of the bacteria. AR-101, like IgM antibodies in general, provides several advantages towards more effective bacterial killing. They possess ten binding sites rather than two for IgG, and they are 100 to 1,000 times more effective than IgG at binding and/or activating key enzymes that facilitate the killing of *P. aeruginosa*. As a result, IgM antibodies are becoming more prevalent as candidates for drug therapies.



Source: Aridis Prospectus dated August 13, 2018

Summary of Preclinical Data

AR-101 reacts with a wide range of *P. aeruginosa* serotype O11 clinical isolates from different hospitals, indicating broad application against infections with this serotype. AR-101 is also capable of stimulating phagocytic immune cells to ingest *P. aeruginosa* bacterial cells in a dose dependent manner, thereby killing the pathogen. Passive immunization with murine mAb recognizing O-polysaccharides in LPS of *P. aeruginosa* conferred protection against lethal challenge with live pseudomonas bacteria in several animal models of pneumonia infections. In preclinical studies, AR-101 was found to demonstrate attenuating protection against pulmonary infections caused by *P. aeruginosa* serotype O11 and exhibited a complementary effect with meropenem, a broadspectrum antibiotic.

Additionally, the following observations were found in preclinical studies of AR-101. AR-101 protected mice in a dose-dependent manner from *P. aeruginosa* infection after a burn-wound

BUSINESS

challenge. Doses of five mg/mouse (corresponding to about 0.2 mg/kg body weight) conferred 70% to 100% protection from systemic *P. aeruginosa* challenge. Administration of decreasing doses resulted in lower survival rates and administration of AR-101 led to rapid clearance of *P. aeruginosa* from the lung in mice and was associated with milder lung pathology six and 24 hours after infection. In addition, AR-101-treated animals had a significantly lower systemic *P. aeruginosa* bacterial load compared to control animals that received saline. To mimic the adjunctive use of AR-101 in humans, AR-101 was administered in combination with meropenem (used clinically to treat pseudomonal infections) in a modified lung challenge model. When meropenem and AR-101 were administered in combination, significant reductions in lung weight (a surrogate marker for injection-induced inflammation), bacterial load and lung inflammation were observed in infected mice compared to each agent given alone.

Summary of Clinical Trial Data

Overview

Two clinical studies of AR-101 were completed, including a phase I safety and tolerability trial of single ascending doses of AR-101 in healthy adults and an open-label phase IIa safety and pharmacokinetics trial of up to three single doses of AR-101 in pneumonia patients. These studies suggested AR-101 to be generally well tolerated in both healthy adults and HAP and VAP patients. Also, a contemporaneous control cohort suggested that AR-101 therapy may improve survival, cure rate of the index pneumonia, and time to cure pneumonia.

Trial Design

Phase I study was a randomised, double-blind, placebo-controlled study in healthy volunteers to assess the safety and pharmacokinetic characteristics of AR-101. The study enrolled 32 volunteers in four antibody treatment cohorts at doses of 0.1, 0.4, 1.2 and 4.0 mg/kg as well as placebo cohort.

The open-label phase IIa study was the first study performed in the target indication of patients with severe bacterial pneumonia caused by *P. aeruginosa* serotype O11. Patients treated with AR-101 (n=17), including 13 patients receiving the full treatment (three doses of 1.2 mg/kg), were compared to 14 patients who did not receive the antibody. Overall, the 17 patients receiving AR-101 were more ill.

Phase I Clinical Data

No SAEs were observed, and no subject was discontinued due to an AE. Reported AEs were mild or moderate in intensity, and all resolved without sequelae, and the incidence of AEs did not increase with the dose. There was no activation of an immune response against AR-101. Pharmacokinetic characteristics that were observed were consistent with the characteristics of a human IgM, with a serum half-life between 70 and 95 hours.

Phase IIa Clinical Data

Adjunctive therapy AR-101 resulted in an improved clinical outcome in the group receiving the full three-course AR-101 treatment, with a resolution rate of 85% (11/13) versus 64% (9/14) (p=0.048). The data showed a statistically significantly shorter time to clinical resolution in this group of patients (8.0 versus 18.5 days in those who did not receive the antibody; p=0.004), and more disease-free days (22 versus 12.5 days in those who did not receive the antibody (p=0.028)). Adjunctive therapy AR-101 may improve clinical outcome in a shorter time if patients receive the full treatment (three doses). The mortality rates were not statistically significant between groups.

BUSINESS

These preliminary results suggest that AR-101 targeting LPS may be a complementary strategy for the treatment of *P. aeruginosa* pneumonia.

	All patients (n=31)	Not treated with AR-101 (n=14)	AR-101“intent-to-treat”, ≥1 dose (n=17)	AR-101“per-protocol”, three doses (n=13)	<i>p</i> -Values: not treated vs. ≥1 dose, not treated vs. three doses
Time (days) to clinical resolution of pneumonia, median (IQR) . . .	12.0 (8.0-30)	18.5 (8.0-30)	10.0 (7.0-23)	8.0 (7.0-12)	NS, 0.004
Clinical resolution of pneumonia, <i>n</i> (%)	20 (65%)	9 (64%)	11 (65%)	11 (85%)	NS, 0.048
Disease-free days	18 (0-22)	12.5 (0-22)	20 (7.5-23)	22 (18.5-23)	NS, 0.028
Relapse within 30 days, <i>n</i> (%)	4 (13%)	1 (7%)	3 (18%)	2 (15%)	NS, NS
Survival at day 30, <i>n</i> (%)	25 (81%)	11 (79%)	14 (83%)	13 (100%)	NS, NS

IQR interquartile range

Source: Y.-A. Que et al., 2014 Assessment of AR-101 as adjunctive immunotherapy for the treatment of nosocomial *Pseudomonas aeruginosa* pneumonia

Clinical Development Plan

Aridis is currently preparing for the phase IIb clinical trial. As with the prior phase IIa study, the primary efficacy endpoint in this study will include clinical cure rate. Time to clinical cure will be evaluated in detail in the phase IIb study. Microbiological endpoints as well as select pharmacoeconomic endpoints and pharmacokinetics will also be assessed.

RVX—208

RVX-208 is an investigational first in class oral BET inhibitor that preferentially targets bromodomain 2 (BD2) of BET proteins, indicated for treating type 2 diabetes patients with coronary heart disease (CHD) and patients with chronic kidney disease (CKD). We obtained the exclusive development and commercial rights in Greater China from Resverlogix in July 2015, in which we held 38.80% equity interest as of the Latest Practicable Date.

Market opportunity and competition

There is significant market potential for the treatment of type 2 diabetes with CHD and CKD in China. According to Frost & Sullivan, the diagnosed patients of type 2 diabetes with CHD in China grew from 5.1 million in 2014 to 6.1 million in 2018, representing a CAGR of 4.6%, and is expected to increase to 10.8 million by 2028 at a CAGR of 5.9%, and to 12.5 million by 2035 at a CAGR of 2.1%. The diagnosed diabetic patients of CKD in China increased from 10.6 million in 2014 to 12.7 million in 2018, representing a CAGR of 4.6%, which is expected to reach 23.4 million by 2028 at a CAGR of 6.3%, and 28.3 million by 2035 at a CAGR of 2.8%.

Although treatment of cardiovascular disease (CVD) includes many therapeutic agents, for example lipid lowering drugs such as statins, heart rate lowering agents such as beta blockers and blood pressure lowering drugs such as ACE inhibitors, there still remains a large residual risk of MACE in patients that receive these treatments. RVX-208 has illustrated potential to become an important and differentiated therapeutic for this high-risk population. All BET proteins contain highly-conserved bromodomains that play a key role in epigenetic control of gene expression in many cell types, and RVX-208 functions via inhibition of BET bromodomain binding to chromatin, thereby

BUSINESS

modulating transcription of particular targets. Moreover, RVX-208 preferentially binds to the second bromodomain of BET family members, including BRD2, BRD3 and BRD4, with a 20-fold or higher selectivity for the second bromodomain versus the first bromodomain. Also, RVX-208 has effects on multiple pathways and biomarkers that function in concert to reduce CVD events, which is highly differentiated from other therapies that focus only on single biological targets, such as increasing HDL or decreasing low-density lipoprotein in plasma.

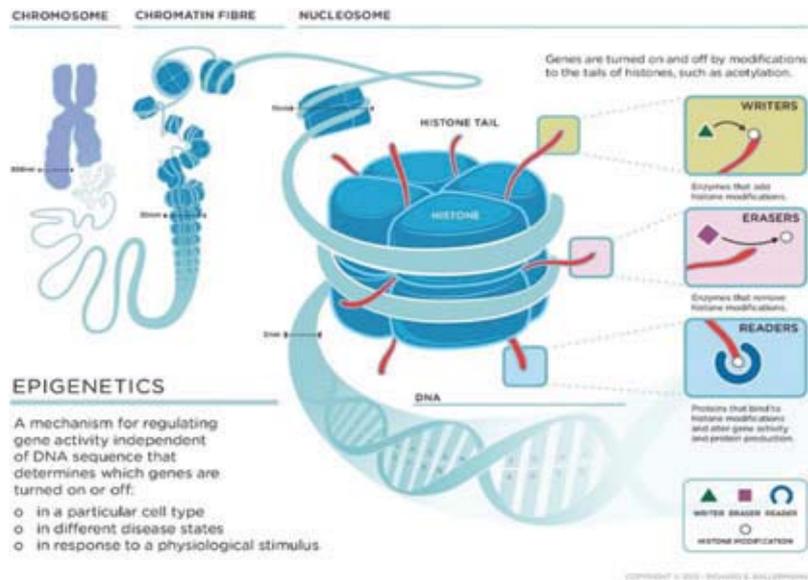
According to Frost & Sullivan, as of the Latest Practicable Date, RVX-208 was the only selective BET inhibitor in the field of high risk CVD and CKD with no known competitor. Please refer to the sub-sections headed “Industry Overview—Innovative Drug Market—Type 2 Diabetes with CHD” and “Industry Overview—Innovative Drug Market—Chronic Kidney Disease” for more details.

Mechanism of Action

RVX-208 is the first BET inhibitor in clinical trials for high risk vascular disease. Bromodomains (“BRDs”) are a family of evolutionary conserved protein-interaction modules that play key functions in chromatin organisation and regulation of gene transcription. One recognised family of bromodomain-containing proteins is the BET family. RVX-208’s “Epigenetic Mechanism of Action” illustrates that it functions as an inhibitor of the BET proteins. RVX-208 is the first oral agent in the BET inhibitor class that preferentially targets bromodomain 2 (“BD2”) of BET proteins. In binding to this bromodomain, RVX-208 affects the expression of multiple genes with roles in a variety of cellular processes.

The human body is made up of nearly two hundred different cell types that have cell-specific functions resulting from the selective production of the proteins encoded by human DNA and, more specifically, human genes. Aberrant levels of proteins can contribute to disease progression and disease states. Epigenetics describes the mechanisms by which gene activity is regulated, thereby affecting levels of transcription into messenger RNA (“mRNA”) which is then translated into protein. Epigenetics is the study of modifications to chromatin (DNA associated with proteins) that, without affecting the DNA sequence, result in regulation of gene transcription, the first step in producing the proteins that each gene encodes. Such modifications determine whether a gene is “on” or “off” or whether its activity is high or low in a particular cell type, in different disease states or in response to a physiological stimulus. Chromatin modifications are added by enzymes called “writers” and removed by enzymes called “erasers”. Other proteins, called “readers”, recognize a specific pattern of modifications. In contrast to “writers” and “erasers” that add or remove post-translational modifications, “readers” detect the presence or absence of these modifications and serve as a scaffold for the transcriptional machinery directly responsible for gene expression. BET proteins are “readers”, proteins that recognize a specific pattern of modifications and bind to the chromatin at these sites. The BET proteins then serve as a scaffold, recruiting the necessary transcriptional machinery to the chromatin to drive gene expression and ultimately protein production.

BUSINESS



Source: <https://www.resverlogix.com/science-and-programs/epigenetics>

RVX-208 targets BET proteins to impact several important biological processes that are contributors to the pathophysiology of chronic vascular diseases such as CHD. These pathways include vascular inflammation, vascular calcification, complement and coagulation, reverse cholesterol transport and metabolism.

Summary of Clinical Trial Data

Overview

A phase III clinical trial was completed in the fourth quarter of 2019 to assess the safety and efficacy in treating type 2 diabetes patients with coronary heart disease. Though the primary endpoint was narrowly missed, as a result of the lower than anticipated placebo event rate due to the application of new drugs, the consistent positive trend in the efficacy data suggests that RVX-208 can further decrease MACE risk on top of best available SOC.

Trial Design

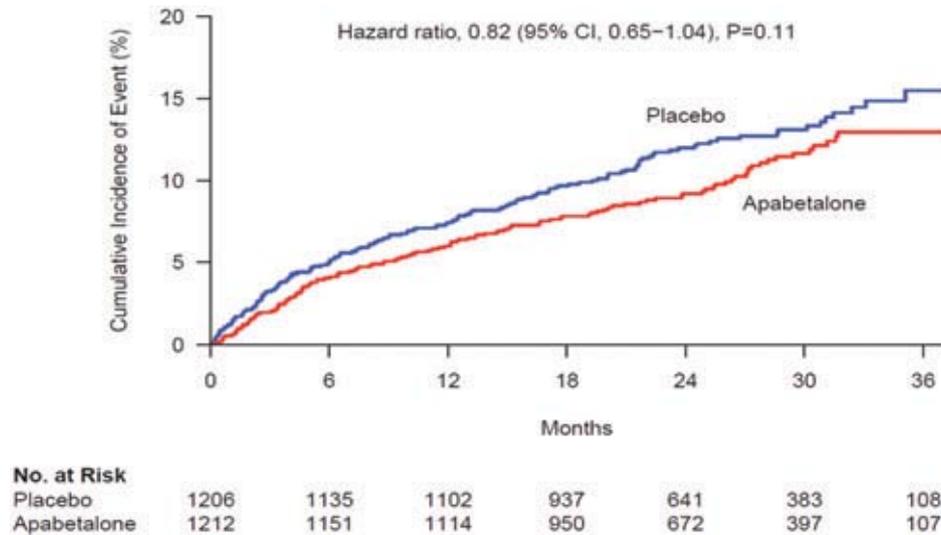
The clinical trial enrolled in total 2,425 patients with diabetes and low HDL cholesterol (< 40 mg/dL for men and < 45 mg/dL for women) who had an ACS event within 7-90 days of screening. The trial was approved in 14 countries and was conducted in 220 sites. Patients were randomized to receive standard of care plus 100 mg of RVX-208 twice daily (n = 1,212) or placebo (n = 1,206) until 250 adjudicated primary endpoint events of cardiovascular death or non-fatal myocardial infarction or stroke occurred, which were defined as triple MACE. The primary endpoint was the time to first occurrence of adjudication-confirmed triple MACE.

BUSINESS

Efficacy Data

The trial results show a narrow miss on the primary endpoint, with an 18% hazard reduction among patients treated with SOC plus RVX-208 compared with patients who received placebo, (p = 0.11).

Kaplan-Meier Estimates of Time to First Occurrence of the Primary Efficacy Endpoint (cardiovascular death or non-fatal myocardial infraction or stroke)

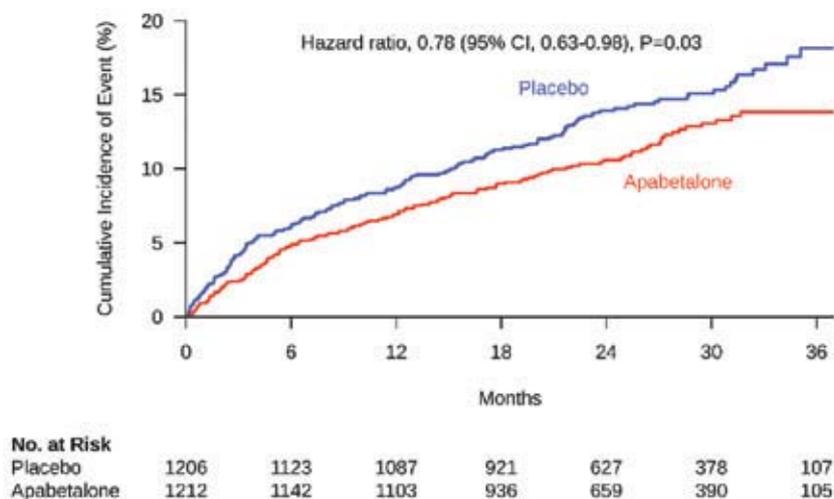


Source: RVX-208 summary report

Post ACS diabetes patients have a high incidence rate of congestive heart failure (CHF) possibly because lack of collateral vessels and a stunned myocardium. In BETonMACE 77 patients had CHF hospitalization as a first event. When CHF was added to the primary endpoint posthoc as the fourth MACE, a nominally significant reduction of 22% was seen, (p = 0.03) as illustrated in the figure below.

BUSINESS

Kaplan-Meier Estimates of Time to First Occurrence of the cardiovascular death, non-fatal myocardial infraction, stroke or first hospitalization for congestive heart failure



Source: RVX-208 summary report

Also, RVX-208 improved CVD outcomes in the subgroup of patients with renal impairment, with baseline estimated glomerular filtration (eGFR) below 60mL/min. Especially, there is a 50% hazard reduction in narrowly defined MACE, among patients treated with RVX-208 plus SOC, compared with patients who receive placebo, (p = 0.03).

Safety Data

RVX-208 was generally well tolerated with an overall incidence of AEs and SAEs similar to that of the placebo group.

Clinical Development Plan

Resverlogix has been continuously discussing with the FDA regarding the clinical development approach based on phase III trial results. Resverlogix will include 11% of participants from BETonMACE in the study of CKD indication and plans to move to phase III in 2020.

H1710

H1710 is a heparin-like compound that inhibits heparanase activity. The drug candidate is currently at preclinical stage. We are preparing for the IND filing for H1710 in both China and the U.S., and we aim to submit the IND application as an oncology drug candidate with the NMPA and the FDA by the end of 2020.

Market Opportunity and Competition

Heparanase is a heparin sulfate specific endo-β-D glucuronidase. Expression of heparanase is observed in almost all types of cancer examined, including various carcinomas, sarcomas and hematological malignancies and tightly correlates with increased tumor size, angiogenesis, metastasis and poor prognosis.

BUSINESS

SST0001 (roneparstat) is one heparanase inhibitor currently under clinical study. Roneparstat is a modified heparin composed of 100% N-acetylated and 25% glycol split. Compared to unmodified heparin, roneparstat is able to inhibit the heparanase enzymatic activity with a decreased ability to release extracellular matrix-bound FGF-2. Roneparstat was well tolerated and safe at all the dose levels tested. Patients are able to consume the drug at the dose levels of 200 and 400 mg/day without showing clinically relevant toxicities. Currently, there is no marketed drugs targeting heparanase. Please refer to the sub-sections headed “Industry Overview—Innovative Drug Market—Heparanase Inhibitors” for more details.

Since heparanase acts on the HS chain of the extracellular matrix (ECM), it plays an important role in tumor metastasis, growth, and regulation of the tumor microenvironment. Different from cytotoxicity or targeting therapeutics, heparanase inhibitors are expected to have a comprehensive inhibitory effect on the growth and metastasis of tumors, and can be combined with cytotoxic drugs, targeting therapeutics or immunotherapy to have a synergistic effect.

As of the Latest Practicable Date, there was no approved or commercialized heparanase inhibitor worldwide, and there were two clinical-stage drug candidates targeting heparanase globally as shown in the table below:

Global Pipelines Targeting Heparanase ¹			
Pipeline	Indication	Company	Status
SST0001	Multiple Myeloma	Sigma Tau	Phase I
PG545	Advanced Solid Tumours	Zucero	Phase I

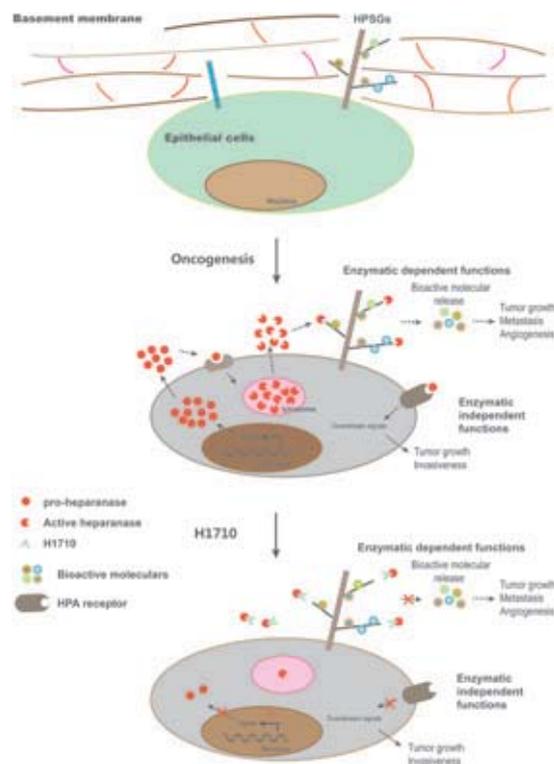
1. Pre-clinical pipelines are excluded.

Source: Frost & Sullivan Report

BUSINESS

Mechanism of Action

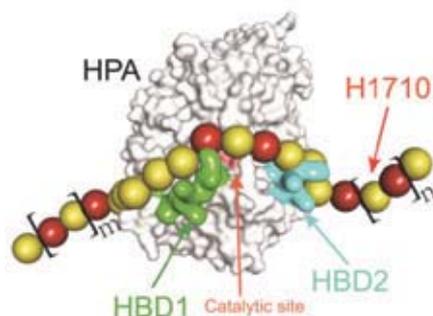
Heparanase is a versatile protein endowed with enzymatic activity dependent and independent functions to play crucial roles in multiple human pathological processes, among them the most attention rendered in tumor biology. Heparanase is the sole endoglycosidase responsible for degrading heparan sulfate (HS) chains in the extracellular matrix (ECM), which function in tumorigenesis via various mechanisms, including promoting the self-assembly, insolubility and structural integrity of ECM, trapping a wide variety of bioactive molecular (i.e., cytokines, chemokines, growth factors, enzymes, protease inhibitors and ECM components) by its abundant negative charge groups. Release of these bioactive molecular by heparanase-mediated HS cleavage will undoubtedly make up a repertoire of fuels for tumor development. Enzymatically inactive heparanase is also recognized as a ligand to interact with an unknown receptor to activate various downstream signal pathways and in turn support tumor growth, invasiveness and chemoresistance, as illustrated in the diagram below.



In addition, numerous mouse model and clinical association studies have consistently demonstrated that enhanced expression of heparanase is observed in almost all types of cancer examined, including various carcinomas, sarcomas and hematological malignancies, and tightly correlates with increased tumor size, angiogenesis, metastasis and poor prognosis.

BUSINESS

H1710 is a potent inhibitor of heparanase. It has suitable chain length to bind the two separate heparin-binding domains (HBDs) of heparanase. Its unique flexible chain can dive into the catalytic pocket and keep it from being degraded. In this way, H1710 decreases the pocket's accessibility and degrading ability to the natural substrate HS. The diagram below illustrates the postulated inhibitory mechanisms of H1710 on heparanase.

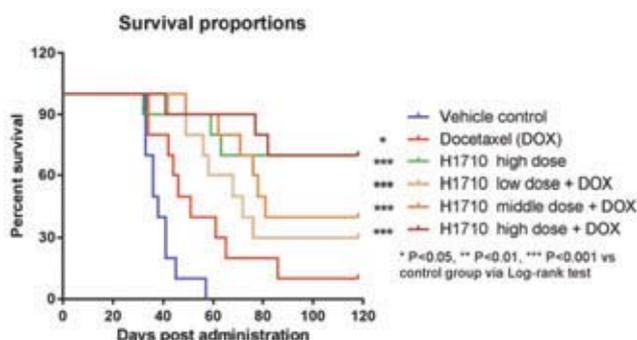


The unique structure and character of H1710 enable it to efficiently inhibit the activity of heparanase, reduce heparanase expression both *in vitro* in tumor cells and *in vivo* in tumors using pancreatic, lung and breast cancer models, and further demonstrate additive and/or synergistic effect with several cancer drugs including docetaxel, cisplatin and gemcitabine both *in vitro* and *in vivo*.

Summary of PreClinical Data

In the *in vitro* screening experiment, the inhibitory IC₅₀ value of H1710 on HPA activity was at the nM level, and it was one of the compounds with the best inhibitory activity currently found. A series of tests *in vitro*, including cell scratching, migration and cell growth, have also confirmed that H1710 is effective in inhibiting tumor cell metastasis and growth.

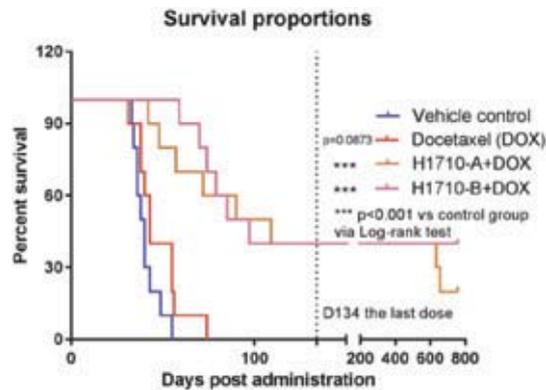
In a preclinical trial, we established a metastasis model by inoculating breast cancer cells 4T1 into mouse mammary fat pad and implementing mastectomy later, to test the efficacy of H1710 in inhibiting tumor metastasis. We found that the application of H1710 alone or application of H1710 combined with docetaxel (DOX) can significantly prolong the survival time of the treated mice ($p < 0.001$), as illustrated in the chart below.



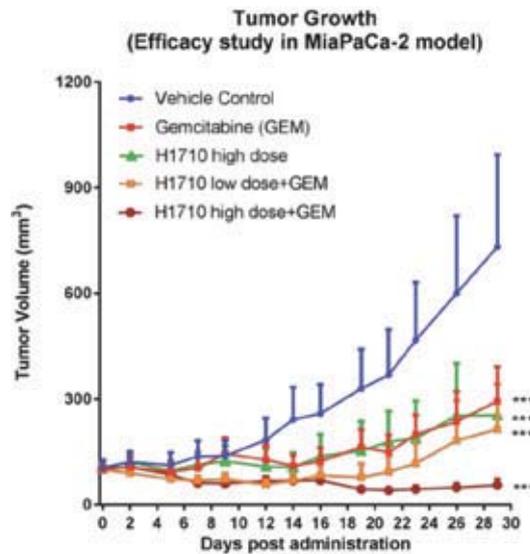
In individual trials of this model, we found that some H1710-treated mice survived more than two years and have achieved the effect of complete tumor healing, as illustrated in the diagram below. We stopped the treatment after 134 days. All the remaining mice survived for 630 days since the

BUSINESS

beginning of the trial, after which, two died because of aging, and the rest are alive until today, which have survived more than 750 days since the beginning of the trial.



We also tested H1710's effect in inhibiting tumor growth by inoculating human tumor cells into the left back of immunodeficient mice to establish a human carcinoma xenograft model. We found that H1710 has a good effect on various models such as pancreatic cancer and lung cancer. The results show that the application of H1710 alone or in combination with gemcitabine can significantly inhibit the growth of subcutaneous tumors. Some of the H1710-treated mice even show tumor shrinkage or disappearance. The diagram below is a subcutaneous tumor model of pancreatic cancer Mia PaCa-2.



Pipeline Drugs of Our Portfolio Companies

We have strategically invested in a number of biotech companies with first-in-class drug candidates in therapeutic areas that address the significant unmet clinical demands.

HighTide's HTD1801

As of the Latest Practicable Date, we held 47.02% equity interest in HighTide. HighTide's leading drug candidate, HTD1801, is a first-in-class oral small molecule drug candidate, currently in Phase II trials for the treatment of NASH and PSC. The FDA has granted HTD1801 Fast Track Designation in both diseases.

BUSINESS

NASH

There is significant market potential for the treatment of NASH in China. According to Frost & Sullivan, the prevalence of NASH in China grew from 32.8 million in 2014 to 36.2 million in 2018, representing a CAGR of 2.5%, which is expected to increase to 43.1 million by 2023 at a CAGR of 3.6%, and to 55.5 million by 2030 at a CAGR of 3.7%.

Currently, the most effective method to control NASH is changes in lifestyle, primarily through diet control and regular exercise. There is no evidence-based approved drug or surgical therapy for the treatment of NASH, suggesting significant unmet medical needs. All the drugs applied are used to treat the complications of NASH, prevent damages to the liver, and control the progression, however, there is no evidence that verifies their effects on treating NASH. Bariatric surgery aims to relieve symptoms and lower the risk of causing cardiovascular diseases, but no evidence has suggested its efficacy in treating NASH. Liver transplantation is also not a promising therapeutic option due to the lack of liver source and the high probability of recurrence. Numerous obstacles make drug development for NASH treatment a challenge. The complexity of the pathogenesis of the disease, which involves multiple pathways, requires targeting of more than one pathway or a combination-based therapy. The complex interactions among numerous metabolic pathways, the immune system and the gut prevent the development of a one drug-based therapy that can provide a cure for NASH.

As of the Latest Practicable Date, there was no approved or commercialized targeted drug for NASH globally. The following table shows the current status of drug candidates for NASH treatment at clinical stages worldwide:

Global Pipelines for NASH Treatment ¹			
Pipeline	Target	Company	Status
Obeticholic Acid	FXR	Intercept Pharmaceuticals	NDA for the indication of NASH
Resmetirom	THRβ	Madrigal Pharmaceuticals	Phase III
GS-4997	ASK1	Gilead Sciences	Phase III
Aramchol	SCD	Galmed Pharmaceuticals	Phase III
GFT-505	PPARα, PPARδ	Genfit	Phase III
Cenicriviroc Mesylate	CCR2, CCR5	Tobira Therapeutics, Inc.	Phase III
MSDC-0602K	NA	Cirius Therapeutics, Inc.	Phase III
HTD1801	Multiple target mechanism	HighTide Biopharma ²	Phase II

1. Pre-clinical pipelines are excluded.

2. Shenzhen Hepalink holds 47.02% of equity interest in HighTide Biopharma, in addition to the drug candidate's exclusive rights to develop and commercialize in Greater China.

Source: Frost & Sullivan Report

Please refer to the sub-section headed “Industry Overview—Innovative Drug market—Non-Alcoholic Steatohepatitis” for more details.

BUSINESS

Kymab’s drug candidates

As of the Latest Practicable Date, we held 8.60% equity interest in Kymab. Kymab has a broad pipeline of therapeutic antibody programmes, with the following four leading drug candidates for immune-oncology therapy with significant growth potential:

- KY1005, a Phase IIa OX40L targeting therapy for Atopic Dermatitis
- KY1044, a Phase I/II first-in-class ICOS targeting immune-oncology therapy for solid tumours
- KY1043, a first-in-class PD-L1 targeted immunocytokine therapy for solid tumours
- KY1051, a CXCR4 targeting immuno-oncology therapy for solid tumours

OUR CDMO BUSINESS

Overview

We operate our CDMO business through two platforms, Cytovance and SPL. The two platforms give our customers access to a truly unique assemblage of CMC services for supporting the vast spectrum of recombinant and naturally derived large molecule pharmaceutical products and critical non-viral vectors and intermediates for gene therapy. Both platforms offer services including R&D services, manufacturing services, quality assurance and program arrangement across the drug development lifecycle from late discovery lead selection to clinical CGMP-compliant manufacture and commercial supply. In addition to dealing with fee-for-service and commercial supply contracts, our CDMO platform also enables us to rapidly develop our own diverse innovative drug pipeline. Our CDMO business is led by Jesse McCool, Cytovance’s chief technology officer, who has the relevant experience in the CDMO industry.

Cytovance specializes in the development and manufacture of large molecule pharmaceutical products, with a 12-year track record of working with over 130 different recombinant products, such as monoclonal antibodies, antibody fragments, bispecific antibodies, cytokines, fusion proteins, vaccines and other recombinant proteins. Cytovance has expertise in both mammalian cell culture and microbial fermentation and possesses integrated single-use technologies for production and purification. Cytovance also supports the rapidly growing gene therapy sector by supplying customers with high quality pDNA.

SPL provides services in the development and manufacturing of large molecule pharmaceutical products derived from animal and plant starting materials such as pancreatic enzymes, heparin and heparin analogs. SPL has a 30-year track record of working on naturally derived pharmaceutical products and has developed core competencies such as developing complex and scalable processes for the extraction, isolation and purification of naturally derived materials.

Our CDMO business has a global and diversified customer base, consisting of leading global pharmaceutical companies as well as small- to mid-sized biotechnology companies and start-ups. We enjoy a high level of customer loyalty and industry referrals. We provided CDMO services to five out of the ten largest pharmaceutical companies in the world during the Track Record Period. During the

BUSINESS

Track Record Period, our CDMO services enabled approximately 20 regulatory filing milestones, including INDs, NDAs, BLAs or amendments. As a further testament to value created by the CDMO platform, several of our customers were acquired by large pharmaceutical companies such as Synageva BioPharma Corp. which was purchased by Alexion Pharmaceuticals, Inc. in 2015, Five Prime Therapeutics, Inc. which was purchased by Bristol-Myers Squibb Company in 2015, Selexys Pharmaceuticals Corporation which was purchased by Novartis International AG in 2016, ARMO Biosciences, Inc. which was purchased by Eli Lilly and Company in 2018 and Synthorx Inc which was purchased by Sanofi in 2019.

As of the Latest Practicable Date, we had a backlog of US\$62.1 million, which represents the total amount of service fees for services that we have contracted to perform but have not performed yet. Out of such backlog, service fees of approximately US\$49.6 million and US\$12.5 million are expected to be generated in 2020 and 2021 onwards, respectively, based on the assumption that the relevant contracts will be performed in accordance with their respective terms and expected timetables. As of the Latest Practicable Date, we had 39 on-going projects. The following table sets forth the status of our on-going projects as of the Latest Practicable Date:

<u>Biologics development stage</u>	<u>Number of on-going projects</u>
Pre-IND	
—Drug discovery	2
—Preclinical development	10
Clinical trial	
—Early-phase (phase I & II) clinical development	20
—Late-phase (phase III) clinical development	4
Commercial manufacturing	<u>3</u>
Total	<u><u>39</u></u>

Our CDMO Services

R&D Services

We offer comprehensive development services from late discovery to stage 1 of process validation.

For customers with recombinant products at preclinical stage, Cytovance provides development activities including cell line development for mammalian derived proteins, strain development for microbial derived proteins, process development, analytical method development and qualification and pilot process demonstration. The material from the pilot runs may be used by clients for GLP tox studies. The R&D pilot plant features a 200 L single-use bioreactor and a 30 L single-use fermenter. In addition, Cytovance offers bioanalytical testing services for supporting animal and clinical PK/PD studies.

For customers who have advanced drug candidate beyond clinical phase I, both Cytovance and SPL provide development activities including method pre-validation and process characterization. These types of CMC activities are typically referred to as late clinical phase development and our procedures are designed to comply with the FDA guidance for industry on process validation (2011).

BUSINESS

In addition to fee-for-service R&D, we are committed to the continual improvements of technologies by organizing industry and academic connections, collaborations and research projects. Such collaborations have helped us to rapidly acquire institutional knowledge, develop new or enhanced services, make publications and obtain intellectual properties. Some of the collaborations have led directly to new client acquisition.

R&D Services for Large Molecule Recombinant Products

With respect to R&D services for large molecule recombinant products, one of our core competencies is the generation of cell substrates for microbial and mammalian cell line derived recombinants.

For the generation of microbially produced recombinant proteins, we leverage a proprietary protein expression technology, the Keystone Expression System[®]. Keystone Expression System[®] is a microbial strain development toolbox that is used to derive stable, well-characterized cell substrates for intended use in the preparation of biotechnological/biological products. The toolbox was developed by scientists at Cytovance and made accessible to customers in 2014 as a value-add component of a CMC service known as strain development. The generation and characterization of the cell substrate are critical CMC activities required prior to establishing the manufacturing process and producing materials in compliance with CGMPs. Our extensive expertise in molecular biology, microbiology, process development, CGMP-compliant manufacturing practices and knowledge of patents help to ensure that the customer is supplied with a productive, robust and scalable cell substrate that is free and clear of intellectual property infringement issues. The parental *E. coli* strains BL21 and K-12 and common derivatives of those form the basis of the Keystone Expression System[®]. These strains have been used extensively in the industry for IND filings and commercial production around the world. Cytovance is actively pursuing continuous improvements to the Keystone Expression System[®] and working to integrate enhanced features into its strain development offering.

For the generation of mammalian produced proteins, we leverage an off-the-shelf, widely-adopted, recombinant protein expression technology, Freedom CHO-S[®] from Thermo Fisher Scientific. Scientists at Cytovance have been using the Freedom CHO-S[®] system to derive well-characterized CHO cell substrates for intended use in the preparation of biotechnological/biological products. On top of the experience with Freedom CHO-S[®], our cell line experts have decades of experience working with a huge array of mammalian cell lines.

Once a stable cell substrate has been created, Cytovance will advance a customer’s program through key process development milestones such as cell culture process development, microbial fermentation process development, primary recovery development, purification and formulation development, bench scale process demonstration, pilot scale process demonstration and analytical method qualification. Depending on the protein and expression system used, standard processes can be leveraged to save time and cost in CMC development.

R&D Services for Naturally Derived Products

SPL works closely with its customers to transfer their existing process technology at bench scale to SPL’s laboratory. Once transfer is completed, SPL will perform a demonstration batch at bench scale to demonstrate the process and establish the platform for further process development and scale-up. SPL has experience in a wide range of process technologies relating to the extraction and purification of high-value biopharmaceuticals from natural materials.

BUSINESS

Analytical Testing Capabilities

Strong analytical testing capabilities, including mass spectrometry, support all of our CMC activities. Such capabilities enable us to develop and quality analytical test methods that support the process development and quality control for product release. Our core analytical competences of the analytical development team include method development, method transfer, method optimization and robustness testing, pre-qualification, quality control method transfer, pre-formulation development, and product characterization including mass spectrometry. Our experienced scientists will create a product specific testing strategy to measure process performance and confirm product safety and other criteria. In addition to developing product specific methods, our analytical scientists have extensive experience in the transfer and optimization of methods developed at any stage and preparing standard operating procedures, which can be used in a quality control laboratory. We leverage on numerous platform method technologies to evaluate the appropriateness for each new product. Platform methods can decrease method development time and help drive more cost-effective CMC paths.

CGMP-compliant Manufacturing Services

Manufacturing Sciences

Once we complete the demonstration batches to establish process robustness limits, the process is then transferred to CGMP-compliant manufacturing through our manufacturing sciences team. Our manufacturing sciences team is responsible for the following:

- completing facility fit evaluation form
- generating the technology transfers
- generating the technology transfers number
- reviewing and approving the technology transfers
- editing the technology transfers
- storing and controlling the technology transfers

Mammalian Cell Banking and Storage

Cytovance manufactures cryostores of master and working cell banks to support present and future production requirements. Cell banks are cryostored in the vapor phase of liquid nitrogen freezers. We manage and coordinate all required testing per FDA and ICH guidelines.

Mammalian Cell Culture

Cytovance has installed CGMP-compliant production capacity for recombinant pharmaceutical products, including 250 L, 1000 L and 2000 L single-use disposable bioreactors and a 500 L stainless steel bioreactor. These scales are well matched to meet the majority of demand coming from the customers for products that are in early clinical development. Though Cytovance had not manufactured commercialized large molecule products from mammalian cell culture as of the Latest Practicable Date, Cytovance’s facility can accommodate the installation of additional capacity supporting future commercial demands.

Microbial Fermentation

Cytovance has installed CGMP-compliant production capacity for recombinant products including 10 L glass fermenter, 200 L and 1000 L stainless steel fermenters and 30 L, 300 L single-use

BUSINESS

disposable fermenters. These scales are well matched to meet demands from our customers for products that are in early and late clinical development, and Cytovance’s facility can easily accommodate the installation of additional capacity supporting future commercial demands. The microbial fermentation offered by Cytovance is differentiated by its single-use fermentation systems. The Thermo Scientific HyPerforma Single-Use Fermenter (S.U.F.) system is a first-in-class single-use technology delivering unique and rigorous solutions for microbial fermentation applications while offering flexibility, ease of use and efficiency associated with single-use systems. The system delivers an optimal growth environment through powerful agitation with three Rushton impellers and baffles, high gas flow rates, and efficient cooling through a greater vessel surface area. SPL is also equipped with 5L and 30L fermentators and various types of incubators and biosafety cabinets for microbial fermentation.

pDNA manufacture

The gene therapy market has been growing rapidly and demand for high-quality pDNA is very high. Cytovance launched the pDNA manufacturing service in October 2019. Cytovance’s strong focus on microbial fermentation is highly synergistic with pDNA bioprocessing. The key features of Cytovance’s platform include:

- Industry-leading robust upstream process: HyperGRO™ process, developed by a third party Nature Technology Corporation (Lincoln, NE) is an inducible fed-batch fermentation process consisting of a cell bank and fermentation process that reduce plasmid-mediated metabolic burden, enabling high yield production of optimized plasmids, as well as successful production of previously known unstable or toxic vectors. Due to the controlled addition of nutrients, much higher cell densities can be achieved with a fed-batch process, as opposed to a batch process, and specific growth rates can be reduced, which generally results in increased plasmid copy number.
- S.U.F. equipment: Thermo Scientific HyPerforma S.U.F. system is a first-in-class single-use technology, which allows Cytovance to more rapidly move from one customer process to the next. Cytovance has installed 30 L and 300 L scale S.U.F. system for pDNA manufacture.
- Single-use lysis equipment: Thermo Scientific™ imPULSE™ Single-Use Mixer (S.U.M.) system is a low-shear mixing system used for the lysis step in the pDNA process. It was designed with proven engineering mixer principles and can be used for upstream and downstream mixing applications. The linear-scale design delivers uniform, superior mixing in every model, from 30 L to 5000 L and mixes to empty. The mixer provides consistent scalability. Cytovance has installed 30 L, 500 L, 1500 L SUM system for scalable pDNA production.
- Efficient chromatography technology: BIA Separations’ HiP2 platform, Convective Interaction Media (CIM®) monolith chromatography supports, is designed for the purification of large molecules such as pDNA. Monoliths enable high productivity of pDNA downstream processes due to high dynamic binding capacity, fast operating flow rates and high resolution due to convection-based mass transfer.

Natural product extractions

SPL provides services in the extraction of large molecule products from natural sources, including through processing both animal-derived and plant-derived materials, at scales ranging from

BUSINESS

laboratory to CGMP development suites to metric ton, full-scale commercial production. SPL operates a flexible multi-product manufacturing facility in Waunakee, Wisconsin, the U.S. in support of its CDMO business. Our team has extensive expertise and experience in sourcing natural materials, establishing complete traceability, extracting high-value products from naturally derived materials, purification, viral inactivation and characterization of complex mixture of large glycoprotein molecules.

Purification

Our teams in Cytovance and SPL have extensive experience with an array of purification capabilities to meet our customers’ CGMP production needs. Our purification suites are segregated and customized with equipment to specifically meet the requirements of each client process. Single-use options are available throughout all purification steps with cutting-edge technologies. Our purification personnel are experts with multiple chromatography techniques, tangential flow filtration and bulk drug substance filling.

Process validation

We also offer process validation services in accordance with FDA Industry Guidance (2011) on Process Validation. To ensure that critical parameters are identified and tested, an extensive process characterization (“stage 1” of the 2011 FDA Guidance) is performed. A given process is operated within established parameters in the process performance qualification (“stage 2” of the 2011 FDA Guidance).

Quality Assurance

All of our manufacturing and support operations in Cytovance and SPL are built on the framework of a quality management system, including quality control testing, quality assurance, stability testing and regulatory support.

Our CDMO quality management systems are driven by three organizational functions including validations, quality control, and quality assurance. Quality assurance is further organized into four functional departments, including incoming materials, quality assurance operations, quality systems and regulatory affairs. The department of incoming materials is responsible for the incoming material sampling, inspection and testing, non-conforming material oversight and supplier management. The department of quality assurance operations is responsible for customer project oversight, deviation management, investigation review and approvals, batch record review and lot disposition. The department of quality systems is responsible for document control, training coordination, CAPA and audit management, and metrics and trending. The department of regulatory affairs is responsible for regulatory reporting, pharmacovigilance, complaint and change management and policy-level compliance oversight.

Quality control testing

Quality control testing is to ensure that the product strictly meets the FDA and USP guidelines. Our team has relevant experience in CGMP compliance and microbial root cause investigations.

Quality assurance

We ensure quality of the products by following established systems that are compliant with domestic and international regulations. Our quality systems provide planned and systematic quality

BUSINESS

requirements for our services. The established systems ensure traceability of materials from receipt through final disposition and storage and ensure the products’ compliance with quality requirements from the clinical stage through commercialization. These systems also provide feedback to ensure robust monitoring and continuous improvement.

Stability testing

ICH stability testing is a critical aspect to any early-stage manufacturing project. We provide state-of-the-art services to screen excipients, determine an optimum formulation and get the product on its stability regimen as quickly as possible. We provide stability chamber storage and analysis that are compliant with the ICH guidelines and suit the properties of each product.

Regulatory support

Every stage of the manufacturing process has regulatory implications. Initially, we advise on meetings with regulatory authorities. Production processes and manufacturing strategies are specifically designed for optimal regulatory outcomes. We are a critical partner for CMC section preparation, assisting clients throughout the production process to target regulatory success. We believe we are poised to successfully complete regulatory inspections such as a PAI and general CGMP audits. We host numerous customer quality audits each year in addition to our internal auditing program.

Program Management

Both Cytovance and SPL provide professional CMC program management services for their customers, including project planning, resource management, sample shipment coordination, batch scheduling and project team communications. Customers are assigned a dedicated program manager who plays a central communications role while leading the coordination of project milestones, project resources and the working project plan. The program manager is responsible for escalation processes and other business processes enabling the most efficient timeline achievable.

Marketing of Our CDMO Services

We directly market our services to pharmaceutical and biotechnology companies by actively participating in trade conferences and trade shows. During these conferences, we set up booth to introduce our integrated CDMO platform and our technical staffs will also give presentations that highlight the advantages of our end-to-end CMC services. We have also established active online presence through our corporate websites. We provide extensive information about our integrated services and our technology platforms, our competitive and technical advantages, training and education resources as well as announcements of our most recent project development on our corporate websites. After we have established contact with our target customers, we market our services through regular meetings with their representatives and senior management, where we present how we can expedite the customers’ product development process. In light of our broad customer base, customer referrals and word-of-mouth marketing have also significantly contributed to new customer acquisition.

We have a team of experienced business development specialists, consisting of 11 people, who are dedicated to understanding the demands of existing and potential customers and work closely with our technical experts to prepare quotes and to secure customer orders. Over 45% of the members of our

BUSINESS

sales and marketing team have attained a master’s or higher degree in biologics-related disciplines as of the Latest Practicable Date.

Our CDMO Fee Model

We enter into long-term service agreements with our major customers. Services for each project under a long-term service agreement are provided pursuant to a separate and distinct work order. A work order typically comprises a number of tasks, each in turn including several steps.

According to our contractual arrangements with our customers, we typically bill our customers after we complete a task. A task is deemed to be completed after all the steps within such task are completed. Our contracts with customers and work orders include specifications about the services to be rendered at each step and the deliverables that we should send to the customer upon completion of such step. Our project team also interacts with each customer’s project-management team through daily emails, bi-weekly reports and regular conference calls to give the customer timely updates of the progress of its projects. We are typically required to deliver a technical laboratory report, product/samples and/or other deliverables and transfer the relevant data and rights to the customer after all the services have been rendered for a step. A particular step is deemed to be completed upon the customer’s acceptance of the deliverables in relation to such step, which indicates that the customer is satisfied with the services provided by us at such step and would like us to proceed.

SALES AND MARKETING

We implement differentiated and localized sales and marketing strategies which are suitable for our various pharmaceutical products in different markets. We use a combination of academic marketing by our in-house sales and marketing team and collaboration with a network of independent distributors and third-party promoters to generate market demands for our products. We have not engaged in any sales and marketing activity for innovative drug candidates as they are currently at development stage. We directly market our CDMO services to pharmaceutical and biotechnology companies by actively participating in trade conferences, trade shows and scientific conferences. For the marketing of our CDMO services, please refer to “—Our CDMO Business—Marketing of Our CDMO Services.”

Our Sales of Enoxaparin Sodium Injection

We use a combination of academic marketing by our in-house sales and marketing team and collaboration with a network of independent distributors and third-party promoters to generate market demands for our products. Specifically, our marketing for enoxaparin sodium injection can be categorized into three models, depending on our marketing efforts.

In-House Marketing Model

The in-house marketing model is currently applied only in certain EU countries. Under our in-house marketing model, all market demands are generated directly by our sales and marketing team. Our sales and marketing team directly market our products and develop relationships with physicians, hospitals and pharmacies, participate in the bidding process to create sales to hospitals and further through the prescription of physicians promote sales of our products to pharmacies. We sell our products either through distributors or directly to hospitals in these countries.

BUSINESS

Sales through Distributors

In Germany, UK, Spain and Italy, during the Track Record Period, we primarily sold our enoxaparin sodium injection under the brand name Inhixa to distributors, who then resold to hospitals and pharmacies. Our products are sold to distributors at a fixed price set by relevant regulatory authorities based on retail price. We do not enter into any sales agreement with our distributors. In Germany, UK and Spain, distributors place purchase orders to our appointed logistics providers on an as-needed basis, depending on the orders they receive from customers. We generally enter into a services agreement with each logistics provider, subject to further extension, under which, such logistics provider is responsible for providing integrated logistics services, including storage, secondary packaging and final shipment. The logistic providers are responsible for accepting and processing orders from distributors, issuing sales invoices to the distributors, collecting payment from the distributors on our behalf and settling payment with us within 30 days upon payment by the distributors to them. We are responsible for delivering our products to the logistics providers, and pay service fee in consideration of the services they provided. The ownership of the products will not be transferred to the logistics provider at any time. In Italy, distributors directly place orders and settle payment with us. We typically grant credit terms of one to two months to the distributors in Italy.

We also sell enoxaparin sodium injection under our brand name Neoparin to SciencePharma in Poland, who owns the marketing approval of Neoparin. We have entered into a supply agreement with SciencePharma, which will remain in force as long as SciencePharma is the holder of the marketing approval of Neoparin. We have also entered into a separate service agreement with SciencePharma, under which, we have acted as a marketing service provider to assist SciencePharma in selling Neoparin with our sales and marketing team in Poland. SciencePharma purchases Neoparin from us on an as-needed basis by placing purchase orders from time to time, and we deliver the products to its designated agent.

Direct Sales

During the Track Record Period, we sold enoxaparin sodium injection under the brand name Inhixa directly to hospitals and pharmacies in certain countries in the EU, such as Italy. We deliver our products to hospitals pursuant to the purchase orders we receive at the price set during the bidding process.

Co-Marketing Model

Under co-marketing model, besides our in-house academic marketing, we also rely on third-party promoters and distributors to market our products, especially enoxaparin sodium injection, by leveraging their local connection and marketing network. Each of our distributors and third-party promoters has its own sales force that focuses on marketing in its designated territory, which expands our marketing coverage and deepens our marketing penetration while allowing us to maintain operational flexibility and optimize our resource allocation.

EU

In certain EU countries such as Croatia, we enter into consignment arrangements with our distributors, where we issue invoice to our distributor upon its sales to the customers at the price negotiated among the distributor, its customer and us. The distributor assists us to market and sell our products in its designated region. Pursuant to the agreement, we are responsible for delivering our

BUSINESS

products to the distributor, while the legal ownership of the products is only transferred to the distributor when the product is withdrawn from the consignment stock and delivered to its customers. We provide typically three months of credit terms for the distributors.

China

We collaborate with our third-party promoters for the marketing of our enoxaparin sodium injection in China. For our sales in China, we generally enter into a standard agreement with a third-party promoter in each province with a term of one year. We work with our third-party promoters to design marketing strategies in respective regions, participate in academic conferences and engage in patient education to increase the awareness of our brand and product. Pursuant to our agreement, each third-party promoter is also responsible for introducing and promoting our product to target hospitals and physicians in the designated province, as well as assisting with the bidding process of our product through submitting bidding materials and communicating with local authorities. Each third-party promoter is assigned with a quarterly and annual marketing plan in each target hospital within its designated province, the failure to comply with which may lead to termination of the agreement at our discretion. Our third-party promoter will generally appoint a CSO in their covered region, with whom we enter into a standard one-year CSO agreement. Each CSO is required to assist with the marketing and promotion of our product by organizing or attending various events and leveraging their connection with local hospitals. Each of our CSOs is prohibited from marketing or selling our products outside its designated province, and is generally not allowed to promote other products that directly compete with ours.

We rely on an extensive network of distributors to distribute our enoxaparin sodium injection under the brand name Prolongin in China. Generally, there are multiple distributors in each province, each covering the hospitals that it has access to. The Distributor is responsible for processing orders and delivering our products to the designated hospitals. For each sale, we will enter into a sales agreement with the distributor that specifies the product, purchase amount and price. Pursuant to our agreement, each distributor will pay us the fixed price set in the agreement when placing the order. We typically do not provide any credit term for the distributors. We believe that our existing distribution model is consistent with customary industry practice and serves to ensure efficient coverage of our sales network while controlling our cost of distribution and account receivables.

Outsourced Marketing Model

For our sales of enoxaparin sodium injection in certain countries in the EU and other overseas regions, we rely on our local distributors' marketing efforts and resources for the promotion of our product in respective regions.

EU

We rely on exclusive distribution arrangement to market and sell our enoxaparin sodium injection in certain countries, such as France, Austria and the Republic of Cyprus. Our distribution agreement with each distributor generally has a term of three to five years, subject to renewal at the end of each term. Each distributor is responsible for using its best efforts to promote and sell our products in the designated region. Pursuant to the agreement, the distributor is obligated to purchase a minimum amount of products at the prices set in the agreement applicable to respective purchase amount. We are responsible for delivering our products to the distributor under the agreement, and the

BUSINESS

legal ownership of products is transferred to the distributor upon delivery. The distributor is responsible for delivering products to its customers within the designated region. The credit terms we grant to the distributors vary depending on market conditions, and is typically less than two months.

U.S.

We have entered into a supply agreement of enoxaparin sodium injection with a multinational pharmaceutical company as its major supplier of enoxaparin sodium injection in the U.S. As of the Latest Practicable Date, we have not supplied our enoxaparin sodium injection to this customer pursuant to the supply agreement.

Other markets

We sell enoxaparin sodium injection through distributors in other markets. In certain countries, such as Peru and Sri Lanka, we sell enoxaparin sodium injection under our brand name Prolongin. In other countries such as Brazil, Colombia and Vietnam, we supply enoxaparin sodium injection to our customers for them to sell under their own brand names. We generally enter into a supply agreement with our distributors for a term of five years, under which, we manufacture and deliver enoxaparin sodium injection as requested. Our distributors are responsible for registering the enoxaparin sodium injection and applying for marketing approval in the designated regions, and we will assist them in obtaining the marketing approval by providing materials and product samples as requested by the regulatory authority. Our distributors will purchase our products at a set price pursuant to the agreement and are committed to purchase a minimum amount. We generally grant credit terms of one month to our distributors.

Our Sales of Heparin Sodium Injection

We have established and maintained a cooperative relationship with a world-leading pharmaceutical distributor for the promotion and distribution of heparin sodium in the U.S. We have granted such distributor with exclusive rights to use our ANDAs to market, sell and distribute heparin sodium injection in the U.S. that are manufactured, packaged and labeled by authorized manufacturers. We have also granted such distributor with exclusive rights to use our label in connection with its marketing, sale and distribution of the heparin sodium products. Pursuant to the agreement with such distributor, we are responsible for supplying heparin sodium API for the manufacturing and production of heparin sodium injection. In addition to the payments for purchasing heparin sodium APIs, such distributor agrees to pay a licensing fee to access and use our certain intellectual properties, ANDAs, ANDSs and applicable product specifications in connection with the sourcing, manufacturing, packaging and labeling of the heparin sodium injection.

Moreover, we sold heparin sodium injection to distributors in China through Hepatunn in 2017 and 2018, before we disposed our equity interests in Hepatunn in June 2018. We applied marketing and distribution model similar to our sales of enoxaparin sodium injection, through collaborating with third-party promoters and CSOs for marketing and appointing distributors for delivery to hospitals.

Our Sales of API Products

Heparin Sodium API

We primarily sell heparin sodium API directly to pharmaceutical companies for their production of heparin sodium injection or LMWH products. During the Track Record Period, our

BUSINESS

major customers included Techdow before it became our wholly-owned subsidiary in 2018, with whom we conducted the transactions on an arm’s length basis, and international suppliers of heparin products, including Sanofi, with whom we have established and maintained a long-term business relationship. Our customers are global leading manufacturers of heparin products or the leading manufacturers in their respective regional markets.

We also sell to distributors in certain regions, who are designated as the exclusive distributors in their covered regions to further sell our heparin sodium API to pharmaceutical companies for their production of heparin products.

We generally enter into a supply agreement with our major purchasers of heparin sodium API for a term of three to five years subject to renewal. Under the agreement, we are responsible for delivering the products pursuant to each order, and our direct customers and distributors are required to make payment within 30 to 60 days at the price set in the supply agreements. Our products are generally sold according to a schedule in each supply agreement that sets a price for different periods during the term of the agreement, based on our estimates of the market conditions that may affect the cost of sales or our estimates of the effect on our costs of sales of certain events that have occurred. For example, the price of our raw materials may fluctuate as a result of the outbreak of swine fever or certain crisis such as Baxter Incident. The price may also vary with discounts applicable to respective purchase amount. The price schedule of our products are generally subject to renewal each year or upon certain unexpected market changes, subject to adjustment in each order based on parties’ negotiation.

Enoxaparin Sodium API

We primarily sell enoxaparin sodium API directly to manufacturers of enoxaparin products. The regions where we sell our enoxaparin sodium API generally do not overlap with regions where we sell our enoxaparin sodium injection. For the major markets, we generally enter into supply agreements with regional leading manufacturers of enoxaparin products.

We also sell our enoxaparin sodium API through distributors which have extensive and long-term connections with local manufacturers of enoxaparin products in their covered regions.

We generally enter into a supply agreement with our major purchasers of enoxaparin sodium API for a term of two years subject to renewal. The supply agreements generally set credit terms of 30 to 60 days with our direct customers or distributors. Our products are sold at a price subject to parties’ negotiation for each order based on changes in the raw materials market or certain unexpected market changes.

Our Sales and Marketing Team

We have an experienced and specialized in-house sales and marketing team with international exposure. As of the Latest Practicable Date, our sales and marketing team consisted of 107 staff in total, with 49 people in the EU, 44 people in China and 14 people in the U.S.. The head of our sales and marketing department has more than 25 years of experiences in the field. Our overseas sales and marketing team is led by Wen Shi, vice president of business development, who has vast experience in the pharmaceutical industry.

BUSINESS

Our Sales and Marketing Team for Enoxaparin Sodium Injection

Our Regional Sales and Marketing Team

We have a dedicated sales and marketing team for enoxaparin sodium injection, divided into four sub-teams by market, including China, the EU, the U.S. and other regions, each led by a director, who reports on a regular basis to our management. As of the Latest Practicable Date, our sales and marketing team for enoxaparin sodium injection consisted of 86 people in total, including 49 people in the EU and 37 people in China, among whom, six people had over 20 years of experience in pharmaceutical sales. To penetrate into local markets in the EU, we have formed a sales and marketing team in each major market, each led by a regional manager. We do not maintain a local office for the sales of enoxaparin sodium injection in each province in China or in other overseas markets. We divide the China market into seven major regions, including East China, North China, Central China, South China, Northeast China, Northwest China and Southwest China, each with a designated sales and marketing team. Our respective sales and marketing teams for the U.S. market and other regions are based in China and are primarily responsible for coordinating with our major clients for the sales and distribution of our products in relevant markets.

Our penetration into local market and broad market exposure allow our sales and market team for enoxaparin sodium injection to design marketing strategies and engage in promotion activities in each region, based on respective market conditions, such as competitive landscape and regulatory environment. Specifically, each team is responsible for establishing and maintaining relationships with hospitals and other health institutions and increasing the awareness and recognition of our products among physicians in the covered region, through academic marketing activities and other promotional efforts. They also collect feedback on our products for further improvement. Besides, our sales team also coordinates with third-party promoters and distributors in the promotion and distribution of our products. Our management closely oversees the sales activities and results in the major markets and determine the sales and pricing policies in each market.

Academic Marketing

Our sales and marketing efforts are characterized by a strong emphasis on academic promotion, in order to promote and strengthen the awareness and recognition of our products and our brand among medical professionals. We regularly organize and participate in various academic conferences, seminars and symposia, as well as smaller events tailored for specific cities and hospital departments. We invite leading experts in relevant therapeutic areas to speak on the latest developments and share their experience in the academic conferences, such as the latest application of enoxaparin sodium injection, their experience in using enoxaparin sodium injection as the anticoagulant in practice and its effect in treating different indications. We also set up exhibitions at large-scale academic conferences to present our products’ innovative and advantageous features.

We conduct academic marketing activities to establish and maintain relationships with key opinion leaders (“KOLs”), as well as department heads and senior physicians in our target hospitals. We provide these experts with detailed information on our products and help them make independent comparisons among competing products in the market. We depend on KOLs to introduce and recommend our products to physicians and hospitals. We have maintained regular contact with various KOLs, who are generally medical experts with substantial national or regional influence, especially in the anticoagulant field, and some hold leadership positions in national medical associations. Our sales and marketing team is responsible for establishing relationships with KOLs and introduce them the

BUSINESS

features of our products. We maintain lists of national and regional KOLs, which are updated annually. We select KOLs primarily based on the therapeutic areas they specialize in, their professional qualifications and their reputation in the medical community. We also consider whether they have participated in clinical studies or published academic articles related to our products. Prescription of our products is not a criterion for our selection of KOLs. We provide KOLs with assistance in organizing high profile domestic and international academic conferences and seminars and conducting clinical studies. We maintain regular communication with the KOLs regarding the application of our products, and we also invite them to visit our facilities, where we present our integrated quality control management throughout the production process. We believe that KOLs' independent reviews and studies of our products, which may be published in academic journals or shared in conferences and seminars, help increase the recognition of our products among the wider medical community. We do not pay KOLs for their promotion of our products, however, we may reimburse them for expenses incurred by their attendance of academic conferences, such as related travel expenses.

We target to establish relationships with department heads and senior physicians in the therapeutic areas targeted by our products. We generally provide them with assistance in organizing and attending regional academic conferences and conducting clinical studies in our targeted therapeutic areas. We sponsor the education of physicians by encouraging them to attend academic conferences pertaining to their specialization to learn about the latest medical advances and develop their professional skills. For conferences sponsored by us, we may reimburse these physicians for registration fees and traveling expenses through the academic associations that organize these conferences. We also organize communication among the physicians to discuss the latest development in relevant therapeutic fields.

Our Sales and Marketing Team for API Products

We have a dedicated sales and marketing team for each API product. We generally have long-term supply arrangement with our existing customers, and potential purchasers tend to approach us directly in reliance on the high quality of our API products, and therefore, we tend to keep a lean and efficient sales and marketing team for our API products.

The team process purchase orders, arrange for delivery and engage in constant communication with our customers to assist with the sales of our products. Moreover, they are responsible for the marketing and promotion of our API products in conferences and exhibitions such as the Convention on Pharmaceutical Ingredients (CPhI). When we enter into a new market, our team will conduct research and connect with the leading regional manufacturers of heparin products and LMWH products to create sales and penetrate into the local market.

Our Distributors

Selection of Distributors

We sell a significant portion of our enoxaparin sodium injection to distributors who then resell our products to pharmacies and hospitals, and we also sell a small portion of our API products to distributors for their sales to pharmaceutical manufacturers. All of our CDMO services are directly offered to our customers. We believe that our sales arrangement is in line with market practice. In 2017, 2018 and the nine months ended September 30, 2019, our sales through logistics providers in the UK, Germany and Spain accounted for approximately 0.0%, 0.2% and 5.1%, respectively, of our total revenue, our sales to distributors not through logistics providers accounted for approximately 18%, 23% and 21%, respectively, of our total revenue, and our direct sales (including CDMO) accounted for the rest of our revenue in the respective periods. We select our distributors based on their

BUSINESS

qualifications, reputation, market coverage and sales experience. To distribute our products, a distributor must maintain relevant licenses and permits, as well as extensive customer coverage in the designated region. For distributors who are responsible for the storage and delivery of our product, they should also have the capacity to store and deliver the product at appropriate conditions. We also conduct credit assessments of each of our distributors before we enter into a distribution agreement.

As of December 31, 2017, 2018 and September 30, 2019, we had a total of 442, 687 and 735 distributors for the sales of our products, respectively. The following table sets forth the changes in the number of our distributors for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,
	2017	2018	2019
As of the beginning of the period	70	442	687
Additions of new distributors	339	427	186
Termination of existing distributors	21	182	138
Net increase in distributors	318	245	48
As of the end of the period	442	687	735

The increased number of distributors during the Track Record Period was primarily attributable to the increased number of distributors for enoxaparin sodium injection. The increased number of distributors in 2017 was primarily because we further increased our sales of our enoxaparin sodium injection in China and launched Inhixa in Italy, Germany and the UK in 2017. The increased number of distributors in 2018 was primarily because we further increased our sales of enoxaparin sodium injection in China and Germany and launched Inhixa in Spain in 2018. The increased number of distributors in the nine months ended September 30, 2019 was mainly because we further increased our sales of enoxaparin sodium injection in Germany in 2019.

Management of Distributors

Our arrangement with each distributor varies for different products and in different markets, however, we generally keep a few principal terms, which are summarized in the table below:

Designated geographical regions and hospitals	The geographic region within which a distributor is permitted to promote and distribute our enoxaparin products. The distributor cannot market or sell our products outside the designated geographical area. The distributor is also prohibited from promoting and selling competing products in the designated region.
Sub-distribution	We prohibit our distributors from engaging sub-distributors to sell our products.
Transportation	We are responsible for transporting our products to each distributor, and bear the costs and risk of loss of the transportation.
Product returns	Generally, the purchaser may not return or exchange our products except for product quality issues at our fault. We should replace the defective products at our own costs within an agreed period.
Obsolete stock return	None.

BUSINESS

Termination	If either of the parties breaches or defaults on any of its obligations under the agreement, and the breaching or defaulting party does not cure the breach or default within the period of time specified, then the non-breaching or non-defaulting party has the right to terminate the agreement.
Regulatory compliance	The distributor is required to comply with all applicable laws and regulations, including, among other things, anti-bribery and anti-kickback laws and regulations. The distributor is also required to obtain relevant permits to sell and distribute medical devices and maintain storage facilities compliant with regulatory standards on medical device storage, and provide us with copies of the relevant licenses, permits and certificates.
Intellectual property rights	The distributor shall have a non-sublicensable, nontransferable, non-assignable and non-exclusive right to use our trademark for selling our products in the designated area during the term of our distribution agreement. Our distributor shall not use the trademark for any other product and shall use the trademark only for the purpose of selling our products in accordance with the agreement.

During the Track Record Period, we maintained effective management and control over our distributors. Our distributors are required to provide us with supply forecast, which allow us to reserve capacity, plan our manufacturing activities and prepare for the supply and delivery. We regularly communicate and conduct review with our distributors primarily regarding their inventory level, sales amount and marketing activities, as applicable. Our monitor of distributors’ inventory allows us to reasonably allocate and transfer our products among the distributors and us, which helps to avoid product stock-up and ensure sufficient supply and circulation of our products in the local market. For example, in 2019, we purchased certain amount of enoxaparin sodium injection from one distributor at the same price they purchased from us, in order to meet the demand from local tender process.

During the Track Record Period, our distributors did not materially breach our contract terms, and we did not have any material disputes with our distributors relating to the settlement of trade receivables. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors, which could adversely affect our reputation, business operation or financial contribution.

PRICING

Pricing of Enoxaparin Sodium Injection

EU

Our enoxaparin sodium injection is covered by national medical insurance in eight EU countries where we sell our enoxaparin sodium injections. Suppliers need to negotiate with local governmental authorities for the listing price of their pharmaceutical products, which will be the ceiling price at which such pharmaceutical products can be sold in the market. Each country may have its own policy regarding the listing price of biosimilar drugs in comparison with their reference drugs.

BUSINESS

In some major markets such as Poland, Spain and Italy, the listing price for the biosimilar drug is required by relevant laws or regulations to be lower than the price of the respective reference drug. In other major markets including UK and Germany, though the regulatory authority does not set a ceiling price for the biosimilar drug, its listing price is generally not higher than the price of the respective reference drug in the market. For the sales to the pharmacies, the price generally follows the listing price.

For the sales to hospitals, suppliers are generally required to go through a public bidding process to be selected as the supplier for hospitals in the respective regions. Selection of bidders and drugs primarily takes into consideration of several factors, including the drug’s offer price, potential effect and quality and the supplier’s capacity to provide the amount of drugs requested by the hospitals. If we win the bids in the bidding process, our enoxaparin sodium injection will be sold to hospitals at the bid prices, which primarily determines the prices at which we sell our product to our distributors. For the sales to some hospitals in certain markets, the sales price are determined based on our negotiation with each hospital.

For our sales to distributors pursuant to a distribution agreement between the distributor and us, our enoxaparin sodium injection is sold at a fixed price set in the agreement, which may vary depending on the market conditions in different regions, taking into account of our cost of sales, our target gross profit margin, the margin for our distributor, the distributor’s purchase amount and services provided by the distributor, such as marketing and promotion efforts. The fixed purchase price is negotiated and determined, based on the retail price at which the products will be sold to the distributor’s customers. We are mindful of keeping a reasonable gap between the retail price, and our average selling price to the distributor. For our sales to some of our distributors, mainly wholesalers with which we do not enter into distribution agreement, our products are sold at a wholesale price set by relevant laws and regulations based on the retail price of our enoxaparin sodium injection.

China

During the Track Record Period, we sold enoxaparin sodium injection in China to our distributors who then sold to public hospitals and other public medical institutions. In May 2015, seven state agencies in China including the NDRC and the NMPA issued a notice regarding pharmaceutical price reform, pursuant to which government price controls on pharmaceutical products (other than narcotic drugs and Class I psychiatric drugs) were lifted starting June 1, 2015, allowing for a more market-based drug pricing system. Meanwhile, the PRC government continues to regulate prices mainly through a centralized tender process, medical insurance reimbursement standards and regulation of medical and pricing practices. During the Track Record Period, the NDRC price adjustments, the centralized tender process or the inclusion in the NRDL did not have a material negative impact on our results of operations.

Our enoxaparin sodium injection, Prolongin, has been included in the NRDL since 2015, with a tender price based on the negotiation with the government, as the ceiling price for the product to be sold in the market. Each public medical institution must make substantially all of their purchases of pharmaceutical products through a centralized tender process. The centralized tender process is held in different provinces and cities across China with varying terms, procedures and preferences and is usually organized at the national, provincial or city levels. The frequency that a drug is required to resubmit a tender under the centralized tender process varies across different provinces, which generally ranges from two to three years. Please refer to “Regulatory Overview—PRC Laws and

BUSINESS

Regulations in Relation to the National Medical Insurance and Price of Pharmaceutical Products—Drug Purchase by Hospitals” for further details of the centralized tender process in China. The selection of the winning bidder is based on a number of criteria, including bid price, product quality, clinical effectiveness, qualifications and reputation of the manufacturer and after-sale services. The successful bid price in the centralized tender process dictates the price at which distributors sell the relevant product to the relevant public medical institutions. If we are successful in winning bids in the centralized tender process, our enoxaparin sodium injection under the brand name Prolongin will be sold to public medical institutions at the bid prices, which primarily determines the prices at which we sell our product to our distributors. Our bidding strategy generally focuses on differentiating our product instead of competing solely based on pricing.

Our sales and marketing department and our third-party promoters work closely to monitor new policies affecting the pricing of pharmaceutical products in China, and formulate strategies to stay competitive and profitable. Our sales and marketing team designated for different regions actively communicates with the local authorities in charge of the public tendering process, studies the tendering proposals, including minimum bidding requirements, if any, pricing trends for each strength and format of our product and of our competitor products on a province-by-province basis to form a bid. Our sales and marketing department also creates and executes a master plan to cope with competition in different provinces, with the goal of maintaining the price levels of our product and maximizing our overall sales in China.

There have been certain changes in regulatory policies that may affect the price of our Prolongin enoxaparin sodium injection. The PRC government launched the national pilot scheme for tendering with minimum procurement quantities in November 2018, which is aimed at reducing drug prices. Please refer to “Regulatory Environment—Other Related Regulations in the PRC Pharmaceutical Industry—The Drug Centralized Procurement in ‘4+7 Cities’ and Wider Areas.” Although it is a pilot program, this scheme for tendering with minimum procurement quantities has resulted in increased pricing pressure on us. Please refer to “Risk Factors—Risks Relating to Our Business and Industry—The retail prices of certain of our products are subject to price control or downward adjustment by the government authorities or other pricing pressure.” for further details of risks associated with pricing regulation. Moreover, the NMPA requires existing generic drugs to undergo QCE. See “Regulatory Environment—Laws and Regulations Related to Our Business in the PRC—Regulations on Drug Research and Development & Registration Services—Drug Registration.” Generic drugs that have passed QCE are afforded certain advantages, including preferential treatment in centralized tender process. We have submitted application for QCE approval of Prolongin in April 2018. Once Prolongin obtains the QCE approval, it is expected to significantly increase our product’s sales potential.

U.S.

We have entered into a supply agreement with a multinational pharmaceutical company for its sale of enoxaparin sodium injection in the U.S. The purchase price for each strength as stipulated in the agreement is subject to adjustments on a semi-annual basis having regard to, among other things, our costs for crude heparin sodium and comparable prices of other third-party suppliers.

Other Markets

For our sales of enoxaparin sodium injection in other regions, the price may vary depending on the market conditions in each local market, taking into account of our cost of sales, our target gross

BUSINESS

profit margin and the customer’s purchase amount, and subject to periodic renewal or based on parties’ mutual agreement.

Pricing of API products

Governments generally do not set a controlling price on the API products and there will not be a listing price or ceiling price for the API products in the market, as the API products are not directly applied to patients and are not covered by any medical insurance. We sell our API products to our customers at the prices set in the supply agreements, which generally take into consideration of the market price, our cost of sales, our target profit margin, term of the agreement and the purchase amount. We generally build in the agreement a price schedule that lays out the price for each month or year under normal market conditions during the term of the agreement and ensure that the price can be periodically re-negotiated or changed based on parties’ mutual consent, so that we can adjust our sales price as a prompt response to events such as outbreak of swine fever that may significantly affect the costs of our raw materials.

CUSTOMERS

For the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, the aggregate sales to our five largest customers were approximately RMB1,707.8 million, RMB2,873.8 million and RMB1,549.3 million, representing approximately 60.4%, 59.9%, and 49.5% of our revenue for the same periods, respectively. Sales to our largest customer for the same periods were approximately RMB1,126.9 million, RMB1,804.7 million and RMB896.3 million, representing 39.8%, 37.6% and 28.6% of our revenue for the same periods, respectively.

One of our five largest customers in 2017, 2018 and during the nine months ended September 30, 2019 was distributors. Please see below a summary of the sales to our five largest customers for the periods indicated:

<u>Five Largest Customers for the year ended December 31, 2017</u>	<u>Company Background</u>	<u>Our Products</u>	<u>Sales Amount</u> RMB'000	<u>Percentage of Revenue</u>
Customer A	A public multinational pharmaceutical company	Heparin sodium API	1,126,899	39.8%
Customer B	A professional service provider for pharmaceutical industry	Enoxaparin sodium injection, pharmaceutical service	214,547	7.6%
Customer C	A subsidiary of a public multinational pharmaceutical company	Heparin sodium product	166,987	5.9%
Customer D	A pharmaceutical manufacturer	Heparin sodium API	114,731	4.1%
Customer E	An API pharmaceutical manufacturer	Heparin sodium API, enoxaparin sodium API	84,589	3.0%
Total			<u>1,707,753</u>	<u>60.4%</u>

BUSINESS

<u>Five Largest Customers for the year ended December 31, 2018</u>	<u>Company Background</u>	<u>Our Products</u>	<u>Sales Amount</u> RMB'000	<u>Percentage of Revenue</u>
Customer A	A public multinational pharmaceutical company	Heparin sodium API	1,804,652	37.6%
Customer B	A professional service provider for pharmaceutical industry	Enoxaparin sodium injection, pharmaceutical service	471,461	9.8%
Customer C	A subsidiary of a public multinational pharmaceutical company	Heparin sodium product	226,402	4.7%
Customer F	A biotech company	Pancreatin API	204,675	4.3%
Customer G	A biotech company	CDMO service	166,618	3.5%
Total			<u>2,873,808</u>	<u>59.9%</u>

<u>Five Largest Customers for the nine months ended September 30, 2019</u>	<u>Company Background</u>	<u>Our Products</u>	<u>Sales Amount</u> RMB'000	<u>Percentage of Revenue</u>
Customer A	A public multinational pharmaceutical company	Heparin sodium API	896,310	28.6%
Customer G	A biotech company	CDMO service	225,539	7.2%
Customer B	A professional service provider for pharmaceutical industry	Enoxaparin sodium injection, pharmaceutical service	190,988	6.1%
Customer E	An API pharmaceutical manufacturer	Heparin sodium API, Enoxaparin sodium API	146,047	4.7%
Customer H	A pharmaceutical manufacturer	Enoxaparin sodium injection	90,398	2.9%
Total			<u>1,549,282</u>	<u>49.5%</u>

During the Track Record Period, none of our Directors or any Shareholders, who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following the completion of the [REDACTED] (but without taking into account the exercise of the [REDACTED]) nor any of their respective associates had any interest in any of our five largest customers.

RESEARCH AND DEVELOPMENT

Our R&D activities primarily include the improvement of the technologies relating to our existing products, and the R&D of our innovative pipeline drugs, through a combination of investing and licensing in drug candidates with significant market potential, collaboration with CROs and involving our CDMO team in the R&D of our drug candidates from preclinical stage to

BUSINESS

commercialization stage. We plan to continue to diversify and expand our product pipeline through both in-house research and development, investment and collaboration with CROs and our own CDMO team.

We employ a clinical-demand-oriented and market-driven approach to our R&D efforts. Our experienced R&D team identifies innovative product candidates with significant market potential, conducts preclinical development and clinical trials, and ultimately assists with the commercialization of these products. We carefully select drug development programs by balancing the commercial potential of each drug candidate and its likelihood of successful development, its potential competition and market size.

As of the Latest Practicable Date, our research and development personnel consisted of 345 employees. Our research and development personnel include 34 PhDs and 243 holders of bachelor or above degrees, most of whom have extensive working experience in the healthcare and biotechnology research fields.

R&D Center

In order to enhance our capacity in technology innovation and cultivate our core competitiveness, we founded our R&D center in 2008, primarily focusing on development of innovative drugs and providing technology support to our commercialized pharmaceutical products. The R&D center consists of major groups, including R&D service, operation support and overall management.

Our R&D center's operation support group primarily includes the administration of R&D projects through establishing development management system, providing technology and professional support for the team's R&D services and the training of R&D personnel. The management group focuses on the administration and allocation of R&D resources. The R&D service group primarily takes responsibilities listed below, including R&D information technology, early-stage R&D, preclinical R&D, pharmaceutical R&D and technology support to the commercialized pharmaceutical products.

- R&D information technology: The team provides technology evaluation of the projects we invested during the stages of project selection and due diligence, based on which the team provides suggestions regarding investment decision-making.
- Early-stage R&D: The team explores new R&D opportunities, conducts feasibility research and provides evaluation opinion for the opportunities. The team also designs and prepares new types of chemical compounds, conducts systematic research regarding the manufacturing process and quality management of the new drugs, and develops technology platforms to support, manage and supervise the related technologies.
- Preclinical R&D: The team coordinates and accomplishes preclinical R&D activities in relation to pharmacology, efficacy, toxicology, and safety. The team also assists in the registration process of the new drugs by collecting and preparing the required information and materials.
- Pharmaceutical R&D: The team conducts extensive early-stage investigation on drug candidates. The team also develops and optimizes our proprietary technologies in the manufacturing process and quality control of our API products and enoxaparin sodium

BUSINESS

injection products in accordance with the ICH guidelines and QbD principles, after which the team will assist in the transfer of manufacturing technology to our manufacturing department.

- Technology support to the commercialized pharmaceutical products: The team stipulates specific activity plans and provides technology support at each stage of the products’ commercialization, in order to accommodate the continuing changes of our supply chains, production and operation, quality management requirements, and our customers’ and market demands. Such adjustment will help enhance our technology levels and ensure the quality consistency of our products.

Collaboration with Third Parties

During the Track Record Period, our portfolio companies primarily conducted the R&D of our drug candidates that we obtained exclusive development and commercial rights in Greater China from them. We plan to gradually participate in the clinical trial for our drug candidates in China as part of their global trial under the MRCT. For AR-301, our subsidiary, Shenzhen Arimab, is in charge of employing the principal investigators for the clinical trial of AR-301 in China. Shenzhen Arimab has entered into a master service agreement with an international CRO, under which, we provide separate work order with detailed specification and schedule that the CRO should follow in providing services for each clinical trial, such as the clinical trial for AR-301 to be conducted in China. Pursuant to the agreement, the CRO is required to perform its services in accordance with the standard operating procedures as set out in each work order that specifies the tasks and responsibilities of the CRO with respect to each project, which are designed based on the applicable regulatory authority requirements defined by the ICH-GCP guidelines.

With respect to our self-developed drug candidate, our in-house R&D team plays a leading role in the design and management of the R&D projects, and outsources the execution work to leading CROs.

R&D in CDMO Business

We provide various R&D services for our clients. For details, see “—Our CDMO Business—R&D Services.” As of the Latest Practicable Date, we had an experienced R&D team consisting of 146 people, among which, over 23 possessed a doctorate degree and over 20 had a master degree.

In addition, Cytovance currently participates as a fee-for-service CDMO vendor in the development of certain of our drug candidates. OncoQuest has been a customer of Cytovance since 2016 for the development of Oregovomab, and OncoVent has been a customer since 2019 for the development of mAb-AR20.5. The work completed for Oregovomab includes process development and one scale-up manufacturing batch for phase III clinical supply. The work completed for mAb-AR20.5 includes process development.

MANUFACTURING

We currently manufacture most of our biopharmaceuticals at our production facilities in Shenzhen, China and SPL’s production facilities in Waunakee, Wisconsin, the U.S. We also outsource a small portion of the manufacturing of enoxaparin sodium injection to our OEM partners, who follow our manufacturing process and quality standards, as well as the CGMP requirements. Substantially all packaging activities in relation to these products in the PRC are conducted at our Shenzhen facilities.

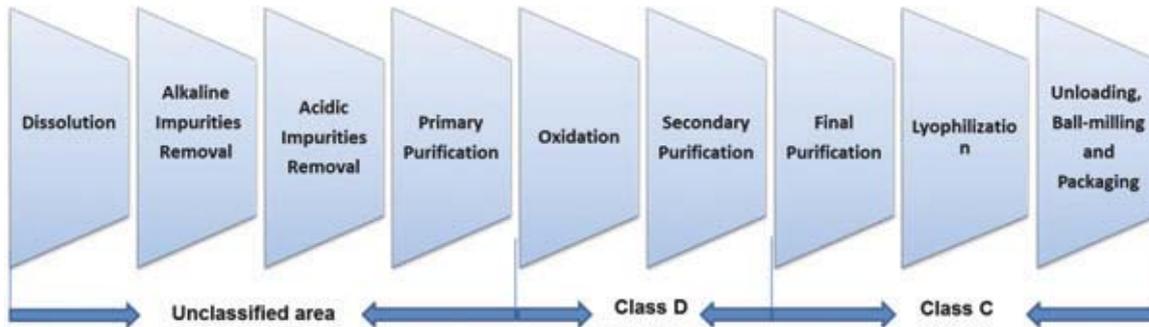
BUSINESS

We generally manufacture our products based on quarterly and monthly order forecasts. We expect that our existing manufacturing facilities and our OEMs will allow us to meet manufacturing needs for our biopharmaceuticals and product candidates that are in clinical trials in the near future.

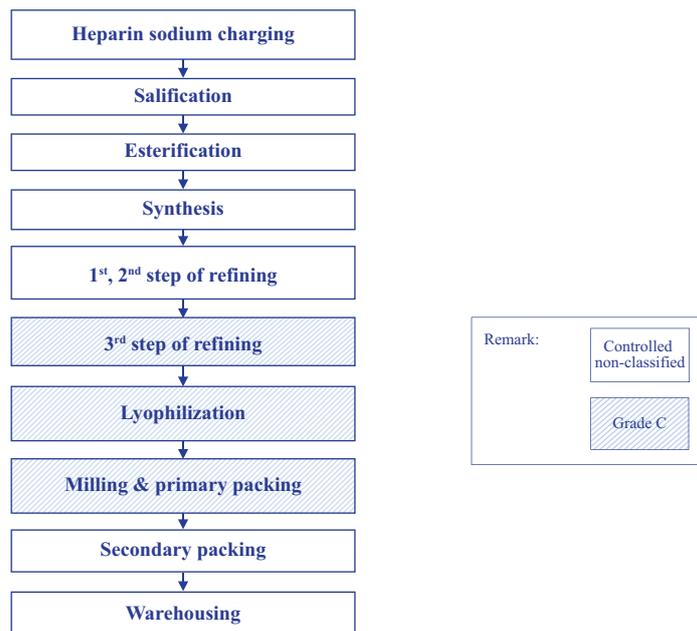
Manufacture of Our Products

Process

The following diagram summarizes the manufacturing process for our heparin sodium API:

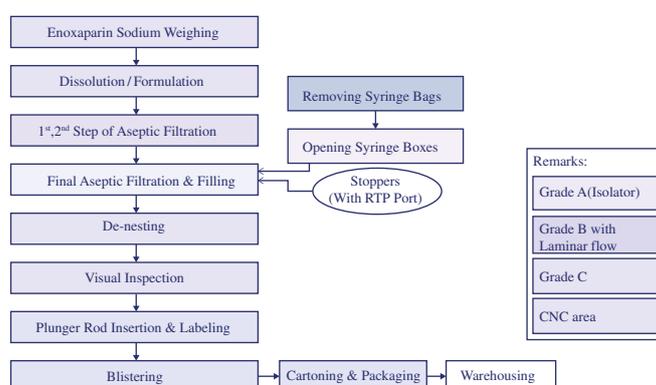


The following diagram summarizes the manufacturing process for our enoxaparin sodium API:



BUSINESS

The following diagram summarizes the manufacturing process for our enoxaparin sodium injection in the format of pre-filled syringes:



Our Manufacturing Activities

Most of our production activities are currently carried out at our Techdow Nanshan, Hepalink Nanshan and SPL facility. We have also completed the construction and process validation of our Pingshan Industrial Park located in Shenzhen, China, which is expected to significantly enhance our manufacturing capacity. Our key production processes are highly automated and can be used to produce our enoxaparin sodium injection in different strengths. Therefore, we are able to adjust our production to meet market demand and our sales target in response to market demand. As of the Latest Practicable Date, we believe our facilities and equipment are in good working condition. We own all of our production facilities and workshops. We conduct regular maintenance and repair work in compliance with applicable CGMP requirements.

The following table sets forth the designed capacity, production volume and utilization rates of our production sites:⁽¹⁾

	For the year ended December 31,		For the nine months ended September 30,
	2017	2018	2019
Hepalink Nanshan			
<i>Heparin sodium API (mega)</i>			
Designed production capacity	10,000,000	10,000,000	7,500,000
Production volume	5,501,804	6,877,959	4,380,030
Utilization rate ⁽²⁾	55.0%	68.8%	58.4%
Techdow Nanshan			
<i>Enoxaparin sodium API (kg)</i>			
Designed production capacity	9,350	9,350	7,013
Production volume	4,672	8,815	6,300
Utilization rate ⁽³⁾	50.0%	94.3%	89.8%
<i>Enoxaparin sodium Injection (pre-filled syringes)</i>			
Designed production capacity	80,000,000	140,000,000	120,000,000
Production volume	28,090,714	77,210,552	85,287,897
Utilization rate ⁽⁴⁾	35.1%	55.2%	71.1%
SPL			
<i>Heparin sodium API (mega)</i>			
Designed production capacity	3,000,000	3,000,000	2,250,000
Production volume	2,078,644	2,116,517	1,580,339
Utilization rate	69.3%	70.6%	70.2%

Notes:

(1) Utilization rate equals actual production volume divided by designed production capacity.

BUSINESS

- (2) The increase in the utilization rate from 2017 to 2018 was primarily attributable to a significant increase in the production volume of our finished dose pharmaceutical products driven by an increasing demand from our EU market, and the decrease in the utilization rate from 2018 to the nine months ended September 30, 2019 was primarily due to the outbreak of the swine fever and the decrease in the market demand.
- (3) The increase in the utilization rate from 2017 to 2018 was primarily attributable to a significant increase in the production volume of our finished dose pharmaceutical products driven by an increasing demand from our EU market, and the decrease in the utilization rate from 2018 to the nine months ended September 30, 2019 was primarily due to the increase in the price of raw materials and the decrease in the API orders.
- (4) The increase in the utilization rate from 2017 to 2018 was primarily attributable to a significant increase in the production volume of our enoxaparin sodium injection products driven by an increasing demand from our EU market, and the decrease in the utilization rate from 2018 to the nine months ended September 30, 2019 was primarily due to the increase in the price of raw materials and the decrease in the market demand.

Our CDMO Manufacturing Services

Cytovance operates the manufacturing services from facilities in Oklahoma City, Oklahoma, the U.S. The facilities in total include over 2,108 sq.m of CGMP-compliant manufacturing clean room, 964 sq.m of quality control laboratories, and additional facilities that house our process development, analytical development and administrative functions. As of the Latest Practicable Date, Cytovance had three production lines: microorganism production line, mammalian cell culture production line and pDNA production line. Each of the production lines has facilities with different designed capacities.

The following table sets forth the manufacturing capacity and utilization rates of our CDMO production lines during the Track Record Period:

	For the year ended December 31,		For the nine months ended September 30,
	2017	2018	2019
	(in l)		
Cytovance			
<i>Mammalian cell culture</i>			
Designed production capacity	14,800	14,800	21,000
Production volume	9,600	7,900	2,325
Utilization rate ⁽¹⁾	64.9%	53.4%	11.1%
<i>Microbial fermentation</i>			
Designed production capacity	5,670	18,670	30,578
Production volume	4,620	17,490	15,180
Utilization rate ⁽¹⁾	81.5%	93.7%	49.6%

Notes:

(1) Utilization rate equals actual production volume divided by designed production capacity.

RAW MATERIALS AND SUPPLIERS

Our Suppliers

For the years ended December 31, 2017, 2018, and the nine months ended September 30, 2019, purchases from our five largest suppliers in aggregate accounted for 32.8%, 22.5% and 20.2% of our total purchases (including value added tax), respectively, and purchases from our largest supplier accounted for 9.6%, 9.3% and 7.0% of our total purchases for the same periods (including value added tax), respectively. During the Track Record Period, our purchases mainly include raw materials, machines and equipment and services from third parties such as syringes and porcine small intestines.

The table below sets forth the procurement of our top five suppliers. We have worked together with the majority of our top five suppliers for an average of three years. During the year ended

BUSINESS

December 31, 2018 and the nine months ended September 30, 2019, we sold porcine small intestines to Supplier A and the revenue and gross profit attributable to such sales represented around 0.13% and 0.10% of our total revenue and around 0.02% and 0.03% of our gross profit, respectively. During the same periods, we sold porcine small intestines to Supplier C and the revenue and gross profit attributable to such sales represented around 0.05% and 0.21% of our total revenue, respectively and generated negative gross profit in the respective periods. During the same periods, we provided examination services to Supplier D and the revenue and gross profit attributable to such services represented around 0.04% and 0.07% of our total revenue and around 0.09% and 0.21% of our gross profit, respectively. None of our Directors or any Shareholder who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [REDACTED] (but without taking into account the exercise of the [REDACTED]) nor any of their respective associates had any interest in any of our five largest suppliers during the Track Record Period.

<u>Five Largest Suppliers for the year ended December 31, 2017</u>	<u>Company Background</u>	<u>Purchases</u>	<u>Purchase Amount</u>	<u>Percentage of Total Purchases</u>
			RMB'000	
Supplier A	A supplier of crude heparin, sausage casing and other sideline products	Crude heparin	185,301	9.6%
Supplier B	A supplier of crude heparin, sausage casing and other sideline products	Crude heparin	152,571	7.9%
Supplier C	A supplier of crude heparin, sausage casing and other sideline products	Crude heparin	115,608	6.0%
Supplier D	A supplier of disposal medical supplies	Syringes	90,355	4.7%
Supplier E	A food processing company	Porcine small intestine and porcine pancreas	86,568	4.5%
Total.			<u>630,403</u>	<u>32.8%</u>

BUSINESS

Five Largest Suppliers for the year ended December 31, 2018	Company Background	Purchases	Purchase Amount	Percentage of Total Purchases
			RMB'000	
Supplier D	A supplier of disposal medical supplies	Syringes	257,976	9.3%
Supplier E	A food processing company	Porcine small intestine and porcine pancreas	106,241	3.8%
Supplier C	A supplier of crude heparin, sausage casing and other sideline products	Crude heparin	95,623	3.5%
Supplier F	A supplier of research laboratory products	Raw material for CDMO Service	83,968	3.0%
Supplier A	A supplier of crude heparin, sausage casing and other sideline products	Crude heparin	79,142	2.9%
Total			<u>622,950</u>	<u>22.5%</u>

Five Largest Suppliers for the nine months ended September 30, 2019	Company Background	Purchases	Purchase Amount	Percentage of Total Purchases
			RMB'000	
Supplier D	A supplier of disposal medical supplies	Syringes	153,913	7.0%
Supplier C	A supplier of crude heparin, sausage casing and other sideline products	Crude heparin	84,552	3.8%
Supplier B	A supplier of crude heparin, sausage casing and other sideline products	Crude heparin	74,714	3.4%
Supplier E	A food processing company	Porcine small intestine and porcine pancreas	67,250	3.1%
Supplier A	A supplier of crude heparin, sausage casing and other sideline products	Crude heparin	63,016	2.9%
Total			<u>443,445</u>	<u>20.2%</u>

Raw Materials and Packaging Materials

We have established an integrated supply chain to support the entire manufacturing process of our products. Heparin sodium API and enoxaparin sodium API are our primary products and at the same time the principal raw materials for our respective heparin sodium injection products. The heparin sodium API also serves as the principal raw material for the production of our enoxaparin sodium API. We have stringent quality control measures in place that manage the quality of the raw materials we produce, and we have also established sufficient control on the quality management of our suppliers to ensure the quality of the raw materials we purchase from Independent Third Parties.

BUSINESS

For the principal packaging materials and raw materials we purchase from third parties, including syringes, porcine small intestines and crude heparin, we select our suppliers based on various factors, including their product quality, reputation and business scale. The purchase price of our principal materials is primarily based on the prevailing market prices for raw materials of similar quality. We generally contract with more than one supplier for each major type of materials. We also currently maintain two alternative suppliers for syringes in China. We currently maintain 242 alternative suppliers for our porcine small intestines, and 52 alternative suppliers for crude heparin. All of our suppliers of porcine small intestines were in China during the Track Record Period. We have not experienced significant difficulties in maintaining reliable sources of supplies and expect to be able to maintain adequate sources of quality supplies in the future.

We generally enter into supply agreement with a term of one to three year with our syringe suppliers, which lists the product specifications and quality standards our suppliers should comply with. We generally enter into supply agreements with a term of one year with our suppliers of porcine small intestines. The supply agreements set forth our requirements and specifications for the porcine small intestine to ensure its high quality. We have entered into procurement agreement for a term of two to five years with our principal suppliers for crude heparin. Our procurement agreement sets forth relevant requirements to ensure the traceability of the crude heparin. All suppliers are obligated to conduct their production in compliance with relevant requirements, such as CGMP standards, and their manufacturing facilities and process are subject to our audit from time to time.

During the Track Record Period, except as disclosed in this Document, fluctuations in raw materials costs have not had a material impact on our results of operations or gross profit margin. We do not believe we have experienced any discernible trends in raw materials costs during the Track Record Period.

INVENTORY

Our inventory primarily consists of finished products, work in progress, raw materials, active pharmaceutical ingredients, excipients and packaging materials. We generally maintain an inventory level of three months of inventory for our API products and four months of inventory for our enoxaparin sodium injection and such level will vary according to the demand of our customers, sales and production plans. We generally keep one week’s supply of our raw materials, and specifically for our principal raw material, we keep two weeks’ supply of porcine small intestines, one months’ supply of crude heparin and two months’ supply of syringes. Our inventory is sufficient for our production, primarily because the procurement for our principal raw materials, such as crude heparin, usually takes at most two weeks and the production cycle of our valve products is usually approximately three to four weeks/months. Our raw materials, porcine small intestines have to be fresh when used in production and crude heparin has a 24-month effective period. Our API products have a shelf life of two to five years, and our enoxaparin sodium injection products have a shelf life of two to three years.

All our products are sold on a first-in-first-out basis. To minimize the risk of building up inventory, we regularly review our inventory levels. We also carry out physical stock counts and stock inspections from time to time to identify damaged products or obsolete or about-to-expire products, which are disposed of or for which provisions are made. In 2017 and 2018 and the nine months ended September 30, 2019, we incurred write-down of inventories of approximately RMB37.6 million, RMB40.6 million and RMB36.9 million respectively.

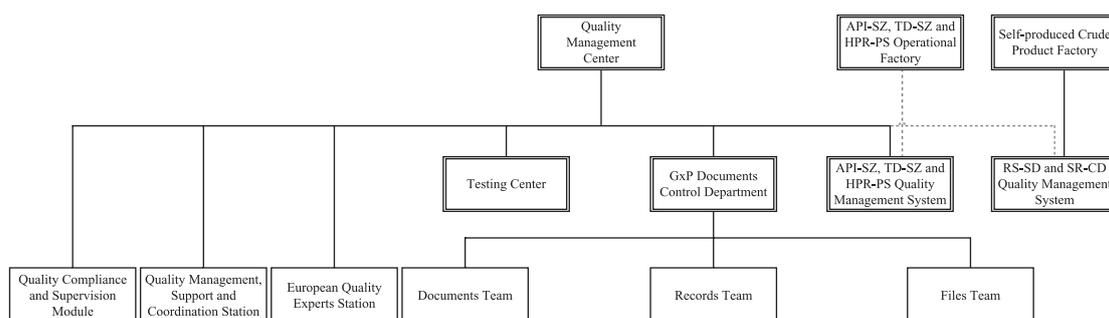
BUSINESS

We have established an inventory management system that monitors each stage of the warehousing process. Warehousing personnel are responsible for the inspection, storage and distribution of production materials and finished products. All materials and products are stored in different areas in warehouse according to their storage condition requirement, properties, usage and batch number. Warehousing personnel regularly check to ensure consistency among the raw material or product, logbook and material card. Our production material control department, production plan control department and raw material supply chain department manages our inventory levels by monitoring in real time our production activities and sales orders and also taking into consideration any emerging trends through discussions with our quality management department and other departments. Based on this information, the production material control department and raw material supply chain department develops a production and inventory plan, which is updated on a monthly basis, and raw materials supply chain department places orders with suppliers for any inventory which is expected to decline below targeted levels.

QUALITY CONTROL

We have established a comprehensive quality control system that manages the quality control through our entire business operation, ranging from procurement of raw materials, manufacturing process and the sales and distribution of our products. We have devoted significant attention and resources to quality control, led by our management, who is actively involved in setting quality control policies and targets. Our quality management department is responsible for the design and implementation of quality control measures and standards, with the cooperation of other departments in their respective fields.

As of the Latest Practicable Date, our quality management center consisted of 278 employees, including 79 members in our quality assurance team, 157 members in our quality control team and 42 members in our GxP document control department. The diagram below illustrates the structure of the quality management center:



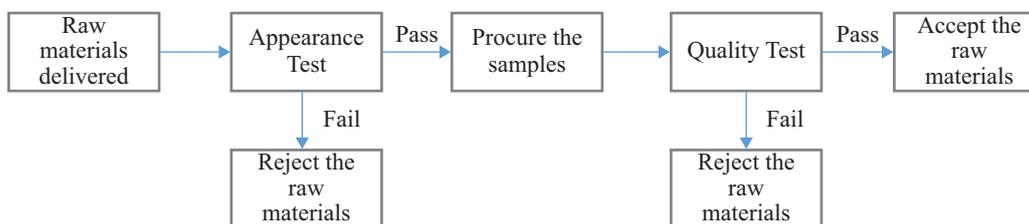
Quality Control of Raw Materials

Prior to entering into supply agreements with our raw material suppliers, we perform background checks on the operating history, track record and market reputation of a list of potential suppliers, procure different product samples from the potential suppliers for inspection and testing by our quality control team, conduct site visits and examine the production facilities of the potential suppliers to ensure that the suppliers we select meet our quality requirements.

We routinely conduct on-site audits at the suppliers’ premises to monitor their compliance with the quality management requirements pursuant to our agreement. Traceability of the raw material

BUSINESS

supplies is required for our principal suppliers. Upon receiving supplies, we retain the right to reject or return based on our inspection and examination results. The diagram below shows the verification process for raw materials:



Quality Control of Manufacturing

Our quality management center is responsible for ensuring that we comply with applicable regulatory and industry standards throughout the entire manufacturing process through regular on-site inspections. In addition, each subsidiary has set up its own quality control department and quality assurance department to carry out the duties of supervision and routine inspection. After completing each step of the production process, we perform cleaning and maintenance procedures to prevent contamination or cross contamination before we proceed to the next production cycle. We also perform regular dust and microbiological testing in our production facilities in accordance with our detailed manufacturing standards.

Each batch of our products is subject to a strict inspection before sales. We conduct sample testing on certain work in progress and semi-finished products at particular stages of production. In addition, our quality assurance department inspects the documentation relating to product quality, including its batch records, laboratory control records, production process records and other information that may impact product quality. Thereafter, they conduct a final review on all documents and determine whether a specific product can be released for shipment. Products that do not meet our quality standards are destroyed or otherwise disposed of in accordance with the relevant disposal requirements.

Quality Control of Inventory

Our inventory, including crude heparin and our finished products, are required to be stored below a certain temperature. We have designated warehouse personnel to monitor our inventory and conduct regular inspection of the facility and the inventory strictly following our protocol.

Quality Control of Transportation

Our quality management center monitors the transportation process and administers transportation records, and our sales and marketing department provides technical support.

After-Sale Quality Control

We are able to track our products sold to our end customers. The team continues to focus on the safety risks of post-marketing products, to protect patient safety. If we determine that an incident involving our product constitutes a major adverse event under relevant regulations, we will report the incident to governmental authorities, such as the NMPA, FDA, and analyze the expectedness, severity, and causality of the event.

BUSINESS

We analyze feedback from our distributors and hospitals and handle any customer complaints with respect to the quality of our products. Quality complaints, both verbal and written, are documented and investigated pursuant to standard procedures. We have dedicated employees responsible for responding to complaint calls. If any product falls short of the relevant quality standards due to our fault, we will replace the defective product at our own costs. During the Track Record Period and up to the Latest Practicable Date, we did not experience any product returns, recalls or product liability claims, nor have we received any major customer complaints.

INVESTMENT IN FUNDS

We intend to seek opportunities to expand our business through investment in funds. We are primarily interested in funds with attractive portfolio company in the biotechnology or pharmaceutical industry. Most of the funds we have already invested in focus on biotechnology companies. For instance, we are the biggest LP of TPG Biotechnology Partners V, holding 68.52% of its shares. In addition, we are the 99.00% LP of Maple Sea Capital. We sit on the investment committee of the fund’s GP, participating in the decision-making process regarding the fund’s investment portfolio selection and routine management. In the future, we may expand our investment portfolio via funds investment by identifying and investing in the biotechnology start-ups and mature pharmaceutical companies with significant growth potential, which will help solidify our leading position in the biopharmaceutical industry.

INTELLECTUAL PROPERTY

We have acquired intellectual property in and outside China and may seek additional patents to protect our innovations in the future.

As of the Latest Practicable Date, we had been granted with 43 patents in total, among which 27 were in China, seven were in the U.S., four were in the EU and five patents were in other overseas region. As of the Latest Practicable Date, we had pending applications for 32 patents in total, among which six were in China, five were in the U.S., five were in the EU, 13 were in other overseas regions and three pending applications were under PCT. As of the Latest Practicable Date, we owned 144 registered trademarks and nine pending trademark applications in China. We also had exclusive in-licensing arrangements with respect to patents for the development of our innovative drug candidates. For details of our intellectual property, please refer to “Appendix VI—Statutory and General Information—Further Information About Our Business—Intellectual Property Rights” in this document.

The following table summarizes the material patents and patent applications we owned as of the Latest Practicable Date:

<u>Product/Technology</u>	<u>Coverage of Patent Protection</u>	<u>Status</u>	<u>Covered Regions</u>
DS	Method	Granted	China
HS	Method	Granted	China
Sulodexide	Method	Granted	China
Lower anticoagulant heparin	Product and usage	Granted	China
Sulphated oligosaccharide	Product and Method	Granted	China
Sulphated oligosaccharide	Product and Method	Pending	Europe
Sulphated oligosaccharide	Product and Method	Pending	Japan
Sulphated oligosaccharide	Product and Method	Pending	United States

BUSINESS

<u>Product/Technology</u>	<u>Coverage of Patent Protection</u>	<u>Status</u>	<u>Covered Regions</u>
Heparanase inhibitor	Product and Method and Usage	Pending	PCT
Heparanase inhibitor	Product and Method and Usage	Pending	Taiwan
Enoxaparin sodium injection	Method	Granted	China
Dalteparin Sodium injection	Method	Granted	China
Heparanase deficient non-human mammals	Method	Granted	China
Heparanase deficient non-human mammals	Product and Method	Granted	United States
Heparanase deficient non-human mammals	Method	Granted	Japan
Heparinase I	Method	Granted	China
Heparinase I and Heparinase III	Method	Granted	China
Heparinase II	Method	Granted	China
Heparinase from <i>Sphingobacterium daejeonense</i>	Method and product	Granted	China
Heparinase from <i>Sphingobacterium daejeonense</i>	Method	Granted	Japan
Heparinase from <i>Sphingobacterium daejeonense</i>	Method	Granted	United States
Heparinase from <i>Sphingobacterium daejeonense</i>	Method and product	Pending	Europe
Heparinase from <i>Pseudomonas stutzeri</i>	Method and product	Pending	China
Heparinase from <i>Pseudomonas stutzeri</i>	Method and product	Pending	Europe
Heparinase from <i>Sphingobacterium multivorum</i>	Method and product	Pending	China
Chondroitinase B and AC	Method	Granted	China
Immobilization of Heparinase II	Method	Granted	China
Immobilization of Heparinase III	Method	Granted	China
Electrophoresis method	Analysis method	Granted	China
Detecting of Enoxaparin by HPLC	Analysis method	Granted	China
Separating of oligosaccharides by RP-IP-HPLC	Analysis method	Granted	China
Detecting of Sulodexide by HPLC	Analysis method	Pending	China
Molecular weight and distribution of LMWH	Analysis method	Granted	China
Analysis of degraded fragments of dalteparin by nitrous acid	Analysis method	Pending	PCT
Chain mapping method of LMWH	Analysis method	Pending	PCT
Heparinase from <i>Pseudomonas stutzeri</i>	Method and product	Pending	Japan
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Granted	China
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Granted	Europe
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Pending	India
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Pending	Japan
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Granted	Korea
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Pending	United States
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Granted	China
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Granted	Europe
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Pending	India
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Pending	Japan
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Pending	Korea
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Pending	United States

BUSINESS

The following table summarizes patents and patent applications we licensed from other entities for the development of our innovative drug candidates as of the Latest Practicable Date:

<u>PRODUCT</u>	<u>Scope of patent protections</u>	<u>Jurisdiction</u>	<u>Patent status</u>	<u>Applicant.</u>	<u>Patent expiration</u>
Oregovomab	Tumor antigen specific antibodies and TLR3 stimulation to enhance the performance of checkpoint interference therapy of cancer	China	Pending	Oncoquest	—
mAb-AR20.5	Tumor antigen specific antibodies and tlr3 stimulation to enhance the performance of checkpoint interference therapy of cancer	China	Pending	Oncoquest	—
AR-301	Human monoclonal antibody againsts <i>S. aureus</i> derived alpha-toxin and its use in treating or preventing abscess formation	China	Granted	Aridis	2030/8/10
AR-101	Human monoclonal antibody specific for lipopolysaccharides LPS of the <i>pseudomonas aeruginosa</i> IATSO11 serotype	China	Granted	KENTA BIOTECH AG	2/13/2026
RVX-208	Compounds for the prevention and treatment of cardiovascular diseases	China	Granted	Resverlogix	2/1/2027
		China-DIV	Granted		2/1/2027
		Hong Kong	Granted		2/1/2027
		Hong Kong	Granted		2/1/2027
	Methods of preparing quinazolinone derivatives	China	Granted		6/24/2029
		Hong Kong	Granted		6/24/2029
	Oral immediate release formulations for substituted quinazolinones	China	Granted		10/31/2032
		Hong Kong	Pending		10/31/2032
	Compositions and therapeutic methods for the treatment of complement-associated diseases	China	Pending		3/10/2036
		Hong Kong	Pending		3/10/2036
		Taiwan	Pending		3/11/2036
	Compounds useful in the synthesis of benzamide compounds	China	Granted		10/9/2033
		Hong Kong	Granted		10/9/2033
Novel anti-inflammatory agents	China	Granted		4/21/2030	
	China-DIV	Pending		4/21/2030	
	Hong Kong	Granted		4/21/2030	

We also rely on trade secrets, proprietary know-how and continuing technological innovation to develop and maintain a competitive position for our products. We generally require our employees,

BUSINESS

consultants and advisors to enter into confidentiality agreements. These agreements provide that all confidential information developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except under specific circumstances. In the case of our employees, the agreements provide that all of the technology which is conceived by the individual during the course of employment is our exclusive intellectual property. Furthermore, as a matter of company policy, all scientific and technical employees have entered into agreements that generally require disclosure and assignment to us of ideas, developments, discoveries and inventions made by them which are relating to their employment with us.

We follow procedures to ensure that we do not infringe on the intellectual property rights of others. As of the Latest Practicable Date, we had not been involved in any material intellectual property disputes or encountered major difficulties in enforcing our intellectual property rights in China.

COMPETITION

The pharmaceutical and biopharmaceutical industries are characterized by rapidly advancing technologies, competition, and a strong emphasis on proprietary drugs. While we believe that our development experience and scientific knowledge are able to equip us with competitive advantages in drug development and manufacture, we face potential competition from many different sources, including a number of established pharmaceutical companies and emerging biotechnology start-ups. For our CDMO business, we compete with smaller to medium sized CDMOs, both multinational and locally based.

Our products primarily compete with products that are indicated for similar conditions as our products on the basis of efficacy, price and general market acceptance by medical professionals and hospitals. The identities of our key competitors vary by product or drug candidate, while in certain cases, our competitors may have greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do.

Additionally, for our CDMO business, we face competition from major biologics CDMO providers based on several factors, including but not limited to quality and breadth of services, ability to protect our customers’ intellectual property or other confidential information, timeliness of delivery, maintenance of CGMP compliance, depth of customer relationships, and price. Please refer to “—Our CDMO Business” above and “Industry Overview” for further details of our major competitors.

We believe our continued success will primarily depend on our capability to develop innovative products and advanced technologies, our capability to apply technologies to all production lines, our capability to develop an extensive product portfolio and pipeline, our capability to effectively commercialize and market our products, our capability to establish network and maintain customer relationships, our capability to satisfy the growing demands for biologics CDMO service, our capability to attract and retain seasoned and talented technology development personnel, our ability to maintain high quality standards, our capability to maintain a highly efficient operational model, and our ability to obtain and maintain regulatory approvals.

EMPLOYEES

As of the Latest Practicable Date, we had 2,153 employees, of whom 1,520 were located in China, 584 were located in the U.S., 49 were located in Europe.

BUSINESS

As of the Latest Practicable Date, 843 of our employees held bachelor’s or higher degrees, and 188 held master’s or higher degrees. The following table shows a breakdown of our employees by function as of the Latest Practicable Date:

	<u>Number of Employees</u>	<u>% of total</u>
Manufacturing and service	1,135	52.7%
Research and development	345	16.0%
Sales and marketing	107	5.0%
Quality Control	285	13.2%
General administration	281	13.1%
Total	<u>2,153</u>	<u>100.0%</u>

We believe that our success will depend in part on our ability to attract, recruit and retain quality employees. To maintain the quality, knowledge and skill levels of our workforce, we provide our employees with periodic training, including introductory training for new employees, technical training, professional and management training and health and safety training. We provide our sales and marketing team with extensive training.

We enter into individual employment contracts with our employees to cover matters such as wages, benefits, and grounds for termination. We generally formulate our employees’ remuneration package to include salary, bonus and allowance elements. Our compensation programs are designed to remunerate our employees based on their performance, measured against specified objective criteria. We also provide our employees with welfare benefits in accordance with applicable regulations and our internal policies.

Our employees are represented by relevant labor unions. We believe that we maintain a good working relationship with our employees and we did not experience any significant labor disputes or any difficulty in recruiting staff for our operations during the Track Record Period.

In accordance with applicable regulations we participate in a pension contribution plan, a medical insurance plan, an unemployment insurance plan and a personal injury insurance plan for our employees. We have made adequate provisions in accordance with applicable regulations. Also, in accordance with PRC regulations, we make annual contributions towards a housing fund, a supplemental medical insurance fund and a maternity fund.

INSURANCE

We maintain insurance policies for all of our properties, manufacturing facilities, plant and material machinery, equipment and inventories against damage caused by accidents. We maintain product liability insurance against claims or liabilities that may arise from products that we have sold and key person insurance. We believe that our insurance coverage is in line with industry practice in the PRC. We believe that our insurance coverage is in line with industry practice in relevant jurisdictions. We did not experience any material industrial accidents during the Track Record Period.

PROPERTIES AND FACILITIES

As of the Latest Practicable Date, we owned seven properties in China, primarily in Shenzhen, Linyi and Chengdu, and three properties overseas, primarily in the U.S. We owned in total gross floor

BUSINESS

area of approximately 48,845 sq.m. for production facilities, including 4,458 sq.m. in Hepalink Nanshan facility, 6,848 sq.m. in Techdow Nanshan facility, and 8,852 sq.m. in SPL. We also owned gross floor area of 4,207 sq.m. for R&D activities, 12,307 sq.m. for staff housing, 11,469 sq.m. for storage and 27,185 sq.m. for office space and other general administrative use.

The following table summarizes the major properties we owned as of the Latest Practicable Date:

<u>Entity/Facility</u>	<u>Location</u>	<u>Land Use Right or Property Ownership and Gross Floor Area</u>	<u>Use</u>
Hepalink (Hepalink Nanshan)	Nanshan District, Shenzhen, China	Land use right for a total site area of approximately 10,271 sq.m; Property ownership for building area of approximately 4,874 sq.m	Production facility for our pharmaceuticals for 4,458 sq.m; Storage area for our pharmaceuticals for 88 sq.m; Office area for 331 sq.m
Topknow (Techdow Nanshan)	Gaoxinzhong Road, Nanshan District, Shenzhen, China	Land use right for a total site area of approximately 18,094 sq.m; Property ownership for building area of approximately 20,892 sq.m	Production facility for our pharmaceuticals for 11,027 sq.m; Storage area for our pharmaceuticals for 8,982 sq.m; R&D area for our pharmaceuticals for 3,037 sq.m; Office area for 4,401 sq.m
Hepalink (Pingshan Industrial Park)	Jinxiu East Road And Rongtian Road, Pingshan New District, Shenzhen, China	Land use right for a total site area of approximately 50,721 sq.m	N/A
Hepalink (Pingshan Industrial Park)	Jinxiu East Road And Rongtian Road, Pingshan New District, Shenzhen, China	Land use right for a total site area of approximately 154,111 sq.m	N/A
Shenzhen Beidi Aoke (Technology Development Co., Ltd.)	Nanshan District, Shenzhen, China	Land use right for a total site area of approximately 4,507 sq.m; Property ownership for building area of approximately 9,997 sq.m	R&D area for our pharmaceuticals for 150 sq.m; Office area for 9,867 sq.m
Shandong Ruisheng (crude heparin production)	Volve Road, Shandong Province, China	Land use right for a total site area of approximately 74,666 sq.m; Property ownership for building area of approximately 23,474 sq.m	Production facility for our pharmaceuticals for 13,510 sq.m; Housing area for 6,031 sq.m; Office area for 3,935 sq.m

BUSINESS

<u>Entity/Facility</u>	<u>Location</u>	<u>Land Use Right or Property Ownership and Gross Floor Area</u>	<u>Use</u>
Chengdu Sunrace (crude heparin production)	Mengjiangxi Road, Chengdu City, Sichuan Province, China	Land use right for a total site area of approximately 42,571 sq.m; Property ownership for building area of approximately 23,917 sq.m	Production facility for our pharmaceuticals for 15,179 sq.m; Housing area for 6,276 sq.m; Office area for 2,461 sq.m
SPL	Murray Street, Sioux City, Iowa, United States	Land ownership for a total site area of approximately 188,834 sq.m; Property ownership for building area of approximately 1,910 sq.m	Production facility for our pharmaceuticals for 1,543 sq.m; Storage area for our pharmaceuticals for 641 sq.m; Office area for 325 sq.m
SPL	Main Street, Waunakee, Wisconsin, United States	Land ownership for a total site area of approximately 155,399 sq.m; Property ownership for building area of approximately 10,223 sq.m	Production facility for our pharmaceuticals for 6,937 sq.m; Storage area for our pharmaceuticals for 1,230 sq.m; R&D area for our pharmaceuticals for 1,019 sq.m; Office area for 1,036 sq.m
SPL	Main Street, Waunakee, Wisconsin, United States	Land ownership for a total site area of approximately 35,612 sq.m; Property ownership for building area of approximately 4,182 sq.m	Production facility for our pharmaceuticals for 371 sq.m; Storage area for our pharmaceuticals for 2881 sq.m; Office area for 929 sq.m

As of the Latest Practicable Date, we leased six properties from third parties, primarily in Shenzhen, China and Oklahoma, U.S. We leased gross floor area of 23,999 sq.m., including 6,129 sq.m. for production facilities, 2,261 sq.m. for R&D activities, 10,095 sq.m. for storage and 5,513 sq.m. for office space and other general administrative use.

As of September 30, 2019, none of the properties held or leased by us had a carrying amount of 15% or more of our consolidated total assets. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L), this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which require a valuation report with respect to all our Group’s interests in land or buildings.

With respect to the manufacturing facilities we leased in China with a gross floor area of 665.7 sq.m., the title owner of such property is Office of the Leading Group of Shenzhen Hi-Tech Industrial

BUSINESS

Park (深圳高新技術產業園區領導小組辦公室), who had obtained the planned construction permit although it has not yet obtained the title certificate to the property. Shenzhen Software Park Management Center (深圳市科技評審管理中心) has been authorized to lease such property to us. Since Office of the Leading Group of Shenzhen Hi-Tech Industrial Park has not yet obtained the certificate of ownership for such property, Shenzhen Software Park Management Center could not provide us with the certificate of ownership. In accordance with the relevant PRC laws and regulations, if the lessor fails to obtain the certificate of ownership for the leased property, the lease may become invalid. Nevertheless, since Office of the Leading Group of Shenzhen Hi-Tech Industrial Park has obtained the permit for the planned construction project and has granted an authorization to lease the property to us, our PRC legal adviser is of the view that the likelihood of our lease being invalid is relatively low.

ENVIRONMENTAL AND SOCIAL MATTERS

Environmental Protection

We are subject to national and local environmental laws and regulations of the PRC. During our manufacturing processes, we must comply with PRC laws and regulations concerning the discharge of air, water and solid waste as well as noise control. In addition, manufacturers engaging in any new construction project must prepare an environmental impact study report setting forth the impact the proposed construction project may have on the environment and the measures to prevent or mitigate the impact for approval by the government authority prior to commencement of construction of the relevant project. Please refer to the section headed “Regulatory Environment — Laws and Regulations Related to Our Business in the PRC — Environmental Regulations” in this document for details on PRC environmental laws and regulations we are subject to.

We have established detailed internal rules regarding environmental protection. We test effluent water to ensure compliance with national emission standards. Solid waste is sorted for proper disposal. Hazardous waste is sent to qualified third parties for treatment. When a new construction project is proposed, we conduct comprehensive analysis and testing on the environmental issues involved in the manufacturing processes. Our production team and in-house legal department are primarily responsible for ensuring our compliance with applicable environmental rules and regulations. During the Track Record Period, we did not incur any additional costs specifically attributable to environmental compliance. Going forward, we expect that our annual cost of compliance will be consistent with our scale of operations. All our property, plant and equipment meet the standards required for compliance with applicable environmental rules and regulations, and we believe we have maintained good relationship with the communities surrounding our production facilities.

Our PRC legal adviser has confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had complied with all applicable laws and regulations relating to production safety and environmental requirements in all material respects.

Occupational Health and Safety

We strive to provide a safe working environment for our employees. We have implemented work safety guidelines setting out safety practices, accident prevention and accident reporting. We require new employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. In particular, we invite experts on fire control safety to conduct training sessions and regularly perform emergency evacuation drills to reduce risks associated with potential fire accidents.

BUSINESS

We are subject to various PRC laws and regulations in respect of occupational health and safety. We are committed to complying with PRC regulatory requirements, preventing and reducing hazards and risks associated with our operation, and ensuring the health and safety of our employees and surrounding communities. We have adopted and maintained a series of rules, standard operating procedures and measures to maintain a healthy and safe environment for our employees, including those required under the CGMP certification. For example, we construct and maintain all of our production facilities in accordance with the CGMP certification. We also engage qualified inspectors each year to carry out on-site monitoring of our waste water, noise and boiler emission control, the results of which show that we have complied with relevant PRC laws and regulations in material respects. We require new employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. In particular, we invite experts on fire control safety to conduct training sessions and regularly perform emergency evacuation drills to reduce risks associated with potential fire accidents.

Additionally, we appoint qualified consulting firms to conduct on-site safety assessment and hazard identification, which help us enhance our overall health and safety management effectiveness. As of the Latest Practicable Date, we had not experienced any material accidents in the course of our operation and our Directors were not aware of any claims for personal or property damages in connection with health and occupational safety.

RISK MANAGEMENT AND INTERNAL CONTROL

We are dedicated to establishing and maintaining a robust internal control system. We have adopted and implemented risk management policies in various aspects of our business operations to address various potential risks in relation to our strategic plan, research and development, infrastructure, procurement, manufacturing, marketing and distribution. Our risk management system also covers general finance management, human resources, information technology, projects, logistics, subsidiaries and policy matters.

In addition, as part of our risk management measures, we have implemented specific measures against corruption, bribery and money laundering and to ensure we are compliant with International Sanctions laws. We require our employees, especially those involved in procurement, distribution and sales, and other business functions which are highly susceptible to bribery and corruptions, and exposed to risks relating to International Sanctions, to abide by our compliance requirements, and make necessary representations and warranties to the Company. We generally communicate our anti-bribery, anti-corruption and compliance with International Sanctions requirements and principles to all relevant stakeholders, including customers and suppliers. We have established a system of supervision that allows complaints and reports to be submitted to management regarding non-compliant behavior of our internal employees, external customers and suppliers. We conduct strict customer identification procedures, and create necessary records, analysis, verification and reports in relation to large-sum or suspicious transactions, for purpose of avoiding anti-money laundering and identifying potential risks in dealing with such counterparty. Our internal control and audit department specifically supervises compliance matters in relation to procurement, construction, distribution and retails, and conducts special audit with respect to the implementation of anti-bribery and anti-corruption on a regular or irregular basis.

We refer to the section headed “Risk Factors—A small amount of our revenue was derived from countries that are targets of sanctions imposed by the United States, the European Union,

BUSINESS

Australia and other government entities during the Track Record Period”. We have discontinued our sales and/or deliveries to the Relevant Countries commencing from October 2019 and we are not subject to any claims for compensation as a result of the discontinuation of such sales and/or deliveries. Further, we will not knowingly and intentionally conduct any future business with persons, entities or organizations on the SDN Lists, or any business connected to any comprehensively sanctioned countries and we will not use the [REDACTED] from the [REDACTED] in a manner which would result in a breach of International Sanctions. Hogan Lovells, our International Sanctions legal adviser, is of the view that our business activities during the Track Record Period do not appear to implicate restrictions under International Sanctions, based on the specific facts and circumstances of these sales and deliveries during the Track Record Period.

LEGAL PROCEEDINGS AND COMPLIANCE

We may from time to time be involved in contractual disputes or legal proceedings arising out of the ordinary course of business. During the Track Record Period and up to the Latest Practicable Date, none of us or any of our subsidiaries was subject to any material claims, damages or losses. As of the Latest Practicable Date, no material litigation, arbitration or administrative proceedings had been threatened against us or any of our subsidiaries.

During the Track Record Period and up to the Latest Practicable Date, save as otherwise disclosed, we did not have any non-compliance incidents which our Directors believe would, individually or in aggregate, have a material operational or financial impact on our Group as a whole.

The following sets forth certain incidents which our Company considers to be immaterial and do not constitute material or systemic non-compliances.

During the Track Record Period, we failed to make full contribution to the social insurance and housing provident funds for our employees as required under the applicable PRC law. As of September 30, 2019, the total payable amount of social insurance, premium and housing provident fund was approximately RMB36.9 million for which we had made provision in the financial statement for the nine months ended September 30, 2019. According to the relevant PRC laws and regulations, in respect of overdue social insurance contributions, (a) the relevant PRC authorities may demand us to pay the outstanding social insurance contributions within a stipulated deadline and we may be liable to a late payment fee equal to 0.05% of the outstanding amount for each day of delay; if we fail to make such payments, we may be liable to a fine of one to three times the amount of the outstanding contributions; and (b) in respect of outstanding housing provident fund contributions, we may be ordered to pay the outstanding housing provident fund contributions within a prescribed time period. We have obtained written confirmations from the relevant local social insurance and housing provident fund authorities confirming no administrative penalty has been imposed to Hepalink and Techdow. Based on the consultation with the local social insurance and housing provident fund authorities, it is confirmed that relevant authorities will not take the initiative to request Hepalink, Shenzhen Techdow and Chengdu Sunrace to make full payments, or impose fines or other administrative penalties. Accordingly, our PRC legal adviser is of the view that the likelihood that we will be required to make full payment, or imposed fine or other administrative penalties initiated by the relevant authorities is relatively low.

On January 8, 2013, we entered into Shenzhen land use right grant agreements with the Pingshan Administrative Bureau of Shenzhen Planning and Land Resource Committee (“**Pingshan**

BUSINESS

Administrative Bureau,” currently known as Pingshan Administrative Bureau of Shenzhen Planning and Natural Resources), pursuant to which Pingshan Administrative Bureau agreed to grant us two parcels of land with a total site area of 204,832.69 sq.m. for a total premium of RMB107.75 million. We further entered into supplemental agreements (the “**Supplemental Agreements**”) with Pingshan Administrative Bureau, pursuant to which we are required to complete the construction of Pingshan Industrial Park by January 4, 2019. As of the Latest Practicable Date, we have not completed the construction of certain buildings by the completion date as required under the Supplemental Agreements. According to the relevant PRC laws and regulations, in respect of failure to complete construction in time other than due to the reasons of the government authorities, the relevant PRC authorities may impose liquidated damages on the company since the required completion date set forth under the relevant land use right grant agreement. If the delay is within two years since the required completion date, the company may be imposed a liquidated damages of up to 1.5% of the land premium every three months since the required completion date. If a company fails to complete construction for more than two years since the required completion date, the company may be imposed a liquidated damages of up to 20% of the land premium and the land may be subject to forfeiture to the PRC government. As of the Latest Practicable Date, we paid liquidated damages of RMB2.42 million in total with respect to the delay in construction of Pingshan Industrial Park occurred before January 4, 2019. Pingshan Administrative Bureau has confirmed that the land with respect to the Pingshan Industrial Park is not regarded as idle land and the delay is not due to our reason, therefore such land and the construction built on it are not subject to forfeiture. As advised by our PRC legal advisor, the likelihood of forfeiture and imposition of penalties for the delay in construction due to reasons other than the Company is relatively low.

On December 19, 2019, the Shenzhen Securities Regulatory Bureau (the “**Shenzhen Bureau**”) of the China Securities Regulatory Commission (the “**CSRC**”) issued a letter of caution (“**Caution Letter**”) to the Company which identified three issues of concern, being (i) irregular accounting treatment of our equity investment in Resverlogix; (ii) internal approval process discrepancies with respect to certain related party transactions and other related pricing policy disclosure discrepancies; and (iii) inadequate registration of insiders (the “**Concerned Matters**”). On the same day, the Shenzhen Bureau of the CSRC also issued invitations to three of our Directors, being Mr. Li Li, Mr. Shan Yu and Mr. Bu Haihua and our financial controller, Mr. Zhang Bin (together with the Company, the “**Relevant Parties**”), to attend regulatory interviews in respect of all or certain of the Concerned Matters (the “**Regulatory Interviews**”). As of the Latest Practicable Date, the Regulatory Interviews have been completed. According to our PRC legal adviser, the Concerned Matters may give rise to certain breaches of the Administrative Measures for the Disclosure of Information of Listed Companies and the Provisions for Establishing a Registration and Administration System for Persons with Inside Information published by the CSRC. Nevertheless, the Company’s PRC legal adviser is of the view that the Caution Letter and the Regulatory Interviews do not constitute administrative penalties and therefore, the risk that the Concerned Matters, the Caution Letter and the Regulatory Interviews would result in any other penalties being imposed on the Relevant Parties is low. As such, they do not constitute material non-compliance incidents under the PRC law nor do they represent disciplinary sanctions (紀律處分) taken by the Shenzhen Stock Exchange on the Relevant Parties.

We did not obtain the approvals from NDRC with respect to our outbound investments in certain overseas subsidiaries, including incorporation of Hepalink (Hong Kong) in 2010 and increase in the share capital of Hepalink (Hong Kong) in 2014, in Techdow (Hong Kong) in 2016 and in OncoVent in 2016. In accordance with the Administrative Measures for Approval and Record-filing of Overseas Investment Projects (the “**NDRC Order No.9**”), the NDRC is authorized to suspend the

BUSINESS

unapproved outbound investment activities, and may impose legal and administrative measures upon the responsible party. Based on our consultation with the NDRC Shenzhen Branch, we have obtained the confirmation that as above investments took place before the Measures for the Administration of Overseas Investment (the “NDRC Order No. 11”) such lack of approval will not adversely affect our future outbound investment and we are not required to reapply the NDRC approvals for the above outbound investments. As advised by our PRC legal adviser, the likelihood of us being penalized is relatively low based on the consultation with the NDRC Shenzhen Branch.

LICENSES AND PERMITS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. The table below sets forth the relevant details of the material licenses required for our operation in the PRC and overseas:

<u>License/Permit</u>	<u>Holder</u>	<u>Grant Date</u>	<u>Expiration Date</u>
Registration approval (enoxaparin sodium injection) (China)	Shenzhen Techdow	February 17, 2015	February 16, 2020
Registration approval (enoxaparin sodium API) (China)	Shenzhen Techdow	June 28, 2015	June 27, 2020
GMP certificate (enoxaparin sodium injection) (China)	Shenzhen Techdow	October 12, 2015	October 11, 2020
Drug Manufacturing Certificate	Hepalink	January 1, 2016	December 31, 2020
Drug Manufacturing Certificate	Shenzhen Techdow	January 1, 2016	December 31, 2020
Registration approval (enoxaparin sodium injection) (EU)	Techdow Europe AB	September 16, 2016	September 15, 2021
GMP certificate (enoxaparin sodium API) (China)	Shenzhen Techdow	September 29, 2016	September 28, 2021
FDA 6th Inspection Approval Letter (heparin sodium)	Hepalink	January 13, 2017	N/A
GMP Certificate (heparin sodium) (Germany)	Hepalink	April 18, 2017	April 17, 2020
GMP Certification Approval (heparin sodium) (Norway)	Hepalink	December 25, 2017	December 24, 2022
DUNS Registered Certificate (enoxaparin sodium)	Hepalink	February 1, 2018	January 30, 2020
GMP Certificate (Brazil) (enoxaparin sodium API)	Shenzhen Techdow	February 5, 2018	May 2, 2020
GMP Certificate (Brazil) (enoxaparin sodium injection)	Shenzhen Techdow	February 5, 2018	February 5, 2020
GMP Certificate (Brazil) (enoxaparin sodium API)	Shenzhen Techdow	April 23, 2018	April 23, 2020
GMP Certificate (packaging materials for enoxaparin sodium injection) (EU)	Shenzhen Techdow	April 26, 2018	January 22, 2021
DUNS Registered Certificate	Shenzhen Techdow	April 30, 2018	April 29, 2020
GMP Certificate (enoxaparin sodium API) (EU)	Shenzhen Techdow	May 10, 2018	January 22, 2021
GMP Certificate (enoxaparin sodium injection) (EU)	Shenzhen Techdow	May 14, 2018	January 22, 2021
Drug Sales Certificate (heparin sodium injection)	Hepalink	June 8, 2018	June 8, 2020
GMP Certificate (enoxaparin sodium injection) (Poland)	Shenzhen Techdow	June 13, 2019	March 18, 2022
EDQM-CEP Certificate (heparin sodium)	Hepalink	July 26, 2019	N/A
API Export Certificate (heparin sodium) (EU)	Hepalink	July 31, 2019	July 30, 2022
API Export Certificate (enoxaparin sodium) (EU)	Shenzhen Techdow	October 16, 2019	October 15, 2022

BUSINESS

License/Permit	Holder	Grant Date	Expiration Date
FDA Inspection Approval Letter (enoxaparin sodium)	Shenzhen Techdow	October 28, 2019	N/A

We do not expect any material legal impediment in renewing these licenses, approvals, permits and certificates as long as we are in compliance with applicable rules, laws and regulations.

AWARDS AND RECOGNITION

The table below set forth a summary of the major awards, and projects for which we received government grants as of the Latest Practicable Date:

Award/Project	Grant Year	Grant Authority	Grant Amount
2017 Foreign Investment and Economic Development Special Fund—Shenzhen Foreign Investment Cooperation Project (2017年外經貿發展專項資金深圳市對外投資合作項目)	2017	Shenzhen Commission of Economy and Information Technology	RMB22,558,000
Enterprise R&D funding (企業研發資助)	2017	Shenzhen Commission of Science and Technology Innovation	RMB2,609,000
Enterprise R&D funding (企業研發資助) (Shenzhen Techdow)	2017	Shenzhen Commission of Science and Technology Innovation	RMB1,070,000
2016 International Marketing Network (2016國際營銷網絡)	2017	Shenzhen Commission of Economy and Information Technology	RMB600,000
“Honoring Contracts and Standing Reputation” Enterprise (守合同重信用企業)	2017	Shenzhen Bureau of Market Supervision	N/A
Enterprise R&D Funding (企業研發資助)	2018	Shenzhen Commission of Science and Technology Innovation	RMB2,030,000
Enterprise R&D Funding (企業研發資助) (Shenzhen Techdow)	2018	Shenzhen Commission of Science and Technology Innovation	RMB1,199,000
2018 Technology Transformation Investment Subsidy Project (2018年技術改造投資補貼項目)	2018	Shenzhen Commission of Economy and Information Technology	RMB1,010,000
Nanshan District Industrial Value Added Project (Shenzhen Techdow) (南山區工業增加值項目)	2018	Nanshan Bureau of Economic Promotion	RMB1,000,000
Large-scale Industrial Enterprises Innovation Ability Cultivation and Improvement Plan (大型工業企業創新能力培育提升支持計劃項目)	2018	Nanshan Bureau of Science and Technology Innovation	RMB319,100
International Network Marketing Fund (Nanshan District) (國際網絡營銷資助項目(南山區))	2018	Nanshan Bureau of Economic Promotion	RMB300,000
Key Export Enterprise Exhibition Project (重點出口企業參展資助項目)	2018	Nanshan Bureau of Economic Promotion	RMB161,200
Shenzhen Famous Brand (深圳市知名品牌)	2018	Shenzhen Confederation of Industry	N/A

BUSINESS

<u>Award/Project</u>	<u>Grant Year</u>	<u>Grant Authority</u>	<u>Grant Amount</u>
2018 Annual Enterprise Technology Transformation Funding Plan (Key Project Awards and Subsidies) (2018年度企業技術改造扶持計劃(重大項目獎補))	2019	Shenzhen Bureau of Industry and Information Technology	RMB17,350,000
2019 Enterprise Expansion and Efficiency Increase Support Plan (Shenzhen Techdow) (2019年企業擴產增效扶持計劃)	2019	Shenzhen Bureau of Industry and Information Technology	RMB1,000,000
Nanshan District National High-tech Enterprise Multiplier Support Program (南山區國家高新技術企業倍增支持計劃)	2019	Nanshan Bureau of Science and Technology Innovation	RMB100,000
Shenzhen Top 20 Leading Life Science Enterprise (深圳領先生物科技企業20強)	2019	Shenzhen National High Technology Industry Innovation Centre	N/A
National High-tech Enterprise Certification (國家高新技術企業認定)	2018-2020	Shenzhen Commission of Science and Technology Innovation	N/A

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

Our Company is a joint-stock limited company listed on the Shenzhen Stock Exchange. As of the Latest Practicable Date, Leren Technology, Feilaishi and Jintiantu held approximately 38.01%, 3.23% and 32.72% of the issued Shares, respectively. Immediately following the completion of the [REDACTED], Leren Technology, Feilaishi and Jintiantu will hold approximately [REDACTED]%, [REDACTED]% and [REDACTED]% of the issued Shares (assuming the [REDACTED] is not exercised), respectively.

Leren Technology and Feilaishi are investment holding companies. Jintiantu is an investment holding fund primarily focusing on trade and investments. Leren Technology is owned by Mr. Li and Ms. Li as to 99.00% and 1.00%, respectively. Feilaishi is wholly owned by Mr. Li. Jintiantu is owned by Ms. Li as to 99.00% as a general partner and by Mr. Li as to 1.00% as a limited partner. Ms. Li is the spouse of Mr. Li. As such, Leren Technology, Feilaishi, Jintiantu, Mr. Li and Ms. Li are the controlling shareholders of the Company and will continue to hold a controlling interest in our Company upon completion of the [REDACTED].

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

The Directors consider that our Group is capable of carrying on its business independently of our Controlling Shareholders and their associates for the reasons set out below.

Management Independence

Our Board consists of four executive Directors and three independent non-executive Directors. Our Supervisory Committee consists of three members and our senior management team comprises of four members. The table below sets out the overlapping positions of our Directors, Supervisors and senior management team and in our Controlling Shareholders.

<u>Director/Supervisor/Senior Management</u>	<u>Position in the Company</u>	<u>Position in our Controlling Shareholders and/or its subsidiaries</u>
Mr. Li	Chairman of the Board and Executive Director	Executive director of Leren Technology Executive director of Feilaishi Director of LuckyKind Holdings Limited and Flystone Holdings Limited ⁽¹⁾
Ms. Li	Executive Director and deputy general manager	Managing Partner of Jintiantu Director of KingField Holdings Limited ⁽²⁾

Notes:

- (1) LuckyKind Holdings Limited and Flystone Holdings Limited are wholly-owned subsidiaries of Leren Technology and Feilaishi, respectively. Both LuckyKind Holdings Limited and Flystone Holdings Limited are primarily engaged in the business of investment.
- (2) KingField Holdings Limited is a wholly-owned subsidiary of Jintiantu. KingField Holdings Limited is primarily engaged in the business of investment.

Details of the background of Mr. Li and Ms. Li are set out in the section headed “Directors, Supervisors and Senior Management” in this document.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

Notwithstanding the overlapping roles of our Directors described above, our Directors are of the view that our Company will function independently from our Controlling Shareholders for the following reasons:

- (i) a majority of Directors are independent of our Controlling Shareholders and decisions of the Board require the approval of a majority vote from the Board. Therefore, the Board is not under significant influence of our Controlling Shareholders and can manage the operation of our Company independently of our Controlling Shareholders;
- (ii) according to the Articles of Association, with respect to any matters of conflict or potential conflict of interest which involve a transaction between our Company and another company or entity to which a Director holds office, such Director shall abstain from voting and shall be excluded from the quorum;
- (iii) we have appointed three independent non-executive Directors, comprising more than one-third of the total members of our Board, who have sufficient knowledge, experience and competence to provide a balance of the number of potentially interested and independent Directors with a view to promote the interests of our Company and the Shareholders as a whole; and
- (iv) each of our Directors is aware of his fiduciary duties and responsibilities under the Hong Kong Listing Rules as a director, which require that he acts in the best interest of our Company.

Based on the above, we believe that our Board is able to manage the Company independently from our Controlling Shareholders.

Operational Independence

We have established our own organizational structure, and each department is assigned to specific areas of responsibilities. We have independent access to suppliers and customers. We are also in possession of all relevant assets, licenses, trademarks and other intellectual property necessary to carry on and operate our business and we have sufficient operational capacity in terms of capital and employees to operate independently.

Our Directors are of the view that there is no operational dependence by us on our Controlling Shareholders and our Group is able to operate independently from our Controlling Shareholders after the [REDACTED].

Financial Independence

Our Group has an independent financial system. We make financial decisions according to our own business needs and our Controlling Shareholders does not intervene with our use of funds. We have opened basic accounts with banks independently and do not share any bank account with our Controlling Shareholders. We have made tax filings and paid tax independently of our Controlling Shareholders pursuant to applicable laws and regulations. We have established an independent finance department as well as implemented sound and independent audit, accounting and financial management systems. We have adequate internal resources and a strong credit profile to support our daily operation.

In April 2019, we issued a corporate bond in an aggregate principal amount of RMB700 million with an interest rate of 5.5% per annum (the “**Bond**”). The Bond will mature in April 2024. In

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

connection with the issuance, Shenzhen Gaoxintou Group Co., Ltd. (深圳市高新投集團有限公司) (“**Shenzhen Gaoxintou**”) guaranteed our repayment obligations under the Bond. In return, Mr. Li, our Controlling Shareholder, provided a counter-guarantee to Shenzhen Gaoxintou of such obligations (the “**Counter-Guarantee**”). The Counter-Guarantee period is for a period of two years from the date when Shenzhen Gaoxintou’s repayment obligations expire under its guarantee agreement.

With respect to the Counter-Guarantee, our Directors are of the view that the Group is in a position to obtain replacement financing from independent third parties without guarantee provided by our Controlling Shareholders. This is demonstrated by the following:

- In addition to the Bond, we also issued a tranche of corporate bonds in 2019 which were not guaranteed for an aggregate principal amount of RMB430 million at an interest rate of 6.5% per annum with a duration of three years.
- We have, as of January 19, 2020, total unutilized credit facilities of RMB2.9 billion that has been obtained without any financial assistance from the Controlling Shareholders.

Accordingly, our Directors are of the view that (a) the Company has demonstrated its ability to obtain independent financing without financial support from its Controlling Shareholders and (b) the Group has sufficient liquid assets on hand to meet its financial needs.

We believe that premature release of the Counter-Guarantee given by our Controlling Shareholder is not in the best interests of our Company and its Shareholders. If the Counter-Guarantee was to be terminated prematurely, Shenzhen Gaoxintou would either terminate the guarantee it had granted, or impose additional costs on the Company to continue guaranteeing the Bond. A termination of the guarantee from Shenzhen Gaoxintou would trigger early repayment of the Bond. In that case, the bondholders can require the Group to repay all the outstanding principal and interest. In either scenario, the Group may be required to pay penalties and incur additional costs.

Save as disclosed above, as of the Latest Practicable Date, there was no outstanding loan extended by our Controlling Shareholders or their close associates to us and there is no guarantee provided for our benefit by our Controlling Shareholders or any of their close associates.

Based on the above, our Directors are of the view that there is no financial dependence by us on our Controlling Shareholders or any of their close associates.

COMPETITION

Leren Technology and Feilaishi are investment holding companies. Jintiantu is an investment holding fund primarily focusing on trade and investments. As of the Latest Practicable Date, neither our Controlling Shareholders and their respective close associates nor any of our Directors is interested in any business, other than our Group, which competes or is likely to compete, either directly or indirectly, with our Group’s business and which requires disclosure pursuant to Rule 8.10 of the Listing Rules.

In order to avoid any potential competition between our Controlling Shareholders and us, our Controlling Shareholders have provided a non-competition undertaking in favor of our Company on April 23, 2010 (the “**Non-competition Undertaking**”). In the Non-competition Undertaking, our Controlling Shareholders confirmed that as of the date of undertaking, neither itself nor any of its directly or indirectly controlled companies or entities engaged in any business or operation which was

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

in substantive competition with the business of our Group. Each of our Controlling Shareholder has undertaken that:

- (i) for as long as it is a Controlling Shareholder of the Company, it will not engage (whether alone or in the form of joint venture or cooperation), in any manner, in any business which competes with the business of the Company nor will its current or future wholly owned subsidiaries, controlled subsidiaries or other entities controlled by it engage in any business which competes with the business of the Company; and
- (ii) if it fails to comply with the above non-competition undertaking, it agrees to indemnify the Company for all the losses the Company may suffer as a result of such non-compliance.

CORPORATE GOVERNANCE

Our Company will comply with the provisions of the Corporate Governance Code and Corporate Governance Report set out in Appendix 14 to the Hong Kong Listing Rules, which sets out principles of good corporate governance in relation to, among other matters, directors, the chairman and chief executive officer, board composition, the appointment, re-election and removal of directors, their responsibilities and remuneration and communications with shareholders.

Our Directors recognize the importance of good corporate governance to protect the interests of our Shareholders. We would adopt the following corporate governance measures to manage potential conflict of interests between our Group and our Controlling Shareholders:

- (i) the Company has established internal control mechanisms to identify connected transactions. Upon [REDACTED], if the Company enters into connected transactions with our Controlling Shareholders or its associates, the Company will comply with the applicable Hong Kong Listing Rules;
- (ii) where a Shareholders’ meeting is to be held for considering proposed transactions in which our Controlling Shareholders or their associates have any material interest, our Controlling Shareholders shall not vote on the resolutions and shall not be counted in the quorum for the voting;
- (iii) our Board will consist of a balanced composition of executive and non-executive Directors, including not less than one-third of independent non-executive Directors to ensure that our Board is able to effectively exercise independent judgment in its decision-making process and provide independent advice to our Shareholders. Our independent non-executive Directors, details of whom are set out in the section headed “Directors, Supervisors and Senior Management” individually and together possess the requisite knowledge and experience to perform their roles. They will review whether there is any conflict of interests between our Group and our Controlling Shareholders and provide impartial and professional advice to protect the interest of our minority Shareholders;
- (iv) where the advice from an independent professional, such as that from a financial adviser, is reasonably requested by our Directors (including the independent non-executive Directors), the appointment of such an independent professional will be made at the Company’s expenses; and
- (v) we have appointed Somerley Capital Limited as our compliance adviser, which will provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules including various requirements relating to corporate governance.

RELATIONSHIP WITH THE CONTROLLING SHAREHOLDERS

Based on the above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflicts of interest between our Group and our Controlling Shareholders, and to protect minority shareholders’ rights after the [REDACTED].

CONNECTED TRANSACTION

OVERVIEW

Our Group has entered into a certain transaction with our Director prior to the [REDACTED], and such transaction will constitute an exempt continuing connected transaction under the Hong Kong Listing Rules upon [REDACTED].

Further, as our A Shares are listed on the Shenzhen Stock Exchange, we will continue to be subject to and regulated by the Shenzhen Stock Exchange Listing Rules and other applicable laws and regulations in the PRC as long as our A shares remain listed. However, the requirements of the Hong Kong Listing Rules in relation to connected transactions differ from those of the Shenzhen Stock Exchange Listing Rules. In particular, the definition of connected person (especially the definition of associate) pursuant to the Hong Kong Listing Rules is different from the definition of related party pursuant to the Shenzhen Stock Exchange Listing Rules. Therefore, a connected transaction pursuant to the Hong Kong Listing Rules may not constitute a related party transaction pursuant to the Shenzhen Stock Exchange Listing Rules, and vice versa.

EXEMPT CONTINUING CONNECTED TRANSACTION

Provision of counter-guarantee by our Controlling Shareholder

In April 2019, the Company issued a corporate bond in an aggregate principal amount of RMB700 million with an interest rate of 5.5% per annum (the “**Bond**”). In connection with the issuance, Shenzhen Gaoxintou Group Co., Ltd. (深圳市高新投集團有限公司) (“**Shenzhen Gaoxintou**”) guaranteed the Company’s repayment obligations under the Bond. In return, Mr. Li, our Controlling Shareholder, provided a counter-guarantee to Shenzhen Gaoxintou of such obligations. The counter-guarantee period is for a period of two years from the maturity of the Bond.

The above counter-guarantee was provided by Mr. Li in favor of us and we did not provide any security for such counter-guarantee. As the premature release of the above counter-guarantee is not in the commercial interests of our Company and its Shareholders and is not commercially viable, the counter-guarantee will continue to be in effect after the [REDACTED]. As Mr. Li is our connected person, the above counter-guarantee will constitute a connected transaction for us under Chapter 14A of the Hong Kong Listing Rules. Nonetheless, the Directors are of the view that the above counter-guarantee provided to us by Mr. Li was on normal commercial terms where no security over our Company’s assets was granted in respect of such counter-guarantee, and as such, the transaction will be exempted from the reporting, annual review, announcement and independent shareholders’ approval requirements under Chapter 14A of the Hong Kong Listing Rules pursuant to Rule 14A.90 of the Hong Kong Listing Rules.

Please see the section headed “Relationship with the Controlling Shareholders—Independence from Our Controlling Shareholders—Financial Independence” of this document.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

OVERVIEW

Our Board currently consists of seven Directors, comprising four executive Director and three independent non-executive Directors. All Directors are elected at the Shareholders’ meetings. Directors serve for a term of three years and shall be subject to re-election upon retirement. Independent non-executive Directors shall not hold office for more than six consecutive years.

The Supervisory Committee currently consists of three Supervisors, including the chairman of the Supervisory Committee. The Supervisors include two shareholder supervisors and one employee Supervisor. The shareholder Supervisors and the employee Supervisors are elected at the Shareholders’ meetings and the staff representative assembly, respectively, for a term of three years and shall be subject to re-election upon retirement.

The following tables set forth information regarding our Directors, Supervisors and senior management. All of the Directors, Supervisors and senior management have met the qualification requirements under the relevant PRC laws and regulations and the Hong Kong Listing Rules for their respective positions.

Directors, Supervisors and Senior Management

The following table shows the key information of our Directors:

Name	Age	Date of joining the Company	Date of appointment for the current tenure as Director	Position for the current tenure	Responsibility	Relationship with other Directors, Supervisors and senior management
Mr. Li Li (李鋈)	55	April 1998	May 2017	Chairman of the Board and Executive Director	Participating in decision-marking in respect of major issues such as business operation strategies; overseeing the affairs of the board; overseeing the major financial or external affairs and the evaluation of senior management of our Company	Spouse of Ms. Li and brother-in-law of Mr. Shan
Ms. Li Tan (李坦)	55	April 1998	May 2017	Executive Director and deputy general manager	Participating in decision-marking in respect of major issues such as business operation strategies; overseeing the business development activities and human resources management of our Company	Spouse of Mr. Li and sister of Mr. Shan

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Date of joining the Company	Date of appointment for the current tenure as Director	Position for the current tenure	Responsibility	Relationship with other Directors, Supervisors and senior management
Mr. Shan Yu (單宇)	59	April 1998	May 2017	Executive Director and general manager	Participating in decision-marking in respect of major issues such as business operation strategies;; overseeing the expansion of production capacity, external affairs, security and logistics	Brother of Ms. Li and brother-in-law of Mr. Li
Mr. Bu Haihua (步海華)	44	December 2006	May 2017	Executive Director, secretary to the Board and deputy general manager	Participating in decision-marking in respect of business operation strategies; overseeing the Board office, communication with securities regulatory authorities, information disclosure, investors relationship; responsible for the management of investment, financing and new products developments and compliance and medical affairs	Not applicable
Dr. Lu Chuan (呂川)	49	December 2019	December 2019	Independent non-executive Director	Participating in decision-making in respect of major matters, such as operation strategies; expressing independent opinions on major matters involving the interests of minority shareholders	Not applicable

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Date of joining the Company	Date of appointment for the current tenure as Director	Position for the current tenure	Responsibility	Relationship with other Directors, Supervisors and senior management
Mr. Chen Junfa (陳俊發)	54	May 2017	May 2017	Independent non-executive Director	Participating in decision-making in respect of major matters, such as operation strategies; expressing independent opinions on major matters involving the interests of minority shareholders	Not applicable
Mr. Wang Zhaohui (王 肇輝)	42	July 2017	July 2017	Independent non-executive Director	Participating in decision-making in respect of major matters, such as operation strategies; expressing independent opinions on major matters involving the interests of minority shareholders	Not applicable

The following table shows the key information of our Supervisors:

Name	Age	Date of joining the Group	Date of appointment for the current tenure as Supervisor	Position for the current tenure	Responsibility	Relationship with other Directors, Supervisors and senior management
Mr. Zheng Zehui (鄭澤輝)	50	May 2014	May 2017	Chairman of the Supervisory Committee	Overseeing the affairs of the Supervisory Committee and supervising operation and financial activities of our Company as well as the performance of Directors and senior management	Not applicable

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Date of joining the Group	Date of appointment for the current tenure as Supervisor	Position for the current tenure	Responsibility	Relationship with other Directors, Supervisors and senior management
Ms. Tang Haijun (唐海均)	41	February 2001	May 2017	Supervisor	Supervising the operation and financial activities of our Company as well as the performance of Directors and senior management	Not applicable
Ms. Su Jilan (蘇紀蘭)	40	February 2004	May 2017	Employee supervisor	Supervising the operation and financial activities of our Company as well as the performance of Directors and senior management on behalf of employees	Not applicable

The following table shows the key information of our senior management:

Name	Age	Date of joining the Company	Date of appointment for the current tenure	Position for the current tenure	Responsibility	Relationship with other Directors, Supervisors and senior management
Mr. Shan Yu (單宇)	59	April 1998	May 2017	Executive Director and general manager	Participating in decision-marking in respect of major issues such as business operation strategies; overseeing the expansion of production capacity, external affairs, security and logistics	Brother of Ms. Li and brother-in-law of Mr. Li
Ms. Li Tan (李坦)	55	April 1998	May 2017	Executive Director and deputy general manager	Participating in decision-marking in respect of major issues such as business operation strategies; overseeing the business development activities and human resources management of our Company	Spouse of Mr. Li and sister of Mr. Shan

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Company	Date of joining the current tenure	Date of appointment for the current tenure	Position for the current tenure	Responsibility	Relationship with other Directors, Supervisors and senior management
Mr. Bu Haihua (步海華)	44		December 2006	May 2017	Executive Director, secretary to the Board and deputy general manager	Participating in decision-marking in respect of business operation strategies; overseeing the Board office, communication with securities regulatory authorities, information disclosure and investors relationship; responsible for the management of investment, financing and new products developments and compliance and medical affairs	Not applicable
Mr. Zhang Bin (張斌)	42		April 2016	May 2017	Financial controller	Participating in decision-marking in respect of business operation strategies; overseeing the business strategy and financial activities of our Company	Not applicable

DIRECTORS

Executive Directors

Mr. Li Li (李鋸), aged 55, spouse of Ms. Li and brother-in-law of Mr. Shan, is the chairman of the Board, an executive Director and the founder of our Company. Mr. Li joined the Company and was appointed as the chairman of the Board in April 1998. Mr. Li has also been serving as a director of Topknow since May 2000; a director of Feilaishi since June 2008; a director of Leren Technology since August 2007; a director of Hepalink Europe AB since February 2010; a director of Shenzhen Techdow since November 2010; a director of Hepalink (Hong Kong) since June 2014; a director of Shenzhen Hightide Biopharmaceutical Co., Ltd. since November 2011; a director of Techdow Pharmaceutical (Hong Kong) Co., Ltd. since May 2013; a director of Hepalink USA since April 2014; a director of Shanghai Hightide Biopharmaceutical Co., Ltd. since March 2014; a director of Shenzhen Dekang Investment Development Co., Ltd. since March 2015; a director of Shenzhen Fanpu Biotechnology Co., Ltd. since April 2015; a director of Shenzhen Junshengkang Biotechnology Co., Ltd. since July 2015; a director Cytovance since October 2015; a director of OncoVent since July 2016; a director of Shenzhen Ruidi Biomedical Co., Ltd. since July 2018; and a director of HighTide Therapeutics, Inc. since October 2018.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Li graduated from Chengdu University of Science and Technology (which later became Sichuan University) in China with a bachelor of science degree in chemistry in July 1987 and obtained the qualification of senior manager from the Vocational Skills Identification Center in February 2005.

Ms. Li Tan (李坦), aged 55, spouse of Mr. Li and sister of Mr. Shan, is our executive Director, co-founder and deputy general manager. Ms. Li joined the Company and was appointed as our Director and deputy general manager in April 1998. Ms. Li has also been serving as a director of Topknow since August 2007; the managing partner of Jintiantu since August 2007; a director of Hepalink (Hong Kong) since June 2014; a director of Shenzhen Techdow since November 2010; a director of Hepalink USA, since October 2013; a director of SPL, since August 2015; and a director of Kymbab Group Limited since November 2016.

Ms. Li graduated from Chengdu University of Science and Technology (which later became Sichuan University) in China with a bachelor of science degree in chemistry in July 1987 and obtained the qualification of senior manager from the Vocational Skills Identification Center in February 2005.

Mr. Shan Yu (單宇), aged 59, brother of Ms. Li and brother-in-law of Mr. Li, is our executive Director, co-founder and general manager. Mr. Shan joined the Company and was appointed as our Director and general manager in April 1998. Mr. Shan has also been serving as a director of Shenzhen Topknow Industrial Development Co., Ltd. since October 2000; a managing partner of Shuidi Shichuan since August 2007; a director of Chengdu Sunrace Co., Ltd. since November 2009; a director of Shenzhen Beidi Aoke Technology Development Co., Ltd. since December 2009; a director of Shandong Ruisheng since July 2010; a director of Shenzhen Pingshan New District Hepalink Pharmaceutical Co., Ltd. since July 2013; and a director of Hepalink USA since April 2014.

Mr. Shan graduated from Peking University in China with a bachelor of science degree in applied physics in July 1982 and obtained the qualification of senior manager from the Vocational Skills Identification Center in February 2005.

Mr. Bu Haihua (步海華), aged 44, is our executive Director, secretary to the Board and deputy general manager. Mr. Bu joined the Company in December 2006 and was appointed as Director and secretary to the Board in December 2007 and deputy general manager in June 2010. Mr. Bu has also been serving as a director of Chengdu Sunrace Co., Ltd. since October 2010; a director of Hepalink (Hong Kong) since November 2010; a director of Hepalink USA since April 2014; a director of SPL since August 2015; a director of OncoVent since July 2016; and a director of Shenzhen Ruidi Biomedical Co., Ltd. since July 2018.

Mr. Bu graduated from Shanghai University of Finance and Economics in China with a bachelor's degree in economics in July 1997 and graduated from Shanghai Jiaotong University in China with a master's degree in business administration in January 2005. Mr. Bu became a non-practicing member of the Chinese Institute of Certified Public Accountants in December 2009 and obtained board secretary certificate granted by Shenzhen Stock Exchange in November 2008.

Independent non-executive Directors

Dr. Lu Chuan (呂川), aged 49, is our independent non-executive Director. Dr. Lu joined the Company and was appointed as an independent Director in December 2019. Dr. Lu has been serving as a vice president of Huan Yue Interactive Holdings Limited since October 2019.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Dr. Lu served as an assistant engineer of Nanjing Jinling Shipyard Company Limited from August 1991 to August 1994. From July 1997 to August 2005, Dr. Lu worked at Shenzhen Nonferrous Metals Finance Co., Ltd. as a research fellow of the investment bank department. From August 2005 to November 2018, Dr. Lu worked as a managing director assistant and deputy general manager of Yinjian International Industrial Co., Ltd. Dr. Lu served as a director of Shenzhen Zhongqingbao Interactive Network Co., Ltd. (A share stock code on the Shenzhen Stock Exchange: 300052) from April 2008 to April 2012, a non-executive director of China Geothermal Industry Development Group Limited (a company listed on the Main Board of the Stock Exchange, stock code: 8128) from September 2008 to March 2009, a non-executive director of E-Commodities Holdings Limited (a company listed on the Main Board of the Stock Exchange, stock code: 1733) from June 2010 to July 2016, and director of Ningxia West King Liquor Co., Ltd. from October 2011 to February 2014.

Dr. Lu graduated from Wuhan University of Technology in China with a bachelor’s degree in naval mechanical engineering in July 1991, graduated from Huazhong University of Science and Technology in China with a master’s degree in business management in May 1997 and a doctorate in management in December 2006.

Mr. Chen Junfa (陳俊發), aged 54, is our independent non-executive Director. Mr. Chen joined the Company and was appointed as an independent Director in May 2017. Mr. Chen has also been serving as an independent non-executive director and an audit committee member of Lomon Billions Group Co., Ltd. (A share stock code on the Shenzhen Stock Exchange: 002601) since April 2014; an independent non-executive director and an audit committee member of Shenzhen Mason Technology Co., Ltd. (A share stock code on the Shenzhen Stock Exchange: 002654) since July 2014; the deputy general manager of Shenzhen Pengxin Asset, Land and Real Estate Appraisal Co., Ltd. since April 2016; and an independent non-executive director of O-film Light Group Co., Ltd. (A share stock code on the Shenzhen Stock Exchange: 002456) since November 2017.

Mr. Chen previously served as an independent non-executive director and audit committee member of Shenzhen Yitao Intelligent Control Co., Ltd. (A share stock code on the Shenzhen Stock Exchange: 300131) from May 2011 to November 2017; and an independent non-executive director of Zibo Qixiang Tengda Chemical Co., Ltd. (A share stock code on the Shenzhen Stock Exchange: 002408) from March 2014 to April 2017.

Mr. Chen served as a project manager of Shenzhen Zhonghua Accounting Firm from July 1993 to December 1997. He served as director, chairman of the board and general manager of Shenzhen Zhongqinxin Asset Appraisal Co., Ltd. from October 2000 to June 2008 and served as the general manager of Shenzhen Jinkai Zhongqinxin Asset Appraisal Co., Ltd. from June 2008 to December 2009. Mr. Chen served as the deputy general manager of Shenzhen Dezhengxin International Asset Appraisal Co., Ltd. from January 2010 to March 2016.

Mr. Chen obtained his bachelor’s degree in engineering from Beijing University of Science and Technology in China in July 1988 and graduated from Nankai University in China with a master’s degree economics majoring in political economics in July 1993. Mr. Chen became a non-practicing member of the Chinese Institute of Certified Public Accountants in October 1994 and first obtained the People’s Republic of China Certificate of Certified Public Valuer in August 1997.

Mr. Wang Zhaohui (王肇輝), aged 42, is our independent non-executive Director. Mr. Wang joined the Company and was appointed as an independent Director in July 2017. Mr. Wang has also

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

been serving as the founding partner of Ruchuan Investment Fund since April 2016. From June 2001 to August 2009, Mr. Wang served as a senior journalist of Chinese College Students magazine. Mr. Wang served as the public relations manager of Innovation (Beijing) Software Development Co., Ltd. from September 2009 to January 2011 and served as the public relations manager of Beijing Innovation Ark Technology Co., Ltd. from September 2015 to April 2016. He also worked at Sinovation Ventures (Beijing) Enterprise Management Co., Ltd. as the director and deputy general manager from September 2015 to April 2016.

Mr. Wang graduated from the China University Of Geosciences in China with a bachelor’s degree in engineering in July 2001.

SUPERVISORS

Mr. Zheng Zehui (鄭澤輝), aged 50, is the chairman of our Supervisory Committee. Mr. Zheng has also been serving as the general manager of URIT Medical Electronic Co., Ltd. since October 2006. Mr. Zheng graduated from Wuhan University in China with a bachelor’s degree in biochemistry in July 1992 and graduated from China Europe International Business School in China with a master’s degree in business administration in October 2011.

Ms. Tang Haijun (唐海均), aged 41, is a Supervisor and the manager of the GxP document control department of our Company. Ms. Tang joined the Company in February 2001 and was appointed as our Supervisor in December 2007.

Ms. Tang graduated from Sun Yat-sen University in China with a bachelor’s degree in administrative management in July 2014.

Ms. Su Jilan (蘇紀蘭), aged 40, is an employee Supervisor and the deputy manager of the quality inspection department of our Company. Ms. Su joined the Company in February 2004 and was appointed as our employee Supervisor in December 2007.

Ms. Su graduated from Xi’an Jiaotong University in China with a bachelor of science degree in pharmacy in July 2001. Ms. Su obtained the qualification of assistant engineer from the Department of Human Resources of Shaanxi Province in August 2002.

SENIOR MANAGEMENT

Mr. Shan Yu (單宇), aged 59, is our executive Director and general manager. For the biography of Mr. Shan, please refer to “—Directors— Executive Directors” of this section.

Ms. Li Tan (李坦), aged 55, is our executive Director, co-founder and deputy general manager. For the biography of Ms. Li, please refer to “—Directors— Executive Directors” of this section.

Mr. Bu Haihua (步海華), aged 44, is our executive Director, secretary to the Board and deputy general manager. For the biography of Mr. Bu, please refer to “—Directors— Executive Directors” of this section.

Mr. Zhang Bin (張斌), aged 42, is our financial controller. Mr. Zhang joined our Company in April 2016 and has been appointed as our financial controller in April 2016. Mr. Zhang has been serving as a director of SPL since February 2018; a director of Hepalink USA since February 2018; and a director of Cytovance since February 2018.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

From June 2005 to August 2015, Mr. Zhang served in various positions in KPMG’s offices in China and the United States, including manager and senior manager. Mr. Zhang served as an inspection expert of the Public Company Accounting Oversight Board of the United States from August 2015 to February 2016.

Mr. Zhang graduated from Henan University in China with a bachelor’s degree in law in July 2003 and graduated from Patten University in the United States with a master’s degree in business administration in April 2015. Mr. Zhang became a non-practicing member of the Chinese Institute of Certified Public Accountants in November 2013 and a non-practicing member of American Institute of Certified Public Accountants in July 2015.

Save as disclosed above, none of our Directors, Supervisors and members of senior management is related to other Directors, Supervisors and members of the senior management.

Save as disclosed above, none of our Directors, Supervisors and members of senior management held any directorship in any public companies, the shares of which are listed in Hong Kong or overseas stock markets, during the three years prior to the date of this document.

JOINT COMPANY SECRETARIES

Mr. Bu Haihua, our joint company secretary, is also our executive Director, secretary to the Board, deputy general manager and a member of our senior management. For the biography of Mr. Bu, please refer to “—Directors—Executive Directors” of this section.

Ms. Chan Sze Ting (陳詩婷) is one of the joint company secretaries of the Company. Ms. Chan currently serves as a senior manager of corporate services of Tricor Services Limited, a global professional services provider specializing in integrated business, corporate and investor services. Ms. Chan has over 13 years of experience in the corporate secretarial field. She has been providing professional corporate services to multiple Hong Kong listed companies. Ms. Chan is currently the company secretary of Sinopec Shanghai Petrochemical Company Limited (a company listed on the Main Board of the Stock Exchange, stock code: 338) and the company secretary of Sunfonda Group Holdings Limited (a company listed on the Main Board of the Stock Exchange, stock code: 1771).

Ms. Chan is a Chartered Secretary, a Chartered Governance Professional and an Associate of both The Hong Kong Institute of Chartered Secretaries and The Institute of Chartered Secretaries and Administrators in the United Kingdom. Ms. Chan holds a bachelor of laws degree from the University of London in the United Kingdom.

BOARD COMMITTEES

The Board delegates certain responsibilities to various dedicated committees. In accordance with relevant PRC laws, regulations, the Articles and the Hong Kong Listing Rules, namely the Strategy Development Committee, the Audit Committee, the Remuneration and Evaluation Committee and the Nomination Committee.

Strategy Development Committee

The Strategy Development Committee consists of three Directors, namely Mr. Li Li, Ms. Li Tan, and Dr. Lu Chuan. Mr. Li Li currently serves as the chairman of the committee. The

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

primary duties of the Strategy Development Committee are to study and advise on the long term strategy and major investments and financing plans of the Group.

Audit Committee

Upon [REDACTED], the Audit Committee will consist of three Directors, namely Mr. Chen Junfa, Mr. Wang Zhaohui and Dr. Lu Chuan. Mr. Chen Junfa serves as the chairman of the committee. The primary duties of the Audit Committee are to review and supervise the financial reporting process, risk management and internal control system of the Group.

Remuneration and Evaluation Committee

The Remuneration and Evaluation Committee consists of three Directors, namely Mr. Wang Zhaohui, Mr. Chen Junfa, and Mr. Li Li. Mr. Wang Zhaohui currently serves as the chairman of the committee. The primary duties of the Remuneration and Evaluation Committee are to review and make recommendations to the Board regarding the terms of remuneration packages, bonuses and other compensation payable to our Directors and senior management.

Nomination Committee

The Nomination Committee consists of three Directors, namely Mr. Li Li, Mr. Chen Junfa, and Dr. Lu Chuan. Dr. Lu Chuan currently serves as the chairman of the committee. The primary duties of the Remuneration and Nomination Committee are to make recommendation to the Board regarding the appointment of Directors and senior management.

CORPORATE GOVERNANCE

The Company is committed to achieving high standards of corporate governance with a view to safeguarding the interests of our Shareholders. To accomplish this, the Company intends to comply with Corporate Governance Code set out in Appendix 14 to the Listing Rules and the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 to the Listing Rules after the [REDACTED].

BOARD DIVERSITY POLICY

The Board has adopted a board diversity policy (the “**Board Diversity Policy**”) in order to enhance the effectiveness of our Board and to maintain high standard of corporate governance. The Board Diversity Policy sets out the criteria in selecting candidates to our Board, including but not limited to gender, age, cultural and educational background and professional experience. The ultimate decision will be based on merit and contribution that the selected candidates will bring to our Board.

Our Directors have a balanced mixed of knowledge and skills, including but not limited to overall management and strategic development, finance and accounting and risk management, as well as professional experiences in the pharmaceutical industry. The Board of Directors is of the view that our Board satisfies the Board Diversity Policy.

The Nomination Committee is responsible for reviewing the diversity of the Board. After [REDACTED], the Nomination Committee will monitor and evaluate the implementation of the Board Diversity Policy from time to time to ensure its continued effectiveness.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

REMUNERATION OF DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

The Directors, Supervisors and senior management receive their remuneration in the form of salary and allowances, employer’s contribution to pension schemes, annual bonuses and independent directors’ fee.

For the two years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, the total remuneration paid to our Directors amounted to RMB5.6 million, RMB8.9 million and RMB2.8 million, respectively.

For the two years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, the total remuneration paid to our Supervisors amounted to RMB0.7 million, RMB0.8 million and RMB0.5 million, respectively.

Under the arrangements currently in force as of the date of this document, our Directors and Supervisors will be entitled to receive remuneration for their service which, for the year ending December 31, 2020, is expected to be approximately RMB9.0 million and RMB1.0 million, respectively. The remuneration of Directors and Supervisors consists of annual bonuses and pension schemes contribution, which are determined based on the evaluation of each Directors’ and Supervisors’ performance in 2020. The actual remuneration of Directors and Supervisors in 2020 may be different from the expected remuneration.

For the two years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, the total remuneration and benefits in kind paid to the five highest paid individuals (excluding Directors) by our Group amounted to RMB22.0 million, RMB16.8 million and RMB11.8 million, respectively. See “Appendix I—Accountants’ Report—Notes to Financial Information—9. Directors’ and Supervisors’ Remuneration” and “—10. Five Highest Paid Employees” for further details.

For the two years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, no payment was made by our Group to any of the Directors or the five highest paid individuals as an inducement to join us or as compensation for loss of office. Our Supervisors (excluding employee Supervisor) do not receive any remuneration from the Company. Save as disclosed above, none of the Directors or Supervisors waived their remuneration during the relevant period.

The remuneration of Directors, Supervisors and senior management is determined with reference to factors including the salaries paid by comparable companies, time commitment and responsibilities of the Directors, Supervisors and senior management, employment conditions of other positions in our Company and the desirability of performance-based remuneration.

As of the Latest Practicable Date, save as otherwise disclosed, none of the Directors, Supervisors or senior management is interested in any Shares within the meaning of Part XV of the SFO. Save as disclosed herein, to the best of the knowledge, information and belief of the Directors after having made all reasonable enquiries, there was no additional matter with respect to the appointment of the Directors or Supervisors that needs to be brought to the attention of the Shareholders and there was no additional information relating to the Directors that is required to be disclosed pursuant to Rules 13.51(2)(b) to (v) of the Hong Kong Listing Rules as of the Latest Practicable Date.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

SHARE INCENTIVE SCHEME

In order to motivate, attract and retain our employees, our Company adopted the Share Incentive Scheme II and Share Incentive Scheme III in November 2016 and December 2018, respectively. For details, please see “Appendix VI—Statutory and General Information—C. Share Incentive Schemes II and III”.

COMPLIANCE ADVISOR

The Company has appointed Somerley Capital Limited as the compliance advisor upon [REDACTED] in compliance with Rules 3A.19 and 19A.05 of the Hong Kong Listing Rules. Our Compliance Adviser will provide us with guidance and advice as to compliance with the Listing Rules and applicable Hong Kong laws. Pursuant to Rule 3A.23 of the Listing Rules, our Compliance Adviser will advise our Company in certain circumstances including:

- before the publication of any regulatory announcement, circular, or financial report;
- where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues and share repurchases;
- where we propose to use the [REDACTED] of the [REDACTED] in a manner different from that detailed in this document or where the business activities, development or results of our Group deviate from any forecast, estimate or other information in this document; and
- where the Stock Exchange makes an inquiry to our Company regarding unusual movements in the price or trading volume of its [REDACTED] or any other matters in accordance with Rule 13.10 of the Listing Rules.

Meanwhile, pursuant to Rule 19A.06(3) of the Listing Rules, the compliance advisor shall inform us on a timely basis of any amendment or supplement to the Hong Kong Listing Rules issued by the Hong Kong Stock Exchange from time to time and any new or amended law, regulation or code in Hong Kong applicable to the Company. The compliance advisor shall also provide advice to us on the continuing requirements under the Listing Rules and applicable laws and regulations.

The term of appointment of the compliance advisor shall commence on the [REDACTED] and end on the date of distribution of the annual report of the financial results of the Group for the first full financial year commencing after the [REDACTED] or on the date of the termination of the contract, whichever is earlier.

COMPETITION

Each of our Directors confirms that as of the Latest Practicable Date, he or she did not have any interest in a business which competes or is likely to compete, directly or indirectly, with our business, and requires disclosure under Rule 8.10 of the Listing Rules.

SHARE CAPITAL

BEFORE THE [REDACTED]

As of the Latest Practicable Date, the registered capital of our Company was RMB1,247,201,704, comprising 1,247,201,704 A Shares of nominal value RMB1.00 each, which are all listed on the Shenzhen Stock Exchange.

	Number of Shares	% of issued share capital
A Shares	1,247,201,704	100%

UPON COMPLETION OF THE [REDACTED]

Immediately following completion of the [REDACTED], assuming that the [REDACTED] is not exercised, the entire share capital of our Company would be as follows:

Description of Shares	Number of Shares	Approximate % of the enlarged issued share capital
A Shares	1,247,201,704	[REDACTED]%
H Shares issued pursuant to the [REDACTED]	[REDACTED]	[REDACTED]%
Total	[REDACTED]	100%

Immediately following completion of the [REDACTED] and assuming that the [REDACTED] is fully exercised, the entire share capital of our Company would be as follows:

Description of Shares	Number of Shares	Approximate % of the enlarged issued share capital
A Shares	1,247,201,704	[REDACTED]%
H Shares issued pursuant to the [REDACTED]	[REDACTED]	[REDACTED]%
Total	[REDACTED]	[100]%

SHARE CLASSES

The H Shares and A Shares in issue upon completion of the [REDACTED] will be ordinary Shares in our share capital. Shanghai-Hong Kong Stock Connect, activated on November 17, 2014, and Shenzhen-Hong Kong Stock Connect, initiated on December 5, 2016, have established a stock connect mechanism between the PRC and Hong Kong. A Shares can be subscribed for and traded by PRC investors, qualified foreign institutional investors or qualified foreign strategic investors and must be traded in Renminbi. As the A Shares of our Company are eligible securities under the Northbound Trading Link, they can also be subscribed for and traded by Hong Kong and other overseas investors pursuant to the rules and limits of Shenzhen-Hong Kong Stock Connect. H Shares can be subscribed for or traded by Hong Kong and other overseas investors and qualified domestic institutional investors. If the H Shares of the Company are eligible securities under the Southbound Trading Link, they can also be subscribed for and traded by PRC investors in accordance with the rules and limits of Shanghai-Hong Kong Stock Connect or Shenzhen-Hong Kong Stock Connect.

All dividends in respect of the H Shares are to be paid by us in Hong Kong dollars whereas all dividends in respect of A Shares are to be paid by us in Renminbi. In addition to cash, dividends may also be distributed in the form of Shares. Holders of H Shares will receive share dividends in the form of H Shares, and holders of A Shares will receive share dividends in the form of A Shares.

SHARE CAPITAL

In addition, A Shares and H Shares are regarded as different classes of Shares under our Articles of Association. The differences between the two classes of Shares, provisions on class rights, dispatch of notices and financial reports to Shareholders, dispute resolution, registration of Shares on different branches of the register of Shareholders, the method of Share transfer and appointment of dividend receiving agents are set out in our Articles of Association and summarized in “Appendix V—Summary of Articles of Association” to this document. Further, any change or abrogation of the rights of class Shareholders should be approved by way of a special resolution of the general meeting of Shareholders and by a separate meeting of Shareholders convened by the affected class of Shareholders. See “Appendix V—Summary of Articles of Association” for the circumstances under which a general meeting of Shareholders and class meeting are required. However, the procedures for approval by separate class Shareholders shall not apply:

- (i) where the Company issues, upon the approval by a special resolution of the general meeting of Shareholders, either separately or concurrently once every 12 months, not more than 20% of each of its existing issued A Shares and H Shares;
- (ii) where the plan of the Company to issue A Shares and H Shares at the time of its establishment is carried out within 15 months from the date of approval of the securities regulatory authority under the State Council; or
- (iii) where the transfer of the A Shares held by the A Shareholders of the Company to foreign investors and the listing on overseas stock exchange are approved by the securities regulatory institution under the State Council.

A Shares and H Shares will however rank *pari passu* with each other in all other respects and, in particular, will rank equally for all dividends or distributions declared, paid or made.

A Shares and H Shares are generally neither interchangeable nor fungible, and the market prices of our A Shares and H Shares may be different after the [REDACTED].

In accordance with the Guidelines on Application for “Full Circulation” of Domestic Unlisted Shares of H-share Companies (《H股公司境內未上市股份申請“全流通”業務指引》) (“**Full Circulation Guidelines**”) published and implemented by the CSRC on November 14, 2019, domestic unlisted shares of H-share companies (including domestic unlisted shares held by domestic shareholders prior to the overseas listing, domestic unlisted shares further issued in the PRC after the overseas listing and unlisted shares held by foreign shareholders) could be listed and traded on the Hong Kong Stock Exchange after application to and approval from the CSRC. The Full Circulation Guidelines are only applicable to domestic companies listed on the Hong Kong Stock Exchange only and not applicable to companies dual listed in the PRC and on the Hong Kong Stock Exchange. Up to the Latest Practicable Date, there are no relevant rules or guidelines from the CSRC providing that A shares holders may convert A shares held by them into H shares for [REDACTED] and [REDACTED] on the Hong Kong Stock Exchange.

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

SHARE CAPITAL

[REDACTED]

SUBSTANTIAL SHAREHOLDERS

As of the Latest Practicable Date, our registered share capital was RMB1,247,201,704 comprising 1,247,201,704 A Shares and the following persons directly or indirectly control, or are entitled to exercise the control of, 5% or more of our A Shares:

Shareholders	Nature of Interest	Class	Number of Shares directly or indirectly held	Approximate percentage of shareholding (%)
Leren Technology ⁽¹⁾	Beneficial owner	A Shares	474,029,899	38.01%
Jintiantu ⁽²⁾	Beneficial owner	A Shares	408,041,280	32.72%
Mr. Li ^{(1),(3)}	Interest in controlled corporations and interest of a spouse	A Shares	922,391,179	73.96%
Ms. Li ^{(2),(3)}	Interest in a controlled corporation and interest of a spouse	A Shares	922,391,179	73.96%

Notes:

- (1) Leren Technology is owned as to 99.00% by Mr. Li and 1.00% by Ms. Li, respectively. Mr. Li is also the sole owner of Feilaishi which directly holds 40,320,000 of our A Shares, representing 3.23% of our shareholding as of the Latest Practicable Date. Therefore, Mr. Li is deemed to be interested in 474,029,899 A Shares held by Leren Technology and 40,320,000 A Shares held by Feilaishi. Pursuant to a stock pledge repurchase agreement, Leren Technology has pledged 43,600,000 A Shares held in our Company to Guotai Junan Securities Co. Ltd. on December 19, 2019.
- (2) Jintiantu is owned as to 99.00% by Ms. Li as a general partner and 1.00% by Mr. Li as a limited partner, respectively. Therefore, Ms. Li is deemed to be interested in 408,041,280 A Shares held by Jintiantu.
- (3) Mr. Li and Ms. Li are the spouse of each other and are deemed to be interested in the same number of Shares that the other person is interested in under the SFO.

Immediately following the completion of the [REDACTED] (and assuming the [REDACTED] is not exercised), our share capital comprised of 1,247,201,704 A Shares and [REDACTED] H Shares, representing [REDACTED]% and [REDACTED]% of the total share capital of our Company, respectively.

So far as our Directors are aware, immediately following the completion of the [REDACTED] (and assuming the [REDACTED] is not exercised), the following persons will have an interest or a short position in our Shares or underlying Shares of our Company which would be required to be disclosed to us and the Hong Kong Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO:

Shareholders	Nature of Interest	Class	Number of Shares directly or indirectly held	Approximate percentage of shareholding in the relevant class of Shares of our Company	Approximate percentage of shareholding in the total Shares of our Company
Leren Technology ⁽¹⁾	Beneficial owner	A Shares	474,029,899	38.01%	[REDACTED]%
Jintiantu ⁽²⁾	Beneficial owner	A Shares	408,041,280	32.72%	[REDACTED]%
Mr. Li (李鐸) ^{(1),(3)}	Interest in controlled corporations and interest of a spouse	A Shares	922,391,179	73.96%	[REDACTED]%
Ms. Li (李坦) ^{(2),(3)}	Interest in a controlled corporation and interest of a spouse	A Shares	922,391,179	73.96%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Notes:

- (1) Leren Technology is owned as to 99.00% by Mr. Li and 1.00% by Ms. Li, respectively. Mr. Li is also the sole owner of Feilaishi which directly holds 40,320,000 of our A Shares, representing 3.23% of our shareholding as of the Latest Practicable Date. Therefore, Mr. Li is deemed to be interested in 474,029,899 A Shares held by Leren Technology and 40,320,000 A Shares held by Feilaishi. Pursuant to a stock pledge repurchase agreement, Leren Technology has pledged 43,600,000 A Shares held in our Company to Guotai Junan Securities Co. Ltd. on December 19, 2019.
- (2) Jintiantu is owned as to 99.00% by Ms. Li as a general partner and 1.00% by Mr. Li as a limited partner, respectively. Therefore, Ms. Li is deemed to be interested in 408,041,280 A Shares held by Jintiantu.
- (3) Mr. Li and Ms. Li are the spouse of each other and are deemed to be interested in the same number of Shares that the other person is interested in under the SFO.

For those who are directly and/or indirectly interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at a shareholders' meeting of any other member of our Group, see “Appendix VI—Statutory and General Information” to this document.

As of the Latest Practicable Date, we are not aware of any arrangement which may on a subsequent date result in a change of control of our Company.

FINANCIAL INFORMATION

You should read the following discussion and analysis with our audited consolidated financial information, including the notes thereto, included in the Accountants’ Report in Appendix I to this document. Our consolidated financial information has been prepared in accordance with IFRS, which may differ in material aspects from generally accepted accounting principles in other jurisdictions, including the United States.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance. These statements are based on our assumptions and analysis in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. However, whether actual outcomes and developments will meet our expectations and predictions depends on a number of risks and uncertainties. In evaluating our business, you should carefully consider the information provided in the section headed “Risk Factors” in this document.

Unless the context otherwise requires, references to 2017 and 2018 refer to our financial years ended December 31 of such years. Unless the context otherwise requires, financial information described in this section is described on a consolidated basis.

OVERVIEW

Driven by our innovations across the industry value chain, our mission is to become a leading global pharmaceutical company targeting high-mortality diseases with significant unmet medical needs.

We are a leading China-based pharmaceutical company with global businesses in pharmaceutical, innovative biotech and CDMO sectors. We ranked the first by both export value and export volume of injectable finished doses in 2018 among China-based pharmaceutical companies, with major sales into the EU market.

Founded by a group of seasoned polysaccharide-chemists with scientific insights and profound understanding of immunology, we have built up a portfolio of both leading drugs in the anticoagulant and antithrombotic therapeutic areas and innovative drug candidates focusing on diseases with an immune system disorder axis, including oncology, autoimmune, metabolic and other areas. These diseases are among the largest unmet medical needs globally and represent the leading causes of morbidity and mortality.

Our leading drugs, Inhixa, Neoparin and Prolongin are three different brands of enoxaparin sodium injection which in total have been approved in 36 countries and sold in 15 countries. We have also supplied enoxaparin sodium injection to our customers in 13 other countries. We are the only China-based pharmaceutical company with cumulative sales of enoxaparin sodium injections in the EU exceeding 100 million doses. Enoxaparin is the “gold standard” anticoagulant and antithrombotic drug for various indications, such as venous thromboembolism (VTE) and pulmonary embolism (PE), with huge market demands and significant growth potential. According to Frost & Sullivan, the global usage of enoxaparin exceeded 763.2 million syringes/vials in 2018, and is expected to reach 1,444.3 million syringes/vials in 2024. Its usage in China was 41.9 million syringes/vials in 2018, which is expected to increase at a CAGR of 47.5% to 431.7 million syringes/vials in 2024.

FINANCIAL INFORMATION

Based on our profound understanding of immune response mechanisms, we have strategically constructed a robust portfolio of both exclusive development and commercial rights in Greater China for first-in-class clinical stage drug candidates and self-developed first-in-class drug candidate. These pipeline drugs are being developed to address the significant unmet medical demands in oncology, cardiovascular, inflammation and autoimmune areas. We place great importance in nurturing our partners and provide strong support to them in various areas including clinical development through our CDMO platform and equity investment. For example, Oregovamab, an immune-oncology antibody candidate being developed for first-line treatment of ovarian cancer in combination with chemotherapy, has shown a significant prolongation of median progression-free survival (median PFS 41.8 months vs. 12.2 months in patients treated by chemo-alone, $p=0.0027$) in a phase II trial. It also showed a significant improvement in overall survival (OS) ($p=0.0043$). We own 38.74% equity interest in the developer company of Oregovamab as well as its exclusive development and commercial rights in Greater China.

We operate a fast-growing CDMO business through two platforms, Cytovance, a CDMO platform enabling the development and manufacture of recombinant pharmaceutical products and critical non-viral vectors and intermediates for gene therapy, and SPL, a CDMO platform enabling the development and manufacture of pharmaceutical products from natural sources, to capture the growth opportunities in the global biopharmaceutical sector. Our CDMO business ranks among the top three China-owned biologics CDMO operators based on 2018 revenue according to Frost & Sullivan. Our CDMO revenue grew by 66.8% from RMB325.6 million in 2017 to RMB543.2 million in 2018 and grew by 41.5% from RMB353.0 million for the first nine months in 2018 to RMB499.6 million for the first nine months in 2019. Our customer base ranges from multinational pharmaceutical giants to midsize, small and virtual biotech companies. With continuous investments in capabilities, capacity and innovation, the dual CDMO platform addresses diverse customer needs while leveraging over 45 years of combined experience of Cytovance and SPL in the development and manufacture of large molecule pharmaceutical products for innovative biologically based therapeutics. In addition to supporting a multitude of customer drug pipelines, our own product pipeline is aptly enabled and enhanced by the dual CDMO platform strategy. By addressing the capacity shortage and technological challenge in the CMC process, our CDMO platform empowers our customers to develop drugs from concept to commercial manufacturing stage and ensures CDMO capacities for the development of our own pipeline drugs. Benefiting from the global growth in the biopharmaceutical sector, our CDMO business has contributed to our rapid growth and diversified our revenue source. As of the Latest Practicable Date, we had 39 on-going projects and a backlog of US\$62.1 million, which represents the total amount of contracted service fees pending milestone delivery.

Our revenue increased by 69.7%, from RMB2,828.2 million in 2017 to RMB4,799.8 million in 2018, and decreased by 5.3%, from RMB3,306.7 million for the nine months ended September 30, 2018 to RMB3,132.2 million for the nine months ended September 30, 2019. Our net profit increased by 156.1% from RMB240.9 million in 2017 to RMB617.0 million in 2018, and increased by 59.6% from RMB469.4 million for the nine months ended September 30, 2018 to RMB749.0 million for the nine months ended September 30, 2019.

BASIS OF PRESENTATION

The consolidated financial information of our Group has been prepared in accordance with International Financial Reporting Standards (IFRS) and the interpretations issued by the International Accounting Standards Board (IASB) applicable to companies reporting under IFRS. The consolidated

FINANCIAL INFORMATION

financial information has been prepared under the historical cost convention, except for equity investments designated at fair value through other comprehensive income and financial assets at fair value through profit or loss which we have been measured at fair value. The consolidated financial information of our Group is presented in RMB and all values are rounded to the nearest thousand except when otherwise indicated. The preparation of consolidated financial information in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying our Company’s accounting policies.

We acquired Topknow in 2018. As the acquisition of Topknow constitutes a business combination under common control, the consolidated financial statements of the Company were prepared as if Topknow had been combined throughout the Track Record Period. For the details of our acquisitions and disposals, please refer to “History, Development and Corporate Structure” to this document.

SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations have been, and are expected to continue to be, affected by a number of factors, many of which may be beyond our control. We operate in the global pharmaceutical and CDMO industries and our financial condition and results of operations are influenced by the macroeconomic factors affecting these industries, such as global economic growth, policy and regulatory changes. Additionally, we believe our results of operations are affected by a number of company-specific factors, including the key factors as discussed below.

The growth of the global pharmaceutical industry, in particular, the therapeutic areas that we focus on and the CDMO industry

We believe that the overall growth of the global pharmaceutical industry, in particular, the therapeutic areas we focus on and the overall growth of the global CDMO industry, in particular, the biologics CDMO market, have significantly, and will continue to significantly impact, our revenue growth.

According to Frost & Sullivan, the global pharmaceutical industry is expected to grow at a CAGR of 4.6% from US\$1,267.4 billion in 2018 to US\$1,662.3 billion in 2024. We focus on some of the largest and fast growing therapeutic areas including: (i) anticoagulant and antithrombotic, (ii) oncology, (iii) anti-infectives, (iv) anti-inflammatory, (v) diabetes and (vi) cardiovascular diseases. Our leading drugs, Inhixa, Neoparin and Prolongin (enoxaparin sodium injections), are the “gold standard” anticoagulant and antithrombotic drug with significant growth potential. The anticoagulant market has grown rapidly at a CAGR of 14.2% from US\$11.6 billion in 2014 to US\$19.8 billion in 2018, and is estimated to reach US\$26.0 billion in 2024, according to Frost & Sullivan. Specifically with respect to the market of enoxaparin finished dose products, while the global market by revenue has decreased from US\$3,268.8 million in 2014 to US\$2,733.5 million in 2018, due to the fluctuation of price as a result of the market competition brought by genetic drugs and the termination of Sandoz’s supply of enoxaparin finished dose products in July 2018, the global sales volume of enoxaparin finished dose products has increased at a CAGR of 2.1% from 701.5 million syringes/vials in 2014 to 763.2 million syringes/vials in 2018, representing a growing market demands of enoxaparin finished dose products. It is estimated that the global sales volume of enoxaparin products will increase at a CAGR of 11.2% to 1,444.3 million syringes/vials in 2024 as compared to that of 2018, primarily driven by the growing aging population, increasing market awareness of enoxaparin finished dose

FINANCIAL INFORMATION

products in the emerging markets such as China and the recovery of sufficient supply of high-quality API. The enoxaparin market in China has significant growth potential. The sales volume of enoxaparin products in China has grown rapidly at a CAGR of 29.8% from 14.8 million syringes/vials in 2014 to 41.9 million syringes/vials in 2018, and is estimated to reach 431.7 million syringes/vials in 2024, representing a CAGR of 47.5%.

We have commercial rights in the Greater China of our innovative drug candidates. We believe that the growth of the Chinese pharmaceutical market, in particular, the respective therapeutic areas that our drug candidates are targeting will have significant impact on our future revenue after we commercialize our drug candidates. Our drug candidates are being developed for treatment of diseases with an immune system axis, and the relevant markets for the therapeutic areas we focus on, including oncology, anti-infectives, anti-inflammatory, diabetes and cardiovascular diseases, have grown rapidly in the past years and is expected to continuously grow in the future. For instance, oncology and cardiovascular therapeutic areas grew at a CAGR of 12.8% and 0.9% respectively, from 2014 to 2018. According to Frost & Sullivan, these two therapeutic areas are expected to continue growing rapidly from 2018 to 2024 at a CAGR of 11.1% and 2.1% respectively.

According to Frost & Sullivan, the global CDMO market has grown rapidly at a CAGR of 10.7% from US\$17.8 billion in 2014 to US\$26.8 billion in 2018. The growth of the global CDMO market is primarily driven by the expansion of the global biologics CDMO market, which has expanded from US\$3.1 billion in 2014 to US\$6.4 billion in 2018, and is driven by the increasing investment in the field of biologics industry, the emergence of small and mid-sized pharmaceutical companies, and the increasing penetration rate of outsourcing services in the global biologics manufacture industry. Benefiting from the global growth in the biopharmaceutical sector, our CDMO business experienced rapid growth during the Track Record Period. Revenue from our CDMO business increased from RMB324.3 million to 2017 to RMB548.5 million in 2018, and increased from RMB356.5 million for the nine months ended September 30, 2018 to RMB503.2 million for the nine months ended September 30, 2019. We expect our CDMO business to further grow as the global biologics CDMO market is expected to reach US\$21.6 billion in 2024, representing a CAGR of 22.4% from 2018.

Please refer to “Industry Overview” for further details on the expected growth of these therapeutic areas and the relevant segments. We believe we are well positioned to capitalize on the expected growth of the global pharmaceutical market in general and the therapeutic areas we strategically focus on.

Our ability to expand the sales of our pharmaceutical products and our CDMO business

We focus primarily on the anticoagulant and antithrombotic finished dose pharmaceutical products and their relevant APIs. Sales volume of these products have a significant impact on our results of operation. During the Track Record Period, our revenue primarily comprised of sales of our heparin sodium API and enoxaparin sodium injection. The sales of our finished dose pharmaceuticals accounted for 13.5%, 21.8%, and 23.0% of our total revenue in 2017, 2018, and the nine months ended September 30, 2019, respectively, and the sales of our API products accounted for 65.3%, 57.3%, and 54.0% of our total revenue in the respective period. We expect that the sales of heparin sodium API and enoxaparin sodium injection will continue to account for a substantial portion of our total revenue in the near term.

FINANCIAL INFORMATION

With respect to the sales of our pharmaceutical products, our ability to increase sales volume depends on whether we are able to effectively implement our marketing strategies. For the sales of enoxaparin sodium injection, we intend to increase our sales in various regions by implementing localized and differentiated marketing strategies. In the EU market, we plan to further deepen our penetration in major EU countries where we have established sales and distribution channels, primarily by expanding our sales network to cover more pharmacies through our in-house sales and marketing team or through our distributors, as the sales to pharmacies have a higher profit margin than the sales to hospitals. We also plan to launch our enoxaparin sodium injection in other EU countries. In China, we believe that the sales volume of Prolongin will significantly increase once it obtains the QCE approval in China. We also intend to increase our sales in the U.S. and other regions through our collaboration with leading global or local pharmaceutical companies. We believe that our strong in-house sales team and well-established sales network will enable us to carry out our sales and marketing strategies and increase the sales volume of our pharmaceutical products. For the sales of heparin sodium API, our ability to maintain the long-term supply arrangements with our existing customers is important for us to secure the current sales volume while further expand our sales through establishing cooperative relationships with new customers.

During the Track Record Period, our CDMO business also contributed to our total revenue. Revenue from our CDMO business accounted for 11.5%, 11.4%, and 16.1% of our total revenue in 2017, 2018, and the nine months ended September 30, 2019, respectively. We expect that the revenue generated from our CDMO services will increase and become a more substantial part of our total revenue in the future, as we further develop and expand our business. Growth in our CDMO business depends on our ability to enter into new service contracts and replenish our backlog as our existing contracts are completed. Continuous replenishing our backlog is crucial to our long-term success as it underpins the continued growth of our operations. As of the Latest Practicable Date, our backlog reached US\$62.1 million. Our ability to win new projects from existing and new customers is affected substantially by our service quality, price, range of services and capacity. We provided services to 49, 53 and 43 customers in the years ended December 31, 2017, 2018 and the nine months ended September 30, 2019. For details, see “Risk Factors—Risks Relating to Our CDMO Business—Our CDMO business is dependent on our customers’ spending on and demand for outsourced biologics discovery, development and manufacturing. A reduction in spending or demand could have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.”

Development and commercialization of our innovative drug candidates

Our ability to develop new drugs, replenish our drug pipeline with additional candidates, and further diversify our drug portfolio, has a significant impact on our results of operations and business prospects. Focusing on diseases with an immune system axis, we have strategically invested in a number of biotech companies with first-in-class drug candidates addressing the significant unmet clinical demands and obtained exclusive development and commercial rights for selected drug candidates in the Greater China including two drug candidates in phase III clinical trials, two drug candidates in phase II clinical trials and one drug candidates in phase I clinical trial, as of the Latest Practical Date. We plan to conduct the clinical trials for all our in-licensed drug candidates in China under the MRCT, except for RVX-208. We received the NMPA approval for the clinical trial of AR-301 in China in July 2019. We are also developing an oncology drug candidate currently at preclinical stage.

FINANCIAL INFORMATION

Our results of operations and business prospects also depend on our ability to successfully commercialize new drugs as they come out of pipeline. We have established extensive sales and distribution network and teams in China for our heparin business. We believe we can leverage these resources in China to build specialized in-house sales teams and distribution channel with hospitals and physicals for the academic marketing of our pipeline drugs. Through years of operations, we have and accumulated local insight and vast experiences of business operations in China. We believe we are able to leverage our successful experience in the heparin industry to successfully launch our drug candidates and maximize their commercial value in China.

Our ability to successfully develop and commercialize our drug candidates is subject to a number of risks and uncertainties, many of which are beyond our control. For more information, see “Risk Factors—Risks Relating to the Research and Development of Our Product Candidates.”

Our ability to compete in the tender process and coverage of our drugs in the governmental medical insurance programs

The majority of our pharmaceutical products we sell to our distributors are then sold to public hospitals and other medical institutions. Sales of our finished dose pharmaceutical products to public hospitals and other public medical institutions in China and certain EU countries are required to go through a centralized or regional tender process for the procurement of medicines listed in the medical insurance catalogs and medicines that are consumed in large volumes and commonly prescribed for clinical uses. We submit bids in a tender process to supply our products to these public institutions at specified prices. These bids are generally considered on the basis of price competitiveness, clinical effectiveness, as well as product quality and reputation of the manufacturer, among other things. The tender process for pharmaceuticals with the same chemical composition are conducted periodically, and pharmaceuticals that have won in the tender process previously must participate and win in the following period before new purchase orders can be placed. If we are successful in winning bids in a tender process, our products will be sold to the public hospitals in the respective regions at the bidding prices, which will increase the sales volume of our drug and reduce our sales and marketing expenses in promoting our drugs among individual hospitals.

Our bidding strategy generally focuses on differentiating our products instead of competing solely based on pricing. Our sales volumes and profitability depends on our ability to successfully differentiate our products and price our bids in a manner that enables us to succeed in the tender process. We believe each of our products has had competitive advantages in the tender process during the Track Record Period. If we are unable to differentiate our products or are otherwise not successful in winning bids in the tender process at profitable levels, we will lose the revenue associated with the sale of the affected pharmaceutical products to the relevant public hospitals.

Regulatory and policy changes on tender process may have significant influence on our bidding strategies and therefore on the pricing of our products. In recent years, the PRC government has adopted measures aimed at raising the operating standards of pharmaceutical manufacturing companies in China in order to ensure a stable supply of safe and effective medicines. For example, in March 2016, the General Office of the State Council issued the Opinion on Conducting the Consistency Evaluation of the Quality and Efficacy of Generic Drugs (國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見), which requires existing generic drugs to undergo and pass quality consistency evaluation. Generic drugs that have passed the consistency evaluation in China are afforded certain advantages, including preferential treatment in the centralized tender process. See “Regulatory

FINANCIAL INFORMATION

Environment—Laws and Regulations Related to Our Business in the PRC—Regulations on Drug Research and Development & Registration Services.” In November 2018, the PRC government launched the national pilot scheme for tendering with minimum procurement quantities. The implementation of this program may further impact our strategies on how to commercialize drug products in China and how to best compete in the bidding process.

Moreover, under the medical insurance programs in China and the EU, patients are entitled to reimbursement of all or a portion of the cost of pharmaceutical products covered under the government-sponsored medical insurance programs. Consequently, whether a pharmaceutical product is included in any of these medical insurance programs will significantly affect the demand for such product. Please refer to “Risk Factors—Risks Relating to Our Business and Industry—Sales of our pharmaceutical products depend on the reimbursement policies of the governmental authorities and health insurers. Failure to obtain or maintain adequate medical insurance coverage and reimbursement for our pharmaceutical products could limit our ability to market those products and decrease our ability to generate revenue” for more details. While the inclusion of a pharmaceutical product in government-sponsored medical insurance programs can significantly increase the demand and potentially sales volume, pharmaceuticals so included are subject to relevant pricing regulation and are subject to pricing pressure in the tender process and must undergo pricing negotiation process with the relevant government authorities. As a result, whether our enoxaparin sodium injection can continue to be included in the governmental medical insurance and whether our innovative drug candidates once launched can be included in the governmental medical insurance will significantly affect our financial conditions and results of operations.

On balance, the benefits of inclusion of our pharmaceuticals in the governmental medical insurance programs outweighed the disadvantages of such inclusion during the Track Record Period. We believe that we will continue to benefit from such inclusion in the foreseeable future for our current finished dose pharmaceutical products.

Raw materials supply and pricing and our ability to control costs and expenses

During the Track Record Period, costs of raw materials represented a major component of our costs of sales. For the years ended December 31, 2017 and 2018 and nine months ended September 30, 2018 and 2019, our costs for raw materials amounted to RMB1,158.3 million, RMB1,853.6 million, RMB1,276.4 million and RMB1,173.6 million respectively, representing approximately 58.6%, 63.3%, 62.6% and 56.7%, respectively, of our total costs of sales. Among the costs of raw materials, the costs of heparin raw materials constitute a significant portion; therefore, the supply and pricing of heparin raw materials have a material impact on our results of operations.

During the Track Record Period, we primarily contract with third-party suppliers to acquire porcine small intestine for the manufacturing of crude heparin at our crude heparin factories. We also acquire crude heparin for the manufacturing of heparin sodium APIs at our facilities. The price of heparin raw materials is heavily reliant on the supply of breeding stock pigs. In China, due to the outbreak of African swine fever in late 2018, the number of breeding stock pigs has decreased significantly in 2019. Such decrease in the number of breeding stock pigs has resulted in a shortage of porcine small intestine and an increase in the price of porcine small intestine and crude heparin, which has resulted in an increase in our costs of raw materials and therefore, costs of sales. However, since there is generally one year lag from the price increase of porcine small intestine to that of heparin sodium API, we have limited capability to transfer the increasing costs of raw materials to downstream

FINANCIAL INFORMATION

industry chain in a timely manner. As we typically enter into short term supply agreements with our suppliers, the price is constantly affected by the prevailing market conditions. For the years ended December 31, 2017 and 2018 and nine months ended September 30, 2018 and 2019, the average unit price for crude heparin was RMB151 per mega, RMB162 per mega, RMB159 per mega, and RMB218 per mega, respectively.

The following table sets forth the sensitivity of our profit for the years ended December 31, 2017 and 2018 and nine months ended September 30, 2018 and 2019 in relation to movements in costs of crude heparin for the periods indicated:

Increase / (Decrease) of Costs of crude heparin	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	Change in profit (RMB'000)	% Change	Change in profit (RMB'000)	% Change	Change in profit (RMB'000)	% Change	Change in profit (RMB'000)	% Change
5%	(41,362)	(17)	(62,213.8)	(10)	(47,321.7)	(10)	(47,321.7)	(5)
(5)%	41,362	17	62,213.8	10	47,321.7	10	47,321.7	5

Our profitability has benefited from our effective control of cost of sales. Our cost of sales primarily includes raw material costs, staff costs, depreciation and utilities and others. We have devoted significant efforts to continuously improving our production efficiency, including through increased automation in our production processes. As a result, we were able to increase our production volumes to meet growing market demand without significantly increasing our material costs, staff and other costs. During the Track Record Period, the cost of our raw materials, especially the price of porcine small intestines, was affected by the reduced supply as a result of the outbreak of swine fever. We were able to limit its impact on our raw material costs, through our control on the global supply of the porcine small intestines and our long-term collaboration with the suppliers. The raw material costs accounted for 58.6%, 63.3%, 62.6% and 56.7% of our total cost of sales in 2017, 2018 and the nine months ended September 30, 2018 and 2019. As our production efficiency and economies of scale improve, our cost of sales as a percentage of revenue has remained relatively stable at 69.9%, 61.0%, 61.6% and 66.1%, respectively, for the years ended December 31, 2017 and 2018 and nine months ended September 30, 2018 and 2019.

Our ability to effectively control our operating expenses, particularly our selling and distribution expenses and administrative expenses, also has a material impact on our profitability. Our operating expenses primarily include selling and distribution expenses, administrative expenses, finance costs and share of losses of associates. Selling and distribution expenses and administrative expenses are the two largest component of our operating expenses, with the selling and distribution expenses accounting for 6.8%, 7.7%, 7.3% and 9.3%, respectively, of our revenue and administrative expenses accounting for 15.4%, 10.4%, 10.4% and 11.7%, respectively, of our revenue in 2017, 2018 and the nine months ended September 30, 2018 and 2019. In the future, we intend to continue to control our selling and distribution expenses and enhance our sales productivity through additional tailored training of sales personnel and more targeted marketing activities. Our administrative expenses primarily include R&D expenses, employee compensation and depreciation and amortization. We will continue to control our administrative expenses through more efficient training of our administration personnel and more reasonable allocation of administrative allocation.

Funding for our operations and cost of financing

We fund our business operations primarily through internally generated funds and other financing arrangements during the Track Record Period. As of December 31, 2017 and 2018 and

FINANCIAL INFORMATION

September 30, 2019, our total outstanding bank loans, corporate bonds and other borrowings amounted to RMB5,084.1 million, RMB4,912.9 million and RMB6,360.9 million, respectively. With the continuing expansion of our business and development of product candidates, we may require further funding through public or private equity offerings, debt financing and other sources. Any changes in our ability to fund our operations and any fluctuation in the interest rates will affect our cash flow and results of operation.

Performance of our portfolio companies

We have strategically invested in a number of biotech companies which focus on research and development of innovative drugs with significant growth potential or cutting edge technologies that we believe will advance the healthcare industry. The performance of our invested companies, including but not limited to the commercial success of their drug candidates, will affect our cash flow and results of operation. Given that these portfolio companies are still in the development stages, they may have a higher failure rate. They may not be able to successfully complete clinical development, obtain regulatory approval or commercialize their drug candidate, or experience delays in doing so. Accordingly, we may fail to realize our anticipated returns on investments in such investees, and may even experience a total loss on such investments. As of December 31, 2017, 2018 and September 30, 2019, our share of losses of associates amounted to RMB19.2 million, RMB330.9 million and RMB61.8 million, respectively. Please refer to “History, Development and Corporate Structure—Major Acquisitions and Disposals” for more information regarding our investments.

SIGNIFICANT ACCOUNTING POLICIES AND ESTIMATES

We have identified certain accounting policies that are significant to the preparation of our consolidated financial statements. Some of our accounting policies involve subjective assumptions and estimates, as well as complex judgments relating to accounting items. Estimates and judgments are continually re-evaluated and are based on historical experience and other factors, including industry practices and expectations of future events that we believe to be reasonable under the circumstances. We have not changed our assumptions or estimates in the past and have not noticed any material errors regarding our assumptions or estimates. Under current circumstances, we do not expect that our assumptions or estimates are likely to change significantly in the future. When reviewing our consolidated financial statements, you should consider (i) our critical accounting policies, (ii) the judgments and other uncertainties affecting the application of such policies and (iii) the sensitivity of reported results to changes in conditions and assumptions.

We set forth below those accounting policies that we believe are of critical importance to us or involve the most significant estimates and judgments used in the preparation of our consolidated financial statements. Our significant accounting policies and estimates, which are important for an understanding of our financial condition and results of operations, are set forth in detail in Notes 2 and 3 to the Accountants’ Report in Appendix I to this document.

Significant Accounting Policies

Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

FINANCIAL INFORMATION

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

When the contract contains a financing component which provides the customer a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between the Group and the customer at contract inception. When the contract contains a financing component which provides the Group a significant financial benefit for more than one year, revenue recognized under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

(a) Sale of products

Revenue from the sale of products is recognized at the point in time when control of the asset is transferred to the customer, generally on delivery of the products.

Some contracts for the sale of products provide customers with rights of return. The rights of return give rise to variable consideration.

(b) Contract development and manufacturing organization services

The Group earns revenues by providing research services to its customers through Fee-for-service (“FFS”) contracts. Contract duration ranges from a few months to years. Under FFS model, the contracts usually have multiple task units, which are generally in the form of technical laboratory reports and/or samples, each of which is with an individual selling price specified within the contract. The Group identifies each task unit as a separate performance obligation. The revenue is recognized over time, as the Group’s performance has created an asset with no alternative use and the Group has an enforceable right for payments for performance completed to date. The selection of the method to measure progress towards completion requires judgment and is based on the nature of the products or services to be provided. Depending on which better depicts the transfer of value to the customer, the Group generally measures its progress using either cost-to-cost (input method).

Under the input method, the Group uses the known cost measure of progress when it best depicts the transfer of value to the customer which occurs as the Group incurs costs on its contract, under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation. Revenue is recorded proportionally as costs are incurred.

The Group also engages in contracts by the commercial manufacture and sale of products under customers’ specific order. The Group recognized revenue at a point in time upon acceptance of the deliverable products under customers’ specific order.

FINANCIAL INFORMATION

Other income

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Dividend income is recognized when the shareholders’ right to receive payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably.

Business combinations and goodwill

Business combinations are accounted for using the acquisition method. The consideration transferred is measured at the acquisition date fair value which is the sum of the acquisition date fair values of assets transferred by the Group, liabilities assumed by the Group to the former owners of the acquiree and the equity interests issued by the Group in exchange for control of the acquiree. For each business combination, the Group elects whether to measure the non-controlling interests in the acquiree that are present ownership interests and entitle their holders to a proportionate share of net assets in the event of liquidation at fair value or at the proportionate share of the acquiree’s identifiable net assets. All other components of non-controlling interests are measured at fair value. Acquisition-related costs are expensed as incurred.

When the Group acquires a business, it assesses the financial assets and liabilities assumed for appropriate classification and designation in accordance with the contractual terms, economic circumstances and pertinent conditions as at the acquisition date. This includes the separation of embedded derivatives in host contracts of the acquiree.

If the business combination is achieved in stages, the previously held equity interest is remeasured at its acquisition date fair value and any resulting gain or loss is recognized in profit or loss.

Any contingent consideration to be transferred by the acquirer is recognized at fair value at the acquisition date. Contingent consideration classified as an asset or liability is measured at fair value with changes in fair value recognized in profit or loss. Contingent consideration that is classified as equity is not remeasured and subsequent settlement is accounted for within equity.

An acquisition of a business under common control is accounted for in a manner similar to a uniting of interests whereby the assets and liabilities acquired are accounted for at carryover predecessor values to the other party to the business combination within all periods presented as if the operations of the Group and the business acquired have always been combined. The difference between the consideration paid by the Group and the net assets or liabilities of the business acquired is adjusted against equity. Contingent consideration from the business combination under common control is recognized in equity.

Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred, the amount recognized for non-controlling interests and any fair value of the Group’s previously held equity interests in the acquiree over the identifiable net assets acquired and liabilities assumed. If the sum of this consideration and other items is lower than the fair value of the net assets

FINANCIAL INFORMATION

acquired, the difference is, after reassessment, recognized in profit or loss as a gain on bargain purchase.

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. Goodwill is tested for impairment annually or more frequently if events or changes in circumstances indicate that the carrying value may be impaired. The Group performs its annual impairment test of goodwill as at December 31. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the Group’s cash-generating units, or groups of cash-generating units, that are expected to benefit from the synergies of the combination, irrespective of whether other assets or liabilities of the Group are assigned to those units or groups of units.

Impairment is determined by assessing the recoverable amount of the cash-generating unit (group of cash-generating units) to which the goodwill relates. Where the recoverable amount of the cash-generating unit (group of cash-generating units) is less than the carrying amount, an impairment loss is recognized. An impairment loss recognized for goodwill is not reversed in a subsequent period.

Where goodwill has been allocated to a cash-generating unit (or group of cash-generating units) and part of the operation within that unit is disposed of, the goodwill associated with the operation disposed of is included in the carrying amount of the operation when determining the gain or loss on the disposal. Goodwill disposed of in these circumstances is measured based on the relative value of the operation disposed of and the portion of the cash-generating unit retained.

Fair value measurement

The Group measures its equity investments designated at fair value through other comprehensive income, derivative financial instruments and financial assets at fair value through profit or loss at the end of each relevant period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

Level 1—based on quoted prices (unadjusted) in active markets for identical assets or liabilities

FINANCIAL INFORMATION

Level 2—based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly

Level 3—based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognized in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Track Record Period.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to the statement of profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalized in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognizes such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Buildings	2.375%-4.75%
Machine equipment	19%-9.5%
Motor vehicles	19%-9.5%
Other equipment	19%-9.5%
Leasehold improvement	2.5%-33.3%

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognized in the statement of profit or loss in the year the asset is derecognized is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents a building under construction, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of construction and capitalized borrowing costs on related borrowed funds during the period of construction. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

FINANCIAL INFORMATION

Other intangible assets (other than goodwill)

Other intangible assets acquired separately are measured on initial recognition at cost. The cost of other intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of other intangible assets are assessed to be either finite or indefinite. Other intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the other intangible assets may be impaired. The amortization period and the amortization method for other intangible assets with a finite useful life are reviewed at least at each financial year end.

Other intangible assets with indefinite useful lives are tested for impairment annually either individually or at the cash-generating unit level. Such other intangible assets are not amortized. The useful life of other intangible assets with an indefinite life is reviewed annually to determine whether the indefinite life assessment continues to be supportable. If not, the change in the useful life assessment from indefinite to finite is accounted for on a prospective basis.

Patents and licenses

Purchased patents and licenses are stated at cost less any impairment losses and are amortized on the straight-line basis over their estimated useful lives of 10 to 15 years.

Computer software

Acquired computer software stated at historical cost less amortization. Acquired computer software are capitalized on the basis of the costs incurred to acquire and bring to use the specific software, and are amortized on a straight-line basis over the useful life of 5 years.

Trademarks

Trademarks are initially recognized and measured at costs incurred to register. The costs are amortized on the straight-line basis over their estimated useful lives of 5 years.

Proprietary technology

Proprietary technologies invested by minority shareholders are recognized at fair values assessed at investment day and cost of getting the medicine licenses from the related authorities. Proprietary technologies are amortized on the straight-line basis over the respective estimated useful lives of 20-30 years, and the useful lives of the Proprietary technologies are assessed by the Group after considering the useful lives of similar technologies and the market condition.

Brands

Brands acquired in a business combination are recognized at fair value at the acquisition date. The Brands have a finite useful life and are carried at cost less accumulated amortization. Amortization is calculated using the straight-line method over the expected life of 15 years for the Brands.

Customer relationships

Customer relationships acquired in a business combination are recognized at fair value at the acquisition date. The contractual customer relationships have a finite useful life and are carried at cost less accumulated amortization. Amortization is calculated using the straight-line method over the expected life of 15 years for the customer relationship.

FINANCIAL INFORMATION

Inventories

Inventories are stated at the lower of cost and net realizable value. Cost is determined on the first-in, first-out basis and, in the case of work in progress and finished goods, comprises direct materials, direct labor and an appropriate proportion of overheads. Net realizable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Government grants

Government grants are recognized at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the costs, which it is intended to compensate, are expensed.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to the profit or loss over the expected useful life of the relevant asset by equal annual installments or deducted from the carrying amount of the asset and released to the profit or loss by way of a reduced depreciation charge.

Employee Benefit

Share-based payments

The Company operates share award scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (“**equity-settled transactions**”).

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date on which they are granted. The fair value is computed based on their most recent post-money valuations. The cost of equity-settled transactions is recognized in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of each period until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the consolidated statement of profit or loss for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period.

Pension scheme

The Group contributes on a monthly basis to various defined contribution plans organized by the relevant governmental authorities in various areas other than China. The Group’s liability in respect of these plans is limited to the contributions payable at the end of each period. Contributions to these plans are expensed as incurred.

The employees of the Group’s subsidiaries which operates in Mainland China are required to participate in a central pension scheme operated by the local municipal government. These subsidiaries are required to contribute a certain percentage of its payroll costs to the central pension scheme. The contributions are charged to the statement of profit or loss as they become payable in accordance with the rules of the central pension scheme.

FINANCIAL INFORMATION

Housing fund—China

The Group contributes on a monthly basis to a defined contribution housing fund plan operated by the local municipal government. Contributions to this plan by the Group are expensed as incurred.

Defined benefit retirement plan obligations

The Group’s net obligation in respect of defined benefit retirement plans is calculated separately for each plan by estimating the amount of future benefit that employees have earned in return for their service in the current and prior periods; that benefit is discounted to determine the present value, and the fair value of any plan assets is deducted. The calculation is performed by a qualified actuary using the projected unit credit method. When the calculation results in a benefit to the Group, the recognized asset is limited to the present value of economic benefits available in the form of any future refunds from the plan or reductions in future contributions to the plan.

Service cost and net interest expense/(income) on the net defined benefit liability/(asset) are recognized in profit or loss and allocated by function as part of “cost of sales”, “selling and distribution expenses” or “administrative expenses”. Current service cost is measured as the increase in the present value of the defined benefit obligation resulting from employee service in the current period. When the benefits of a plan are changed, or when a plan is curtailed, the portion of the changed benefit related to past service by employees, or the gain or loss on curtailment, is recognized as an expense in profit or loss at the earlier of when the plan amendment or curtailment occurs and when related restructuring costs or termination benefits are recognized. Net interest expense/(income) for the period is determined by applying the discount rate used to measure the defined benefit obligation at the beginning of the reporting period on high quality corporate bonds that have maturity dates approximating the terms of the Group’s obligations.

Remeasurements arising from defined benefit retirement plans are recognized in other comprehensive income. Remeasurements comprise actuarial gains and losses, the return on plan assets (excluding amounts included in net interest on the net defined benefit liability/(asset)) and any change in the effect of the asset ceiling (excluding amounts included in net interest on the net defined benefit liability/(asset)).

Significant accounting judgments and estimates

The preparation of the Group’s financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

FINANCIAL INFORMATION

Judgments

In the process of applying the Group’s accounting policies, management has made the following judgments, apart from those involving estimations, which have the most significant effect on the amounts recognized in the Accountants’ Report included in Appendix I to this document:

Determining the timing of satisfaction of performance obligations

The Group has different contractual arrangements with different customers. In determining the timing of satisfaction of performance obligations, management reviews the contract terms of each individual contract.

For certain types of revenue under the FFS model, the directors of the Company have determined that performance obligations are satisfied over time. Significant judgment is required in determining whether the terms of the Group’s contracts with customers in relation to certain types of revenue under the FFS model create an enforceable right to payment for the Group.

Determining the method for measuring progress towards complete satisfaction of performance obligations

Depending on which better depicts the transfer of value to the customer, the directors of the Company make judgment to measure the progress of the projects using either input method or output method.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each of the Relevant Periods, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are discussed below.

Impairment of goodwill

The Group determines whether goodwill is impaired at least on an annual basis. This requires an estimation of the value in use of the cash-generating units to which the goodwill is allocated. Estimating the value in use requires the Group to make an estimate of the expected future cash flows from the cash-generating units and also to choose a suitable discount rate in order to calculate the present value of those cash flows. The carrying amounts of goodwill at December 31, 2017, 2018 and September 30, 2019 were RMB2,205.7 million, RMB2,316.8 million and RMB2,387.6 million, respectively. Further details are given in note 16 to the Accountants’ Report included in Appendix I to this document.

Share-based payments

The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. The fair value is computed based on their most recent post-money valuations. Details of share-based payments are contained in notes 40 to the Accountants’ Report included in Appendix I to this document.

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date on which they are granted. The fair value is computed based on their most recent post-money valuations. The cost of equity-settled transactions is recognized in employee benefit expense,

FINANCIAL INFORMATION

together with a corresponding increase in equity, over the period in which the performance and service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the consolidated statement of profit or loss for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period.

Post-employment benefit obligations

The present value of the pension obligations depends on a number of factors that are determined on an actuarial basis using a number of assumptions. Discount rate is one of the assumptions used in determining the net cost (income) for pensions. Any changes in these assumptions will impact the carrying amount of pension obligations.

The Group determines the appropriate discount rate at the end of each year. This is the interest rate that should be used to determine the present value of estimated future cash outflows expected to be required to settle the pension obligations. In determining the appropriate discount rate, the Group considers using market yields at the end of each of the Relevant Period on high quality United States corporate bonds for SPL Acquisition Corp, which is also the currency that benefits will be paid, and make sure terms of corporate bonds will match the estimated term of defined benefit plan.

Other key assumptions for pension obligations are partially based on current market conditions.

Provision for expected credit losses of trade and other receivables

The Group uses a provision matrix to calculate ECLs for trade receivables. The provision rates are based on days past due for groupings of various customer segments that have similar loss patterns (i.e., by geography, product type, customer type and rating, and coverage by letters of credit and other forms of credit insurance).

The provision matrix is initially based on the Group’s historical observed default rates. The Group will calibrate the matrix to adjust the historical credit loss experience with forward-looking information. For instance, if forecast economic conditions (i.e., gross domestic products) are expected to deteriorate over the next year which can lead to an increased number of defaults in the manufacturing sector, the historical default rates are adjusted. At each reporting date, the historical observed default rates are updated and changes in the forward-looking estimates are analyzed.

The assessment of the correlation among historical observed default rates, forecast economic conditions and ECLs is a significant estimate. The amount of ECLs is sensitive to changes in circumstances and forecast economic conditions. The Group’s historical credit loss experience and forecast of economic conditions may also not be representative of customer’s actual default in the future. The information about the ECLs on the Group’s trade receivables and other receivables is disclosed in notes 25 and 27 to the Accountants’ Report included in Appendix I to this document, respectively.

Deferred tax assets

Deferred tax assets are recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgment is required to determine the amount of deferred tax assets that can be recognized, based upon

FINANCIAL INFORMATION

the likely timing and level of future taxable profits together with future tax planning strategies. The carrying value of deferred tax assets relating to recognized tax losses at December 31, 2017, 2018 and September 30, 2019 were RMB76.7 million, RMB26.1 million and RMB17.6 million, respectively. The amount of unrecognized tax losses at December 31, 2017, 2018 and September 30, 2019 were RMB224.9 million, RMB336.9 million, and RMB551.8 million, respectively. Further details are given in note 34 to the Accountants’ Report included in Appendix I to this document.

Fair value of unlisted equity investments

The unlisted equity investments have been valued based on a market-based valuation technique as detailed in note 48 to the Accountants’ Report included in Appendix I to this document. The valuation requires the Group to determine the comparable public companies (peers) and select the price multiple. In addition, the Group makes estimates about the discount for illiquidity and size differences. The Group classifies the fair value of these investments as Level I, II and III. The fair value of the unlisted equity investments at December 31, 2017, 2018 and September 30, 2019 were RMB1,012.6 million, RMB1,435.7 million, and RMB1,867.7 million, respectively. Further details are given in note 20 and note 21 to the Historical Financial Information.

Development costs

Development costs are capitalized in accordance with the accounting policy for research and development costs as detailed in note 2.3 to the Accountants’ Report included in Appendix I to this document. Determining the amounts to be capitalized requires management to make assumptions regarding the expected future cash generation of the assets, the discount rates to be applied and the expected period of benefits. The best estimate of the carrying amount of capitalized development costs at December 31, 2017, 2018 and September 30, 2019 were RMB12.6 million, RMB15.4 million and RMB2.2 million, respectively.

FINANCIAL INFORMATION

DESCRIPTION OF SELECTED COMPONENTS OF STATEMENTS OF PROFIT OR LOSS

The table below sets forth our consolidated statements of profit or loss with line items in absolute amounts and as percentages of our revenue for the periods indicated derived from our consolidated statements of profit or loss set out in the Accountants’ Report included in Appendix I to this document:

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue
Revenue	2,828,225	100.0	4,799,807	100.0	3,306,748	100.0	3,132,171	100.0
Cost of sales	(1,976,442)	(69.9)	(2,926,275)	(61.0)	(2,037,569)	(61.6)	(2,069,583)	(66.1)
Gross profit	851,783	30.1	1,873,532	39.0	1,269,179	38.4	1,062,588	33.9
Other income and gains	209,701	7.4	308,150	6.4	317,777	9.6	740,238	23.6
Selling and distribution expenses	(192,201)	(6.8)	(371,710)	(7.7)	(240,505)	(7.3)	(292,569)	(9.3)
Administrative expenses	(435,629)	(15.4)	(497,735)	(10.4)	(343,676)	(10.4)	(365,580)	(11.7)
Impairment losses on financial assets	(10,884)	(0.4)	(12,454)	(0.3)	(13,404)	(0.4)	(14,676)	(0.5)
Other expenses	(2,707)	(0.096)	(366)	(0.008)	(68)	(0.002)	(477)	(0.015)
Finance costs	(183,268)	(6.5)	(229,207)	(4.8)	(170,519)	(5.2)	(200,693)	(6.4)
Share of profits and losses of associates ...	(79,710)	(2.8)	(305,003)	(6.4)	(233,915)	(7.1)	(41,797)	(1.3)
Profit before tax	157,085	5.6	765,207	15.9	584,869	17.7	887,034	28.3
Income tax credit/ (expense)	83,807	3.0	(148,244)	(3.1)	(115,424)	(3.5)	(138,061)	(4.4)
Profit for the year/ period	240,892	8.5	616,963	12.9	469,445	14.2	748,973	23.9
Attributable to:								
Owners of the parent	238,904	8.4	640,194	13.3	479,041	14.5	763,586	24.4
Non-controlling interests	1,988	0.1	(23,231)	(0.5)	(9,596)	(0.3)	(14,613)	(0.5)
Earnings per share attributable to equity holders of the parent								
Basic								
—for profit for the year/ period	<u>RMB0.19</u>		<u>RMB0.51</u>		<u>RMB0.38</u>		<u>RMB0.61</u>	
Diluted								
—for profit for the year/ period	<u>RMB0.19</u>		<u>RMB0.51</u>		<u>RMB0.38</u>		<u>RMB0.61</u>	

Revenue

During the Track Record Period, a significant portion of our revenue was generated from sales of pharmaceutical products, including heparin sodium API, finished dose pharmaceutical products and other products. Revenues from finished dose pharmaceutical products are generated from sales of heparin and enoxaparin sodium injections. Revenues from API are generated from sales of heparin

FINANCIAL INFORMATION

sodium APIs and enoxaparin sodium APIs. Revenues from other products are mainly generated from sales of pancreatin API and other materials. The following table sets forth a breakdown of our revenue by products and services for the periods indicated:

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue
Sale of Goods								
Finished dose pharmaceutical products	381,197	13.5	1,045,643	21.9	605,142	18.3	720,891	23.0
API	1,846,129	65.2	2,752,386	57.3	2,003,884	60.6	1,690,020	54.0
Others	217,124	7.7	385,403	8.0	310,762	9.4	193,398	6.1
Subtotal	2,444,450	86.4	4,183,432	87.2	2,919,788	88.3	2,604,309	83.1
CDMO services	324,308	11.5	548,469	11.4	356,542	10.8	503,161	16.1
Others	59,467	2.1	67,906	1.4	30,418	0.9	24,701	0.8
Total	2,828,225	100.0	4,799,807	100.0	3,306,748	100.0	3,132,171	100.0

The following table sets forth a breakdown of our revenue by regions for the periods indicated:

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue	RMB'000	% of Revenue
Europe	1,636,938	57.9	2,937,707	61.2	2,066,840	62.5	1,896,382	60.6
U.S.	403,055	14.2	804,715	16.8	575,327	17.4	668,655	21.3
China	352,443	12.5	442,599	9.2	292,992	8.9	257,501	8.2
Other countries/regions	435,789	15.4	614,786	12.8	371,589	11.2	309,633	9.9
Total	2,828,225	100.0	4,799,807	100.0	3,306,748	100.0	3,132,171	100.0

Cost of Sales

The table below sets forth a breakdown of our cost of sales in absolute amount and as percentage of our total cost of sales by products and services for the periods indicated:

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	RMB '000	%	RMB '000	%	RMB '000	%	RMB '000	%
Cost of Sales								
Sale of Goods								
Finished dose pharmaceutical products	214,286	10.8	472,356	16.1	275,261	13.5	392,840	19.0
API	1,175,547	59.5	1,639,945	56.1	1,209,127	59.3	1,105,445	53.4
Others	293,387	14.9	324,251	11.1	229,317	11.3	200,633	9.7
Subtotal	1,683,220	85.2	2,436,552	83.3	1,713,705	84.1	1,698,918	82.1
CDMO services	280,778	14.2	473,418	16.2	323,089	15.9	369,799	17.9
Others	12,444	0.6	16,305	0.6	775	0.0	866	0.0
Total	1,976,442	100.0	2,926,275	100.0	2,037,569	100.0	2,069,583	100.0

FINANCIAL INFORMATION

Our cost of sales primarily consists of raw material costs, employee compensations, depreciation and amortization, utility costs and others. The table below sets forth a breakdown of our cost of sales in absolute amounts and as percentages of our total cost of sales for the periods indicated:

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	RMB '000	%	RMB '000	%	RMB '000	%	RMB '000	%
Cost of Sales								
Cost of inventory sold								
Raw material costs . . .	1,158,347	58.6	1,853,607	63.3	1,276,370	62.6	1,173,580	56.7
Employee compensations	214,623	10.9	227,853	7.8	195,105	9.6	231,524	11.2
Depreciation and amortization	120,851	6.1	133,828	4.6	98,899	4.9	115,060	5.6
Utility Cost	41,838	2.1	43,578	1.5	33,295	1.6	34,616	1.7
Others	147,561	7.5	177,686	6.1	110,036	5.4	144,138	7.0
Subtotal	<u>1,683,200</u>	<u>85.2</u>	<u>2,436,552</u>	<u>83.3</u>	<u>1,713,705</u>	<u>84.1</u>	<u>1,698,918</u>	<u>82.1</u>
Cost of service provided								
Employee compensations	119,879	6.1	160,930	5.5	110,477	5.4	140,677	6.8
Material and utility Cost	101,940	5.2	187,332	6.4	124,186	6.1	114,767	5.5
Depreciation and amortization	18,177	0.9	28,842	1.0	19,714	1.0	37,264	1.8
Others	53,226	2.7	112,619	3.8	69,487	3.4	77,957	3.8
Subtotal	<u>293,222</u>	<u>14.8</u>	<u>489,723</u>	<u>16.7</u>	<u>323,864</u>	<u>15.9</u>	<u>370,665</u>	<u>17.9</u>
Total	<u>1,976,442</u>	<u>100.0</u>	<u>2,926,275</u>	<u>100.0</u>	<u>2,037,569</u>	<u>100.0</u>	<u>2,069,583</u>	<u>100.0</u>

Our raw material costs under cost of inventory sold primarily consist of porcine small intestines, crude heparin, and packaging materials. We purchase raw materials on an as-needed basis at market prices. Raw material costs comprised a significant amount of the total cost of sales, accounting for 58.6%, 63.3%, 62.6% and 56.7% of our total cost of sales in the years ended December 31, 2017 and 2018 and in the nine months ended September 30, 2018 and 2019, respectively.

Our employee compensations under cost of inventory sold include salaries, welfare and pension for employees involved in the production of our products. Employee compensations under cost of inventory sold accounted for 10.9%, 7.8%, 9.6% and 11.2% of our total cost of sales in the years ended December 31, 2017 and 2018 and in the nine months ended September 30, 2018 and 2019, respectively.

Depreciation and amortization under cost of inventory sold mainly relates to plants and equipment used for the production of our products and amortization represents the amortization of relevant patents and technology know-how. Depreciation and amortization under cost of inventory sold accounted for 6.1%, 4.6%, 4.9% and 5.6% of our total cost of sales in the years ended December 31, 2017 and 2018 and in the nine months ended September 30, 2018 and 2019, respectively.

Other costs under cost of inventory sold are mainly comprised of rent and maintenance. Other costs under cost of inventory sold comprised a significant amount of the total cost of sales, accounting for 7.5%, 6.1%, 5.4% and 7.0% of our total cost of sales in the years ended December 31, 2017 and 2018 and in the nine months ended September 30, 2018 and 2019, respectively.

FINANCIAL INFORMATION

Employee compensations under cost of service provided primarily consist of salaries, welfare and pension for employees involved in the CDMO service. Employee compensations under cost of service provided accounted for 6.1%, 5.5%, 5.4% and 6.8% of our total cost of sales in the years ended December 31, 2017 and 2018 and in the nine months ended September 30, 2018 and 2019, respectively.

Our material and utility cost under cost of service provided primarily include the material costs used in our CDMO business. Material and utility cost under cost of service provided accounted for 5.2%, 6.4%, 6.1% and 5.5% of our total cost of sales in the years ended December 31, 2017 and 2018 and in the nine months ended September 30, 2018 and 2019, respectively.

Gross Profit and Gross Margin

Our gross profit represents our revenue less our cost of sales. Our gross margin represents our gross profit as a percentage of our revenue. For the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019, our gross profit was RMB851.8 million, RMB1873.5 million, RMB1269.2 million and RMB1062.6 million, respectively, and our gross profit margin was 30.1%, 39.0%, 38.3% and 33.8%, respectively. The following table sets forth our gross profit and gross profit margin by segments for the periods indicated:

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	Gross Profit	Gross Profit Margin	Gross Profit	Gross Profit Margin	Gross Profit	Gross Profit Margin	Gross Profit	Gross Profit Margin
	RMB'000	%	RMB'000	%	RMB'000	%	RMB'000	%
Sale of goods								
Finished dose pharmaceutical products	166,911	43.8	573,287	54.8	329,881	54.5	328,051	45.5
API	670,582	36.3	1,112,441	40.4	794,757	39.7	584,575	34.6
Others	(76,263)	(35.1)	61,152	15.9	81,445	26.2	(7,235)	(3.7)
Subtotal	761,230	31.1	1,746,880	41.8	1,206,083	41.3	905,391	34.8
CDMO services	43,530	13.4	75,051	13.7	33,453	9.4	133,362	26.5
Others	47,023	79.1	51,601	76.0	29,643	97.5	23,835	96.5
Total	851,783	30.1	1,873,532	39.0	1,269,179	38.4	1,062,588	33.9

FINANCIAL INFORMATION

Other Income and Gains

Our other income and gains primarily consist of bank interest income, government grants related to income, dividend income from financial assets, foreign exchange differences, fair value gains on financial assets, gains on disposal of subsidiaries, gain on deemed partial disposal of associates and others. The table below sets forth a breakdown of our other income and gains for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,	
	2017	2018	2018	2019
	(RMB'000)	(RMB'000)	(RMB'000)	(RMB'000)
Other Income				
Bank interest income	137,740	69,456	50,568	40,170
Government grants related to				
—Assets	2,298	2,242	1,690	1,588
—Income	40,190	31,581	19,641	26,433
Dividend income from financial assets at fair value through profit or loss	781	36,823	25,353	643
Dividend income from financial assets at fair value through other comprehensive income	—	3,694	—	16,449
	<u>181,009</u>	<u>143,796</u>	<u>97,252</u>	<u>85,283</u>
Other gains				
Foreign exchange differences, net	(49,584)	70,545	105,098	23,954
Proceeds from financial assets at fair value through profit or loss	26,363	13,917	12,385	1,456
Fair value gains, net	43,029	38,681	70,960	49,979
Fair value gains on derivative instrument	(3,728)	30,490	38,742	(101,241)
Fair value gains on financial assets at fair value through profit or loss	46,757	8,191	32,218	151,220
Gain on disposal of a subsidiary	—	28,766	28,766	—
Gains on deemed disposal of a subsidiary	—	—	—	573,865
Gain on disposal of items of property, plant and equipment	(383)	2,304	18	1,792
Others	9,267	10,141	3,298	3,909
	<u>28,692</u>	<u>164,354</u>	<u>220,525</u>	<u>654,955</u>
Total	<u>209,701</u>	<u>308,150</u>	<u>317,777</u>	<u>740,238</u>

The government grants mainly represent government grants related to assets and income. We received certain government grants related to assets to invest in laboratory equipment and plant. We also received governments grants related to income to compensate for our research and development expenditures.

FINANCIAL INFORMATION

Selling and Distribution expenses

Our selling and distribution expenses consist of market development expenses, employee compensations, sales agency fees, business fees, exhibition participation and advertisement expenses and others. The table below sets forth a breakdown of our selling and distribution expenses in absolute amounts and as percentages of our total selling and distribution expenses for the periods indicated:

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	RMB '000	%	RMB '000	%	RMB '000	%	RMB '000	%
<i>Selling and Distribution expenses</i>								
Market development expenses	58,655	30.5	175,578	47.3	92,733	38.6	122,159	41.8
Employee compensations	44,569	23.2	82,245	22.1	57,198	23.7	67,194	23.0
Sales agency fees	10,051	5.2	19,184	5.2	13,831	5.8	14,957	5.1
Business fees	18,467	9.6	18,372	4.9	13,525	5.6	13,577	4.6
Exhibition participation and advertisement expenses	7,973	4.2	11,529	3.1	5,586	2.3	7,731	2.6
Others	52,485	27.3	64,802	17.4	57,632	24.0	66,951	22.9
Total	<u>192,201</u>	<u>100.0</u>	<u>371,710</u>	<u>100.0</u>	<u>240,505</u>	<u>100.0</u>	<u>292,569</u>	<u>100.0</u>

Our market development expenses primarily include fees for hosting conferences and seminars and expenses for contract research organizations. Employee compensations include employee salaries and allowance and performance related bonus for our sales personnel. Sales agency fees include office expenses, insurance expenses and rental fees. Business fees primarily include fees incurred for business trips, commuting fees and communication expenses. Exhibition participation and advertisement expenses include the expenses relating to the exhibitions and advertisement. Our other selling and distribution expenses primarily include customs charges relating to our sales in the EU markets and inspection charges relating to the inspections associated with the exports to the EU markets and visa expenses, etc.

FINANCIAL INFORMATION

Administrative Expenses

Our administrative expenses primarily consist of R&D expenses, employee compensation, depreciation and amortization, professional service fees, insurance expenses, office expenses and other expenses including, tax expenses, bank transaction fees, travel expenses, lease expenses, management fees, meeting and related expenses and recruitment expenses. The table below sets forth a breakdown of our administrative expenses in absolute amounts and as percentages of our total administrative expenses for the periods indicated:

	For the year ended December 31,				For the nine months ended September 30,			
	2017		2018		2018		2019	
	RMB '000	%	RMB '000	%	RMB '000	%	RMB '000	%
<i>Administrative Expenses</i>								
R&D expenses	93,814	21.5	186,534	37.5	123,035	35.8	114,867	31.4
Employment compensation ..	140,345	33.2	126,412	25.4	95,887	27.9	101,501	27.8
Depreciation and amortization	64,509	14.8	77,189	15.5	47,711	13.9	63,459	17.4
Professional service fees	52,788	12.1	27,178	5.5	23,406	6.8	18,815	5.1
Insurance expenses	12,426	2.9	14,559	2.9	10,843	3.2	11,205	3.1
Office expenses	15,943	3.7	11,565	2.3	8,496	2.5	11,891	3.3
Others	55,804	12.8	54,298	10.9	34,298	10.0	43,842	12.0
Total	<u>435,629</u>	<u>100.0</u>	<u>497,735</u>	<u>100.0</u>	<u>343,676</u>	<u>100.0</u>	<u>365,580</u>	<u>100.0</u>

Our R&D expenses mainly include employee cost of research and development personnel, third party contracting costs, materials and depreciation and amortization associated with equipment used in research and development. Employee compensation include employee salaries and allowance, performance related bonus and retirement benefit scheme. Depreciation and amortization represents the depreciation and amortization of our machinery, equipment and software.

Impairment losses on financial assets

Our Impairment losses on financial assets were RMB10.9 million, RMB12.5 million, RMB13.4 million and RMB14.7 million for the year ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019, respectively. Our impairment losses on financial assets mainly consist of impairment of trade receivables and other receivables.

Other Expenses

Our other expenses were RMB2.7 million, RMB0.4 million, RMB68 thousand and RMB0.5 million for the year ended December 31, 2017 and 2018 and the nine months ended September 30, 2018 and 2019, respectively. Our other expenses mainly consist of liquidated damages incurred in 2017 relating to delay in the construction of our Pingshan Industrial Park, and other miscellaneous expenses.

FINANCIAL INFORMATION

Finance Costs

Our financial costs mainly consist of interest expenses on bank borrowings, corporate bonds and lease liabilities, and other finance cost, partially offset by interest capitalized. The table below sets forth a breakdown of finance costs for the periods indicated:

	Year ended December 31,		Nine months ended September 30,	
	2017	2018	2018	2019
	RMB'000	RMB'000	RMB'000	RMB'000
Finance Costs				
Interest expenses on:				
bank borrowings	118,923	165,968	117,539	139,586
corporate bonds	33,661	33,721	25,285	44,051
lease liabilities	9,246	7,193	5,754	4,568
Other finance cost	26,028	24,609	24,195	12,488
Less : interest capitalized	4,590	2,284	2,254	—
Total	<u>183,268</u>	<u>229,207</u>	<u>170,519</u>	<u>200,693</u>

Share of Profits and Losses of Associates

The table below sets forth a breakdown of our share of losses of associates for the periods indicated:

	Year ended December 31,		Nine Months Ended September 30,	
	2017	2018	2018	2019
	RMB'000	RMB'000	RMB'000	RMB'000
OncoQuest	(12,927)	(17,956)	(10,890)	(14,702)
Resverlogix	(60,185)	(303,663)	(232,412)	1,056
Shenzhen Asia Pacific Health Management Co., Ltd.	—	(9,255)	(2,015)	(14,936)
HighTide	—	—		(32,298)
Quest PharmaTech Inc.	(4,366)	(3,359)	(2,545)	(3,332)
Shanghai Taiyi Venture Capital Partnership (limited partnership)	(2,232)	29,230	13,947	22,415
Total	<u>(79,710)</u>	<u>(305,003)</u>	<u>(233,915)</u>	<u>(41,797)</u>

Income Tax Credit/(Expense)

Our income tax credit/(expense) mainly consists of EIT from the PRC, Hong Kong, the U.S., the EU and other jurisdictions and deferred income tax in the PRC, the U.S., Hong Kong and other jurisdictions.

Pursuant to the EIT Law, our subsidiaries which operate in China are subject to EIT at a rate of 25% on the taxable income. Our Company and Shenzhen Techdow Pharmaceutical Co., Ltd were accredited as a “High and New Technology Enterprise” and therefore were entitled to a preferential EIT rate of 15% during the Track Record Period. This qualification is subject to review by the relevant tax authority in the PRC for every three years.

Our subsidiaries incorporated in the U.S. were subject to the federal corporate tax rate at 35% for the periods prior to 2018. On December 22, 2017, the 2017 Tax Cuts and Jobs Act was enacted, which reduces the federal corporate tax rate to 21% from 35% and is effective on January 1, 2018. The state income tax rate remains at a range from 1% to 9.5% during the Track Record Period.

FINANCIAL INFORMATION

Under the two-tiered profits tax rates regime in Hong Kong which became effective in March 2018, the first HK\$2 million of profits of our subsidiaries incorporated in Hong Kong will be taxed at 8.25%, and profits above HK\$2 million will be taxed at 16.5%. The profits of our subsidiaries incorporated in Hong Kong not qualifying for the two-tiered profits tax rates regime will continue to be taxed at a flat rate of 16.5%.

Our subsidiary incorporated in Singapore is subject to the corporate income tax rate of 17% during the Track Record Period.

Our subsidiaries incorporated in Sweden are subject to the corporate income tax rate of 22% during the Track Record Period.

Our subsidiary incorporated in Poland is subject to the corporate income tax rate of 19% during the Track Record Period.

Our subsidiaries incorporated in Netherland are subject to the corporate income tax rate of 20% for which taxable income that do not excess the amount of EUR 200,000 and if the taxable income excess the amount of EUR 200,000, the tax rate of 25% should apply to the part that excess the amount of EUR 200,000 during the Track Record Period.

Our subsidiary incorporated in the UK is entitled to the tax rate at 20% before April 1, 2017. The tax rate reduced from 20% to 19% from April 2017. The tax rate remains at 19% during the remaining Track Record Period.

Our subsidiary incorporated in Spain is subject to the corporate income tax rate of 25% during the Track Record Period.

Our subsidiary incorporated in Italy is subject to the national corporate income tax rate of 24% and the provincial income tax rate of 3.9% during the Track Record Period.

Our subsidiary incorporated in France is subject to the corporate income tax rate of 28% for taxable income below EUR 500,000 and if the taxable income excesses EUR500,000, the tax rate of 33.33% should apply to the part above EUR500,000 during the Track Record Period.

During the Track Record Period, we had paid all relevant taxes in accordance with tax regulations and did not have any disputes or unresolved tax issues with the relevant tax authorities.

Nine Months Ended September 30, 2018 Compared to Nine Months Ended September 30, 2019

Revenue

Our total revenue decreased by 5.3%, from RMB3,306.7 million for the nine months ended September 30, 2018 to RMB3,132.2 million for the nine months ended September 30, 2019, which was primarily attributable to the decrease in revenue from sale of API, and offset by an increase in revenue from finished dose pharmaceutical products, CDMO services and other products.

Our revenue from sale of goods decreased by 10.8%, from RMB2,919.8 million for the nine months ended September 30, 2018 to RMB2,604.3 million for the nine months ended September 30,

FINANCIAL INFORMATION

2019, mainly attributable to the decreases in the sales of API products and other products and partially offset by the increase in the sales of finished dose pharmaceutical products.

- **Finished dose pharmaceutical products.** Revenue from our finished dose pharmaceutical products increased by RMB115.8 million or 19.1% from RMB605.1 million in the first nine months in 2018 to RMB720.9 million in the first nine months in 2019. The increase in our revenue from our finished dose pharmaceutical products was primarily due to an increase in our sales volume, resulting from the increasing penetration of our products in major countries in the EU, such as Spain, Italy and UK.
- **API.** Revenue from our API products decreased by RMB313.9 million or 15.7% from RMB2,003.9 million in the first nine months in 2018 to RMB1,690.0 million in the first nine months in 2019. The decrease in our revenue from API products was primarily due to a decrease in the sales volume of heparin sodium API, which was primarily attributable to both the breakout of African swine fever in late 2018 which continued in 2019 and the hog price cycle that aggregately caused the decreased supply of the heparin raw material as well as our control of outbound delivery quantity as we had limited ability to timely transfer the price increase in raw materials to the price of our API products due to the typical time lag between the price increase of raw materials price to API products.
- **Others.** Revenue from our other products decreased by RMB117.4 million or 37.8% from RMB310.8 million in the first nine months in 2018 to RMB193.4 million in the first nine months in 2019. The decrease in our revenue from other products was primarily due to a decrease in sale of pancreatin API products, which was resulted from a decreased demand from our customers based on their drug development progress.

Our revenue from our CDMO services increased by RMB146.7 million or 41.2% from RMB356.5 million in the first nine months in 2018 to RMB503.2 million in the first nine months in 2019. The increase in our revenue from CDMO business was primarily due to an increase in the pricing of our CDMO service as an adjustment to our pricing strategies and an increase in the number of CDMO projects we undertook.

Cost of Sales

Our costs of sales increased by 1.6% from RMB2,037.6 million for the nine months ended September 30, 2018 to RMB2,069.6 million for the nine months ended September 30, 2019, which is primarily attributable to an increase of RMB66.6 million in employee compensations as a result of the increased number of employees and salaries. Our costs of sales accounted for approximately 61.6% and 66.1% of our revenue for the nine months ended September 30, 2018 and 2019, respectively.

Our cost of sales of goods decreased from RMB1,713.7 million for the nine months ended September 30, 2018 to RMB1,698.9 million for the nine months ended September 30, 2019, mainly attributable to the decrease in cost of sales of API and others.

- **Finished dose pharmaceutical products.** The cost of sales of finished dose pharmaceutical products increased by 42.7% from RMB275.3 million for the nine months ended September 30, 2018 to RMB392.8 million for the nine months ended September 30, 2019, which was mainly attributable to the increase in the cost of raw materials and sales volume.

FINANCIAL INFORMATION

- **API.** The cost of sales of API products decreased by 8.6% from RMB1,209.1 million for the nine months ended September 30, 2018 to RMB1,105.4 million for the nine months ended September 30, 2019, which was primarily resulted from the decrease in sales volume.
- **Others.** The cost of sales of other products decreased by 12.5% from RMB229.3 million for the nine months ended September 30, 2018 to RMB200.6 million for the nine months ended September 30, 2019, which was primarily resulted from the decrease in sales volume of pancreatin API products.

The cost of sales of CDMO services increased by 14.5% from RMB323.1 million for the nine months ended September 30, 2018 to RMB369.8 million for the nine months ended September 30, 2019, which was primarily resulted from the increase in the number of new CDMO projects we undertook and the increase in Cytovance’s production capacity and an improvement in Cytovance’s order fulfillment ability, resulting from the completion of Cytovance’s post acquisition integration.

Gross Profit and Gross Profit Margin

Our gross profit decreased by 16.3%, from RMB1,269.2 million for the nine months ended September 30, 2018 to RMB1,062.6 million for the nine months ended September 30, 2019. Our gross profit margin decreased from 38.4% for the nine months ended September 30, 2018 to 33.9% for the nine months ended September 30, 2019, primarily attributable to the decreases in gross profit margin of our sale of goods.

Our gross profit margin of our sale of goods decreased from 41.3% for the nine months ended September 30, 2018 to 34.8% for the nine months ended September 30, 2019, which was mainly attributable to the decreases in gross profit margin of our API products, finished dose pharmaceutical products, and other products.

- **Finished dose pharmaceutical products.** Our gross profit margin of finished dose pharmaceutical products decreased from 54.5% for the nine months ended September 30, 2018 to 45.5% for the nine months ended September 30, 2019. Such decrease in gross profit margin was primarily attributable to the increase in the volume of sales to hospitals in the EU countries which generally have a lower profit margin as compared to sales to pharmacies, and the increase in the cost of raw materials.
- **API.** Our gross profit margin of API products decreased from 39.7% for the nine months ended September 30, 2018 to 34.6% for the nine months ended September 30, 2019. Such decrease in gross profit margin was primarily attributable to the substantial increase in the cost of raw materials and the time lag between increase of porcine small intestine and crude heparin costs and increase of heparin API price.
- **Others.** Our gross profit/(loss) margin from other products decreased from 26.2% for the nine months ended September 30, 2018 to (3.7)% for the nine months ended September 30, 2019. Such decrease in gross profit margin was driven by the decrease in gross profit margin in the sales of pancreatin API products due to the decreased number of orders from our customer.

Our gross profit margin of CDMO services increased from 9.4% for the nine months ended September 30, 2018 to 26.5% for the nine months ended September 30, 2019. Such increase in gross profit margin was primarily attributable to the increase in the pricing of our CDMO services and an

FINANCIAL INFORMATION

improvement in Cytovance’s cost management efficiencies and utilization rate of its facilities, resulting from the completion of Cytovance’s post acquisition integration.

Other Income and Gains

Our other income and gains increased by 132.9%, from RMB317.8 million for the nine months ended September 30, 2018 to RMB740.2 million for the nine months ended September 30, 2019. Such increase was primarily attributable to an increase in gain on deemed disposal of a subsidiary of RMB573.9 million as a result of deconsolidation of HighTide in March 2019, partially offset by a decrease in fair value gains on derivative instrument of RMB101.2 million related to common share purchase warrants we purchased from Resverlogix in the nine months ended September 30, 2019.

Selling and distribution expenses

Our selling and distribution expenses increased by 21.7%, from RMB240.5 million for the nine months ended September 30, 2018 to RMB292.6 million for the nine months ended September 30, 2019. The increase was generally in line with the increase in our revenue along with our marketing and promotion efforts. It was primarily attributable to an increase in our market development expenses of RMB29.4 million and an increase in our employee compensations of RMB10.0 million. Selling and distribution expenses as a percentage of our revenue increased from 7.3% for the nine months ended September 30, 2018 to 9.3% for the nine months ended September 30, 2019.

Administrative Expenses

Our administrative expenses increased by 6.4%, from RMB343.7 million for the nine months ended September 30, 2018 to RMB365.6 million for the nine months ended September 30, 2019, primarily as a result of an increase in depreciation and amortization of RMB15.7 million because we began calculating depreciation of our Pingshan building in August 2018, partially offset by a decrease in R&D expenses of RMB8.2 million because of the deconsolidation of HighTide in March 2019 and a decrease in professional service fees of RMB4.6 million. Administrative expenses as a percentage of our revenue increased from 10.4% for the nine months ended September 30, 2018 to 11.7% for the nine months ended September 30, 2019.

Other Expenses

Our other expense increased by 601.5%, from RMB68 thousand for the nine months ended September 30, 2018 to RMB477 thousand for the nine months ended September 30, 2019, primarily due to the late fee paid for delay in construction and the liquidated damages paid for early termination of an office lease.

Finance Costs

Our finance costs increased by 17.7%, from RMB170.5 million for the nine months ended September 30, 2018 to RMB200.7 million for the nine months ended September 30, 2019, primarily as a result of an increase in interest-bearing loans and borrowings.

Income Tax Expense

Our income tax expense increased by 19.7%, from RMB115.4 million for the nine months ended September 30, 2018 to RMB138.1 million for the nine months ended September 30, 2019,

FINANCIAL INFORMATION

primarily due to an increase in our taxable income. Our effective income tax rate in the nine months ended September 30, 2018 and 2019 was 20% and 16%, respectively.

Year Ended December 31, 2017 Compared to Year Ended December 31, 2018

Revenue

Our total revenue increased by 69.7%, from RMB2,828.2 million for the year ended December 31, 2017 to RMB4,799.8 million for the year ended December 31, 2018, primarily attributable to the significant increases in revenue from sale of goods, which consists of API, finished dose pharmaceutical product and others, and significant increases in revenue from CDMO services.

Our revenue from sale of goods increased by 71.1%, from RMB2,444.5 million for the year ended December 31, 2017 to RMB4,183.4 million for the year ended December 31, 2018, mainly attributable to the significant increases in the sales of API products and finished dose pharmaceutical products.

- ***Finished dose pharmaceutical products.*** Revenue from our finished dose pharmaceutical products increased by RMB664.4 million or 174.3% from RMB381.2 million in 2017 to RMB1,045.6 million in 2018. The increase in our revenue from finished dose pharmaceutical products was primarily due to a significant increase in our sales volume, resulting from the penetration of our enoxaparin products in EU market.
- ***API.*** Revenue from our API products increased by RMB906.3 million or 49.1% from RMB1,846.1 million in 2017 to RMB2,752.4 million in 2018. The increase in our revenue from API products was primarily due to an increase in the price of our API products in 2018 as a result of upstream price increase in porcine small intestines and an increase in our sales volumes.
- ***Others.*** Revenue from our other products increased by RMB168.3 million or 77.5% from RMB217.1 million in 2017 to RMB385.4 million in 2018. The increase in our revenue from other products was primarily due to an increase in sale of pancreatin API products, which was resulted from an increasing demand from our customer who anticipated significant market demand of their new drug once the drug is approved by the FDA.

Our revenue from our CDMO services increased by RMB224.2 million or 69.1% from RMB324.3 million in 2017 to RMB548.5 million in 2018. The increase in our revenue from CDMO business was primarily due to an increase in the pricing of our CDMO service resulting from adjustments to pricing strategies and the increase in the CDMO projects we undertook.

Cost of Sales

Our cost of sales increased by 48.1% from RMB1,976.4 million for the year ended December 31, 2017 to RMB2,926.3 million for the year ended December 31, 2018, which was primarily in line with the increase in the cost of raw materials of RMB695.3 million due to our increased sales volumes as well as an increase of RMB54.3 million in employee compensations as a result of an increase in the number of employees supporting our expansion. Our costs of sales accounted for approximately 69.9% and 61.0% of our revenue for the periods ended December 31, 2017 and 2018, respectively.

FINANCIAL INFORMATION

Our cost of sales of goods increased from RMB1,683.2 million for the year ended December 31, 2017 to RMB2,436.6 million for the year ended December 31, 2018, mainly attributable to the increase in cost of sales of finished dose pharmaceutical products and API.

- **Finished dose pharmaceutical products.** The cost of sales of finished dose pharmaceutical products increased by 120.4% from RMB214.3 million for the year ended December 31, 2017 to RMB472.4 million for the year ended December 31, 2018, which was mainly attributable to the increase in the sales volume.
- **API.** The cost of sales of API products increased by 39.5% from RMB1,175.5 million for the year ended December 31, 2017 to RMB1,639.9 million for the year ended December 31, 2018, which was primarily resulted from the increase in the sales volume.
- **Others.** The cost of sales of other products increased by 10.5% from RMB293.4 million for the year ended December 31, 2017 to RMB324.3 million for the year ended December 31, 2018, which was due to increase in sales volume of pancreatin API products.

The cost of sales of CDMO services increased by 68.6% from RMB280.8 million for the year ended December 31, 2017 to RMB473.4 million for the year ended December 31, 2018, which was primarily resulted from the increase in the CDMO projects we undertook and the increase in Cytovance’s production capacity and an improvement in Cytovance’s order fulfillment ability, resulting from the completion of Cytovance’s post acquisition integration.

Gross Profit and Gross Profit Margin

Our gross profit increased by 120.0%, from RMB851.8 million for the year ended December 31, 2017 to RMB1,873.5 million for the year ended December 31, 2018, respectively. Our gross profit margin increased from 30.1% for the year ended December 31, 2017 to 39.0% for the year ended December 31, 2018, primarily attributable to the increases in gross profit margin of our sale of goods.

Our gross profit margin of our sale of goods increased from 31.1% for the year ended December 31, 2017 to 41.8% for the year ended December 31, 2018, which was mainly attributable to the increase in gross profit margin of our API products, finished dose pharmaceutical products business, and other products.

- **Finished dose pharmaceutical products.** Our gross profit margin of finished dose pharmaceutical products increased from 43.8% for the year ended December 31, 2017 to 54.8% for the year ended December 31, 2018. Such increase in gross profit margin was primarily attributable to the increase in the price of our finished dose pharmaceutical products, and economies of scale brought by the increased production volume driven by the increasing demand from our EU market.
- **API.** Our gross profit margin of API products increased from 36.3% for the year ended December 31, 2017 to 40.4% for the year ended December 31, 2018. Such increase in gross profit margin was primarily attributable to the increase in the price and economies of scale as a result of increase in the sales volume of our API products to our major customers.
- **Others.** Our gross profit/(loss) margin from other products increased from (35.1)% for the year ended December 31, 2017 to 15.9% for the year ended December 31, 2018. Such

FINANCIAL INFORMATION

increase in gross profit margin was driven by the increase of gross profit margin in the sales of pancreatin API products due to sale of our pancreatin API products to a customer with a relatively high unit price.

Our gross profit margin of CDMO services remained relatively stable at 13.4% for the year ended December 31, 2017 and 13.7% for the year ended December 31, 2018.

Other Income and Gains

Our other income and gains increased by 47.0%, from RMB209.7 million for the year ended December 31, 2017 to RMB308.2 million for the year ended December 31, 2018. Such increase was primarily attributable to an increase in the dividend income from financial assets at fair value through profit or loss of RMB36.0 million as a result of dividend distribution from an investee from 2017 to 2018, the foreign exchange gain of RMB70.5 million in 2018, an increase in the gain on disposal of Hepatunn of RMB28.8 million from 2017 to 2018, partially offset by a decrease in bank interest income of RMB68.3 million from 2017 to 2018 and a decrease in net fair value gains of RMB4.3 million from 2017 to 2018.

Selling and distribution expenses

Our selling and distribution expenses increased by 93.4%, from RMB192.2 million for the year ended December 31, 2017 to RMB371.7 million for the year ended December 31, 2018. The increase was generally in line with the increase in our revenue along with our marketing and promotion efforts. It was primarily attributable to an increase in our market development expenses of RMB116.9 million, an increase in our employee compensations of RMB37.7 million and an increase in our exhibition participation and advertisement expenses of RMB3.6 million. Selling and distribution expenses as a percentage of our revenue increased from 6.8% for the year ended December 31, 2017 to 7.7% for the year ended December 31, 2018, which is in line with the growth of our business.

Administrative Expenses

Our administrative expenses increased by 14.3%, from RMB435.6 million for the year ended December 31, 2017 to RMB497.7 million for the year ended December 31, 2018, primarily as a result of an increase in R&D expenses of RMB92.7 million and an increase in depreciation and amortization of RMB12.7 million, partially offset by a decrease in professional service fees of RMB25.6 million paid to a consulting firm. Administrative expenses as a percentage of our revenue decreased from 15.4% for the year ended December 31, 2017 to 10.4% for the year ended December 31, 2018.

Other Expenses

Our other expense decreased by 86.5%, from RMB2.7 million for the year ended December 31, 2017 to RMB0.4 million for the year ended December 31, 2018. The decrease was mainly attributable to liquidated damages incurred in 2017 related to delay in construction of our Pingshan Industrial Park.

Finance Costs

Our finance costs increased by 25.1%, from RMB183.3 million for the year ended December 31, 2017 to RMB229.2 million for the year ended December 31, 2018, primarily as a result of an increase in interest-bearing loans and borrowings.

FINANCIAL INFORMATION

Income Tax Expense/(Credit)

Our income tax expense increased by 276.9%, from RMB83.8 million of credit for the year ended December 31, 2017 to RMB148.2 million of expense for the year ended December 31, 2018. Such change was primarily attributable to a one-off income tax credit we received for our U.S. subsidiary in 2017 due to the promulgation of the Tax Cuts and Jobs Act of 2017. Our effective income tax rate in the year ended December 31, 2017 and 2018 was (53)% and 19%, respectively.

DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The table below sets forth selected information from our consolidated statements of financial position as of the dates indicated, which have been extracted from the Accountants’ Report set out in Appendix I:

	As of December 31,		As of
	2017	2018	September 30, 2019
	RMB'000	RMB'000	RMB'000
Total non-current assets	7,995,387	8,236,874	9,339,287
Total current assets	6,213,469	5,607,404	5,853,542
Total assets	14,208,856	13,844,278	15,192,829
Total current liabilities	3,946,852	4,690,579	5,717,213
Total non-current liabilities	2,208,235	2,877,366	2,269,544
Total liabilities	6,155,087	7,567,945	7,986,757
Total assets less current liabilities	10,262,004	9,153,699	9,475,616
Net assets	8,053,769	6,276,333	7,206,072
Share capital	1,247,202	1,247,202	1,247,202
Reserves	6,584,962	4,852,410	5,834,153
Non-controlling interests	221,605	176,721	124,717
Total equity	8,053,769	6,276,333	7,206,072

FINANCIAL INFORMATION

NET CURRENT ASSETS

The following table sets forth our current assets and current liabilities as of the dates indicated:

	As of December 31,		As of	As of
	2017	2018	September 30,	November 30,
	RMB'000	RMB'000	2019	2019
			RMB'000	RMB'000
Current Assets				
Inventories	1,353,592	1,646,559	2,175,588	2,263,958
Trade and bills receivables	703,202	1,084,489	1,054,996	888,277
Contract assets	11,389	17,384	21,560	21,429
Prepayments, other receivables and other assets	652,415	476,801	591,480	633,090
Due from the related parties	50,285	44,468	302,590	302,261
Financial assets at fair value through profit or loss	293,185	266,293	343,897	358,464
Derivative financial instruments	43,150	77,174	6,811	22,083
Pledged deposits	6,141	3,837	52,027	51,500
Time deposits	2,369,640	464,299	127,510	210,000
Cash and cash equivalents	730,470	1,526,100	1,177,083	1,004,908
Total current assets	<u>6,213,469</u>	<u>5,607,404</u>	<u>5,853,542</u>	<u>5,755,970</u>
Current Liabilities				
Trade and bills payables	162,474	205,273	253,569	334,669
Other payables and accruals	340,024	493,683	484,102	454,209
Contract liabilities	129,398	254,843	257,912	199,692
Interest-bearing bank and other borrowings	3,259,732	2,463,482	4,630,960	3,849,756
Tax payable	24,134	61,788	53,283	61,162
Due to related parties	2,122	1,180,701	5,487	5,473
Lease liabilities	28,968	30,809	31,900	34,297
Total current liabilities	<u>3,946,852</u>	<u>4,690,579</u>	<u>5,717,213</u>	<u>4,939,258</u>
Net Current Assets	<u>2,266,617</u>	<u>916,825</u>	<u>136,329</u>	<u>816,712</u>
Total assets less current liabilities	<u>10,262,004</u>	<u>9,153,699</u>	<u>9,475,616</u>	<u>10,473,057</u>

We had net current assets of RMB593.6 million as of November 30, 2019, latest practicable date for the purpose of liquidity disclosure in this document, as compared to net current assets of RMB136.3 million as of September 30, 2019. The change was primarily due to the repayment of our corporate bond of RMB994.1 million issued in November 2016 using the proceeds from our corporate bonds of RMB430 million due in October 2022 issued in October 2019.

We had net current assets of RMB136.3 million as of September 30, 2019, as compared to net current assets of RMB916.8 million as of December 31, 2018. The change was primarily due to an increase in interest-bearing bank and other borrowings of RMB2,167.5 million as a result of financing of our acquisition of Topknow, and the reclassification of corporate bond issued in 2016 to current liabilities.

We had net current assets of RMB916.8 million as of December 31, 2018, as compared to net current assets of RMB2,266.6 million as of December 31, 2017. The decrease was primarily due to a decrease in time deposits of RMB1,905.3 million and an increase in amount due to related parties of RMB1,178.6 million. Among the above, the decrease in time deposits was primarily due to the financing needs in relation to our acquisition of Topknow, and the increase in amount due to related parties was primarily attributable to unpaid considerations to original shareholders of Topknow in connection with our acquisition of Topknow.

FINANCIAL INFORMATION

Inventories

Our inventories consist of raw materials, work in progress and finished goods. Please refer to Note 2.3 “Summary of Significant Accounting Policies — Inventories” to the Accountants’ Report included in Appendix I to this document for further details of our accounting policies on inventories. See “Business—Inventory” in this document for further details of our inventory management.

The tables below set forth our inventory balances as of the dates indicated:

	As of December 31,		As of September 30,
	2017	2018	2019
	RMB’000	RMB’000	RMB’000
Raw materials and consumables	406,034	559,116	622,507
Work in progress	296,829	298,875	355,520
Finished goods	650,729	788,568	1,197,561
Total	1,353,592	1,646,559	2,175,588

Our inventory balance increased from RMB1,353.6 million as of December 31, 2017 to RMB1,646.6 million as of December 31, 2018 primarily due to an increase in the procurement price of the raw materials and increase in our stock of finished goods in anticipation of an increasing demand of finished dose pharmaceutical products from the EU market.

Our inventory balance increased from RMB1,646.6 million as of December 31, 2018 to RMB2,175.6 million as of September 30, 2019 primarily due to an increase in the procurement price of the raw materials, our control of outbound delivery quantity of API products as a result of price increase in porcine small intestines and an increase in the inventory storage in anticipation of increasing demand of finished dose pharmaceutical products from the EU market.

In 2017 and 2018 and the nine months ended September 30, 2019, we incurred write-down of inventories of approximately RMB37.6 million, RMB40.6 million and RMB36.9 million respectively. For the years ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, our inventories with a carrying amount of RMB353.0 million, RMB302.4 million and RMB380.1 million respectively were pledged as security for our bank loans.

The table below sets forth our inventory and finished goods turnover days for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,
	2017	2018	2019
Inventory turnover days ⁽¹⁾	186	185	249
Average finished goods turnover days ⁽²⁾	94	89	130

Note:

- (1) Inventory turnover days for a year is the arithmetic mean of the beginning and ending balances of inventory for the relevant year/period divided by the sum of cost of sales for the relevant year/period and multiplied by 360 days for 2017 and 2018 and 270 days for the nine months ended September 30, 2019.
- (2) Average finished goods turnover days for a year is the arithmetic mean of the beginning and ending balances of finished goods for the relevant year/period divided by the sum of cost of sales for the relevant year/period and multiplied by 360 days for 2017 and 2018 and 270 days for the nine months ended September 30, 2019.

Our inventory turnover day remained relatively stable in 2017 and 2018. The 64 days increase in inventory turnover days from 2018 to the nine months ended September 30, 2019 was primarily due

FINANCIAL INFORMATION

to the increase of inventory balance as of September 30, 2019. Our average finished goods turnover days decreased slightly from 94 days in 2017 to 89 days in 2018, and increased to 130 days for the nine months ended September 30, 2019, which was primarily attributable to the increase in our stock of finished goods in anticipation of an increasing demand of finished dose pharmaceutical products from the EU market.

As of November 30, 2019, RMB1,199.8 million, representing 88.6% of the RMB1,353.6 million inventory as of December 31, 2017, was utilized, RMB1,372.5 million, representing 83.4% of the RMB1,646.6 million inventory as of December 31, 2018, was utilized, and RMB1,080.3 million, representing 49.7% of the RMB2,175.6 million inventory as of September 30, 2019, was utilized.

Trade and Bills Receivables

Our trade and bills receivables primarily represent the balances due from certain customers. We generally grant our customers credit terms from one month to three months. We take into consideration a number of factors in determining the credit terms of a customer, including its cash flow conditions and credit worthiness. See “Business—Sales and Marketing—Our Distributors—Management of Distributors” in this document for further details of our distributor management. We seek to maintain strict control over our outstanding receivables. Overdue balances are reviewed regularly by senior management. We do not hold any collateral or other credit enhancements over our trade and bills receivable balances. Trade and bills receivables are non-interest-bearing. The table below sets forth our trade and bills receivables as of the dates indicated:

	As of December 31,		As of
	2017	2018	September 30,
	RMB'000	RMB'000	RMB'000
Trade receivables	710,738	1,109,381	1,067,262
Bill receivables	11,097	1,270	22,404
Allowance for expected credit losses	(18,633)	(26,162)	(34,670)
Total	<u>703,202</u>	<u>1,084,489</u>	<u>1,054,996</u>

Our trade and bills receivables balances increased from RMB703.2 million as of December 31, 2017 to RMB1,084.5 million as of December 31, 2018 and slightly decreased to RMB1,055.0 million as of September 30, 2019, which primarily reflected a significant increase in the sales of enoxaparin sodium injections in 2018.

In determining impairment, we conduct regular impairment analysis at the end of each period during the Track Record Period using a provision matrix to measure expected credit losses. The provision rates are based on days past due for groupings of various customer segments with similar loss patterns. The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the end of each period during the Track Record Period about past events, current conditions and forecasts of future economic conditions. Generally, trade receivables are written off when there is information indicating that the counterparty is in severe financial difficulty and there is no realistic prospect of recovery, e.g. when the counterparty has been placed under liquidation or has entered into bankruptcy proceedings.

FINANCIAL INFORMATION

The table below sets forth our trade receivables turnover days for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,
	2017	2018	2019
Average trade receivable turnover days ⁽¹⁾	75	67	92

Note:

(1) Trade receivable turnover days for a period equals the arithmetic mean of the beginning and ending trade and receivable balances divided by revenue for that period and multiplied by 360 days for 2017 and 2018 and 270 days for the nine months ended September 30, 2019.

The calculation of average trade receivable turnover days enumerates the average of trade receivables in the beginning and the end of a year. The average trade receivable turnover days slightly decreased from 75 days for 2017 to 67 days for 2018, and increased to 92 days for the nine months ended September 30, 2019, which is mainly attributable to a significant increase in the sales of enoxaparin sodium injections in 2018, resulting in increase of trade receivable balance as of December 31, 2018 and the credit period we provide to our customers of enoxaparin sodium injections is generally longer than that of API products.

The following table sets forth an aging analysis based on the billing date and net of allowance for expected credit losses as of the dates indicated:

	As of December 31,		As of September 30,
	2017	2018	2019
	RMB'000	RMB'000	RMB'000
Within 90 days	642,198	1,019,880	955,481
90 to 180 days	13,858	33,962	61,226
180 days to 1 year	24,784	11,125	16,361
1 year to 2 years	19,486	14,845	16,299
Over 2 years	2,876	4,677	5,629
Total	703,202	1,084,489	1,054,996

For the periods ended December 31, 2017 and 2018 and the nine months ended September 30, 2019, a significant portion of our trade receivables are due within 90 days. As of November 30, 2019, RMB702.3 million, representing 99.9% of the RMB703.2 million trade receivables outstanding as of December 31, 2017 were settled, RMB998.6 million, representing 92.1% of the RMB1,084.5 million trade receivables outstanding as of December 31, 2018, were settled and RMB713.1 million, representing 67.6% of the RMB1,055.0 million trade receivables outstanding as of September 30, 2019, were settled.

FINANCIAL INFORMATION

Prepayments, Other Receivables and Other Assets

Our current prepayments, other receivables and other assets include prepayments, deposits and other receivables, interest receivables, tax recoverable, VAT recoverable, prepaid tax and prepaid expenses. Prepayments primarily include prepayments to our raw material suppliers and service providers. The table below sets forth our prepayments, deposits and other receivables as of the dates indicated:

	As of December 31,		As of
	2017	2018	September 30, 2019
	RMB'000	RMB'000	RMB'000
Prepayments	252,935	206,628	352,508
Deposits and other receivables ⁽¹⁾	56,239	57,725	52,490
Interest receivables	208,849	68,902	15,273
Export drawback receivable	43,334	48,582	31,752
VAT recoverable	91,609	83,645	77,035
Prepaid tax	203	459	38,045
Prepaid expenses	13,356	20,945	40,038
Less: impairment ⁽²⁾	(8,110)	(10,085)	(15,661)
Total	<u>652,415</u>	<u>476,801</u>	<u>591,480</u>

Note:

- (1) Deposits and other receivables are unsecured, non-interest-bearing and repayable on demand.
- (2) As of December 31, 2017, December 31, 2018 and September 30, 2019, the impairment of the financial assets included in prepayments, other receivables and other assets were measured based on 12-month expected credit loss if they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, they were measured based on lifetime expected credit loss.

Our prepayments, other receivables and other assets decreased from RMB652.4 million as of December 31, 2017 to RMB476.8 million as of December 31, 2018, which was primarily attributable to the decrease of interest receivables as a result of the decrease of our time deposits and cash and cash equivalents due to financing needs in relation to our acquisition of Topknow. Our prepayments, other receivables and other assets increased from RMB476.8 million as of December 31, 2018 to RMB591.5 million as of September 30, 2019, which was primarily attributable to the increase in prepayment to our raw material suppliers as a result of increase in the raw material price.

Trade And Bills Payables

Our trade and bills payables primarily consist of the balances due to our suppliers of raw materials. The table below sets forth our bills payable and trade payable as of the dates indicated:

	As of 31 December		As of
	2017	2018	30 September 2019
	RMB'000	RMB'000	RMB'000
Bills payable	3,344	—	—
Trade payables	159,130	205,273	253,569
	<u>162,474</u>	<u>205,273</u>	<u>253,569</u>

Our trade and bills payables increased from RMB205.3 million as of December 31, 2018 to RMB253.6 million as of September 30, 2019, increased from RMB162.5 million as of December 31, 2017 to RMB205.3 million as of December 31, 2018, primarily because of a significant increase in the

FINANCIAL INFORMATION

sales of finished dose pharmaceutical products, which results in our increased purchase of raw materials.

The table below sets forth our average trade payables turnover days for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,
	2017	2018	2019
	Average trade payables turnover days ⁽¹⁾	21	23

Note:

(1) Trade payables turnover days for a period equals the arithmetic mean of the beginning and ending trade payables balances divided by the sum of cost of sales for the relevant year/period and multiplied by 360 days for 2017 and 2018 and 270 days for the nine months ended September 30, 2019.

The average trade payables turnover days remained relatively stable at 21 days in 2017 and 23 days in 2018 and increase in average trade payable turnover days to 30 days for the nine months ended September 30, 2019 was mainly due to higher trade payable balance as of September 30, 2019. The average trade payables turnover days during the Track Record Period were in line with the credit terms typically granted by our suppliers.

The following table sets forth an aging analysis of the trade and bills payables as of the dates indicated:

	As of December 31,		As of September 30,
	2017	2018	2019
	RMB'000	RMB'000	RMB'000
Within 1 year	161,562	203,668	250,609
1 year to 2 years	225	778	2,375
2 years to 3 years	62	194	367
over 3 years	625	633	218
Total	162,474	205,273	253,569

The trade payables are non-interest-bearing. As of November 30, 2019, 97.2% of the trade payables outstanding as of December 31, 2017 were settled, 96.8% of the trade payables outstanding as of December 31, 2018 were settled and 26.4% of the trade payables outstanding as of September 30, 2019, were settled.

Other Payables and Accruals

Our other payables and accruals primarily consist of other payables, accrued expenses, project equipment payables, accrued purchase of intangible assets, accrued interest expenses, salary payables and tax payables. Other payables are unsecured, non-interest-bearing and repayable on demand.

FINANCIAL INFORMATION

The table below sets forth the details of our other payables and accruals as of the dates indicated:

	As of December 31, 2017	As of December 31, 2018	As of September 30, 2019
	RMB'000	RMB'000	RMB'000
Other payables	46,908	68,842	93,338
Accruals	72,260	80,142	89,772
Payables for purchase of property, plant and equipment	41,395	132,251	68,787
Payables for purchase of other intangible assets	29,259	14,717	—
Interest payables	15,877	19,826	59,071
Salary payables	125,773	157,292	148,767
Other tax payables	8,552	20,613	24,367
Total	340,024	493,683	484,102

Our other payables and accruals remained relatively stable at RMB493.7 million as of December 31, 2018 and RMB484.1 million as of September 30, 2019.

Our other payables and accruals increased by 45.2% from RMB340.0 million as of December 31, 2017 to RMB493.7 million as of December 31, 2018, which was primarily attributable to an increase in payables for purchase of property, plant and equipment and an increase in salary payables to our employees as a result of increase in the number of our employees, consistent with growth of our finished dose pharmaceutical products business.

Our Directors confirm that we did not have any material default in payment of trade and non-trade payables during the Track Record Period and up to the Latest Practicable Date.

Contract Liabilities

The table below sets forth our revenue-related contract liabilities as of the dates indicated:

	As of 31 December		As of 30 September
	2017	2018	2019
	RMB'000	RMB'000	RMB'000
Sale of products	93,611	140,409	172,785
CDMO services	35,787	84,112	55,094
Others	—	30,322	30,033
Total	129,398	254,843	257,912

We generally receive payments from customers based on billing schedules set forth in the sales contracts for our pharmaceutical products. Under certain contracts with our pre-wholesalers, payments are usually received in advance of the performance.

We also receive payments from customers based on billing schedules set forth in the CDMO service contracts. Under our CDMO service contracts, payments are usually received in advance of the performance.

All of such obligations are expected to be recognized within one year. The amounts disclosed above do not include constrained variable consideration.

FINANCIAL INFORMATION

LIQUIDITY AND CAPITAL RESOURCES

Overview

During the Track Record Period, we financed our operations primarily through cash generated from our operating activities. Our primary uses of cash were to fund working capital and other recurring expenses, and capital expenditures.

Cash Flows

The following table sets forth our cash flows for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,	
	2017	2018	2018	2019
	RMB'000	RMB'000	RMB'000	RMB'000
Net cash flows (used in)/from operating activities	(393,474)	672,788	417,508	(111,405)
Net cash flows (used in)/from investing activities	(257,197)	1,835,888	1,725,486	(171,580)
Net cash flows (used in)/from financing activities	503,302	(1,732,475)	(1,428,874)	(74,347)
Net increase/(decrease) in cash and cash equivalents	(147,369)	776,201	714,120	(357,332)
Cash and cash equivalents at beginning of year/period	882,376	730,470	730,470	1,526,100
Effect of foreign exchange rate changes, net	(4,537)	19,429	42,431	8,315
Cash and cash equivalents at end of year/period	730,470	1,526,100	1,487,021	1,177,083

Operating Activities

For the nine months ended September 30, 2019, our net cash used in operating activities was RMB111.4 million, primarily attributable to profit before tax of RMB887.0 million, adjusted for non-cash and non-operating items. Positive adjustment for non-cash and non-operating items primarily include finance costs of RMB200.7 million, fair value loss on derivative instrument of RMB101.2 million and depreciation of property, plant and equipment of RMB146.5 million, offset by negative adjustments primarily include gain on deemed disposal of a subsidiary of RMB573.9 million. The amount was then adjusted downward by changes in working capital, primarily including increase in inventories of RMB529.0 million and increase in prepayments, deposits and other receivables of RMB206.4 million.

For the nine months ended September 30, 2018, our net cash flows from operating activities was RMB417.5 million, primarily attributable to profit before tax of RMB584.9 million, adjusted for non-cash and non-operating items. Positive adjustment for non-cash and non-operating items primarily include share of losses of associates of RMB233.9 million, finance costs of RMB170.5 million and depreciation of property, plant and equipment of RMB116.1 million. The amount was then adjusted downward by changes in working capital, primarily including increase in inventories of RMB271.3 million, increase in prepayments, deposits and other receivables of RMB192.0 million and increase in trade and bills receivables of RMB102.4 million.

In 2018, our net cash flows from operating activities was RMB672.8 million, primarily attributable to profit before tax of RMB765.2 million, adjusted for non-cash and non-operating items. Positive adjustment for non-cash and non-operating items primarily include share of losses of associates of RMB305.0 million, finance costs of RMB229.2 million and depreciation of property, plant and equipment of RMB157.6 million. The amount was then adjusted downward by changes in working capital, primarily including increase in inventories of RMB293.0 million and increase in trade and bills receivables of RMB381.3 million and decrease in prepayments, deposits and other receivables of RMB112.4 million.

FINANCIAL INFORMATION

In 2017, our net cash used in operating activities was RMB393.5 million, primarily attributable to profit before tax of RMB157.1 million, adjusted for non-cash and non-operating items. Positive adjustment for non-cash and non-operating items primarily include finance costs of RMB183.3 million and depreciation of property, plant and equipment of RMB139.6 million, offset by negative adjustments primarily include bank interest income of RMB34.8 million. The amount was then adjusted downward by changes in working capital, primarily including increase in inventories of RMB664.3 million and increase in trade and bills receivables of RMB199.9 million, increase in prepayments, deposits and other receivables of RMB288.9 million and increase in other payables and accruals of RMB149.5 million.

Net Cash from Investing Activities

For the nine months ended September 30, 2019, our net cash used in investing activities was RMB171.6 million, mainly attributable to purchase of financial asset at fair value through profit or loss of RMB1,160.2 million and purchase of other intangible assets RMB2.2 million, partially offset by gains on disposal of financial assets at fair value through profit or of RMB14.3 million and decrease in time deposits of RMB464.3 million.

For the nine months ended September 30, 2018, our net cash flows from investing activities was RMB1,725.5 million, mainly attributable to decrease in time deposits of RMB1,968.6 million, gains on disposal of financial assets at fair value through profit or of RMB4.6 million, partially offset by purchase of financial asset at fair value through profit or loss of RMB537.6 million and purchases of property, plant and equipment of RMB303.4 million.

In 2018, our net cash flows from investing activities was RMB1,835.9 million, mainly attributable to decrease in time deposits of RMB2,268.7 million and gains on disposal of financial assets at fair value through profit or of RMB6.7 million, partially offset by purchase of financial asset at fair value through profit or loss of RMB813.9 million and purchases of property, plant and equipment of RMB498.8 million.

In 2017, our net cash used in investing activities was RMB257.2 million, mainly attributable to purchase of financial asset at fair value through profit or loss of RMB2,008.3 million, purchases of property, plant and equipment of RMB621.5 million and investment in associates of RMB439.1 million, partially offset by gains on disposal of financial assets at fair value through profit or loss of RMB24.4 million and decrease in time deposits of RMB922.5 million.

Net Cash from Financing Activities

For the nine months ended September 30, 2019, our net cash used in financing activities was RMB74.3 million, mainly attributable to repayment of bank loans and other borrowings of RMB2,728.1 million, acquisition of subsidiaries under common control of RMB1,176.0 million, interest on bank loans and other borrowings paid of RMB162.5 million and dividends paid of RMB124.7 million, partially offset by proceeds from new bank loans and other borrowings of RMB4,131.7 million.

For the nine months ended September 30, 2018, our net cash used in financing activities was RMB1,428.9 million, mainly attributable to repayment of bank loans and other borrowings of RMB2,838.7 million and acquisition of subsidiaries under common control of RMB1,224.0 million, partially offset by proceeds from new bank loans and other borrowings of RMB2,797.4 million.

FINANCIAL INFORMATION

In 2018, our net cash used in financing activities was RMB1,732.5 million, mainly attributable to repayment of bank loans and other borrowings of RMB4,205.2 million and acquisition of subsidiaries under common control of RMB1,224.0 million, partially offset by proceeds from new bank loans and other borrowings of RMB3,917.0 million.

In 2017, our net cash flows from financing activities was RMB503.3 million, mainly attributable to proceeds from new bank loans and other borrowings of RMB3,400.9 million, partially offset by repayment of bank loans and other borrowings of RMB2,365.7 million and dividends paid of RMB311.8 million.

WORKING CAPITAL

The Directors are of the opinion that, taking into account of the following financial resources available to us described below, we have sufficient working capital required for our operations at present and for at least the next 12 months from the expected date of this document:

- our future operating cash flows in respective periods;
- cash and cash equivalent of RMB1,004.9 million as of November 30, 2019;
- available financing facilities; and
- the estimated net [REDACTED] from the [REDACTED].

INDEBTEDNESS

The following table sets forth the breakdown of our financial indebtedness as of the dates indicated:

	As of December 31,		As of	As of
	2017	2018	September 30,	November 30,
	RMB'000	RMB'000	RMB'000	RMB'000
Interest-bearing bank and other borrowings	5,084,065	4,912,924	6,360,859	6,219,302
Lease liabilities	156,030	137,527	126,641	123,033
Total	<u>5,240,095</u>	<u>5,050,451</u>	<u>6,487,500</u>	<u>6,342,335</u>

We had total bank and other borrowings of RMB6,219.3 million as of November 30, 2019, the latest practicable date for the purpose of liquidity disclosure in this document, as compared to RMB6,360.9 million as of September 30, 2019. The change was primarily due to the repayment of bond of RMB994.1 million issued in November 2016 using the proceeds from our corporate bonds due in October 2022 issued in October 2019 and our cash on hand, partially offset by the increase in short-term borrowing of RMB217.6 million and long-term borrowing of RMB639.3 million.

We had total bank and other borrowings of RMB6,360.9 million as of September 30, 2019, as compared to RMB4,912.9 million as of December 31, 2018. The change was primarily due to the increase in short-term borrowing and corporate bond to provide liquidity and make payment for the acquisition of Topknow.

We had total bank and other borrowings of RMB4,912.9 million as of December 31, 2018, as compared to RMB5,084.1 million as of December 31, 2017. The change was primarily due to the repayment of borrowings.

FINANCIAL INFORMATION

Bank and Other Borrowings

The following tables set forth the breakdown of our bank and other borrowings as of the dates indicated:

As of December 31, 2017			
	Effective interest rate per annum (%)	Maturity	RMB'000
Current			
Bank loans—secured ^(a)	2.5%-5.6%	2018	326,246
Bank loans—unsecured	2.3%-5.7%	2018	1,741,500
Current portion of long—term bank loans—secured ^(a)	2.2%-5.0%	2018	211,246
	LIBOR+150BP-200BP	2018	
Current portion of long-term bank loans—unsecured	3MLIBOR+130BP	2018	900,740
	LIBOR+150BP	2018	
Other borrowings—unsecured ^(b)	5.8%	2018	80,000
Total			<u>3,259,732</u>
Non-current			
Bank loans—secured ^(a)	4.40%	2019	4,970
Bank loans—unsecured	LIBOR+150BP	2019-2020	826,576
	3MLIBOR+130BP	2019-2020	
Corporate bonds—unsecured ^(c)	3.4%	2021	992,787
Total			<u>1,824,333</u>

As of December 31, 2018			
	Effective interest rate per annum (%)	Maturity	RMB'000
Current			
Bank loans—secured ^(a)	2.5%-6.3%	2019	91,389
Bank loans—unsecured	2.6%-6.3%	2019	1,612,392
	3MLIBOR+130BP		
Current portion of long—term bank loans—secured ^(a)	4.4%	2019	4,999
Current portion of long—term bank loans—unsecured	LIBOR+150BP	2019	476,992
Other borrowings—unsecured ^(b)	3.5%-5.4%	2019	277,710
Total			<u>2,463,482</u>
Non-current			
Bank loans—secured ^(a)	6.5%	2023	862,319
	LIBOR+APPLICABLE MARGIN (1.3-1.9%)		
Bank loans—unsecured	3MLIBOR+130BP-150BP	2020-2021	592,515
Corporate bonds—unsecured ^(c)	3.4%	2021	994,608
Total			<u>2,449,442</u>

FINANCIAL INFORMATION

	As of September 30, 2019		
	Effective interest rate per annum (%)	Maturity	RMB'000
Current			
Bank loans—secured ^(a)	4.8%-5.7%	2019-2020	598,000
Bank loans—unsecured	1.1%-4.9%	2019-2020	1,861,038
	3MLIBOR+130BP		
Current portion of long—term bank loans—secured ^(a)	4.4%-6.5%	2019-2020	59,304
Current portion of long—term bank loans—unsecured	3MLIBOR+130BP	2020	392,066
Other borrowings—unsecured ^(b)	2.9%-4.5%	2019-2020	730,410
Current portion of corporate bonds—unsecured ^(c)	3.4%	2019	990,142
Total			<u>4,630,960</u>
Non-current			
Bank loans—secured ^(a)	6.5%	2023	817,577
	LIBOR+APPLICABLE MARGIN (1.3-1.9%)		
Bank loans—unsecured	3MLIBOR+150BP	2021	217,139
Corporate bonds—secured ^(c)	5.9%	2024	689,310
Corporate bonds—unsecured	6.0%	2021	5,873
Total			<u>1,729,899</u>
	As of November 30, 2019		
	Effective interest rate per annum (%)	Maturity	RMB'000
Current			
Bank loans—secured ^(a)	4.8%-5.7%	2019-2020	598,000
Bank loans—unsecured	1.1%-4.9%,	2019-2020	1,627,594
	3MLIBOR+130BP		
Current portion of long-term bank loans—secured ^(a)	6.5%,	2020	116,562
	LIBOR+APPLICABLE MARGIN		
Current portion of long-term bank loans—unsecured	3MLIBOR+130BP	2020	389,677
Other borrowings—unsecured ^(b)	2.9%-4.5%	2019-2020	691,410
Current portion of corporate bonds—unsecured ^(c)	7.5%	2020	426,513
Total			<u>3,849,756</u>
Non-current			
Bank loans—secured ^(a)	5.4%-6.5%,	2023-2029	1,458,216
	LIBOR+APPLICABLE MARGIN		
Bank loans—unsecured	3MLIBOR+150BP	2021	215,815
Corporate bonds—secured ^(c)	5.9%	2024	689,684
Total			<u>2,363,715</u>

FINANCIAL INFORMATION

Analyzed into:

	As of December 31,		As of	As of
	2017	2018	September 30,	November 30,
	RMB'000	RMB'000	RMB'000	RMB'000
Repayable:				
Within one year	3,259,732	2,463,482	4,630,960	3,849,756
In the second year	459,097	380,442	217,139	215,815
In the third to fifth years, inclusive	1,365,236	2,069,000	1,512,759	1,570,300
Over fifth years	—	—	—	577,600
Total	<u>5,084,065</u>	<u>4,912,924</u>	<u>6,360,858</u>	<u>6,213,471</u>

- (a) As of December 31, 2017, 2018, September 30, 2019 and November 30, 2019, the mortgaged and guaranteed bank loans with the amount of RMB159.2 million, RMB317.0 million, RMB326.8 million and RMB421.5 million were secured by the total assets owned by SPL. As of December 31, 2017, 2018, September 30, 2019 and November 30, 2019, the pledged assets have a net carrying amount of approximately RMB1,189.6 million, RMB1,485.3 million, RMB1,541.7 million and RMB1,517.6 million, respectively. As of December 31, 2017, 2018, September 30, 2019 and November 30, 2019, Mr. Li has guaranteed certain of the Group’s bank loans up to RMB383.2 million, RMB96.4 million, RMB14.8 million and RMB10.0 million, respectively, which have been released upon the repayment of these loans. As of December 31, 2018, September 30, 2019 and November 30, 2019, the pledged bank loans with the amounts of RMB545.3 million, RMB1,133.3 million and RMB1,133.3 million were secured by the pledge of 100% of shares of Shenzhen Topknow Industrial Development Co., Ltd.
- (b) As of December 31, 2017, 2018, September 30, 2019 and November 30, 2019, other borrowings include discounted notes receivable of RMB80.0 million, RMB95.0 million, RMB445.0 million and RMB425.0 million and letter of credit of nil, RMB182.7 million, RMB285.4 million and RMB266.4 million respectively.
- (c) On November 8, 2016, we issued a domestic corporate bond at a par value of RMB1,000.0 million in the PRC (the “**16 Hepalink**”). The 16 Hepalink will mature in five years from the issue date. Upon the third anniversary of the issue date, we shall be entitled to adjust the coupon rate and the bond holders shall be entitled to sell back the whole or partial 16 Hepalink at par. The 16 Hepalink was listed on November 8, 2016 on the Shenzhen Stock Exchange and bears interest at the rate of 3.19% per annum, payable annually in arrears or on the business day nearest to November 8 of each year, beginning November 8, 2017. On November 7, 2019, we paid the bond with a principal of RMB994.1 million and the corresponding interests according to sell-back requests of bond holders. On April 23, 2019, we issued a non-publicly issued bonds at a par value of RMB700.0 million in the PRC (the “**19 Hepalink**”). The 19 Hepalink will mature in five years from the issue date. Upon the third anniversary of the issue date, we shall be entitled to adjust the coupon rate and the bond holders shall be entitled to sell back the whole or partial 19 Hepalink at par. The 19 Hepalink bears interest at the rate of 5.50% per annum, payable annually in arrears or on the business day nearest to April 23 of each year, beginning April 23, 2019.

As of November 30, 2019, we had in total RMB4,405.9 million outstanding bank loans, comprised of unsecured banking loans in aggregate of RMB2,233.1 million from 13 banks and secured banking loans in aggregate of RMB2,172.8 million from three banks. As of November 30, 2019, we had unutilized banking facilities of RMB2,677.8 million.

Generally, the bank loan agreements we have entered into contain covenants that impose certain restrictions or maintenance requirements on the Company, our subsidiaries and/or the guarantor, including:

- the guarantor and/or borrower, as applicable, may not change the general nature of its business;
- the guarantor and/or borrower, as applicable, may not create encumbrances on any part of its property or assets; and
- the guarantor and/or borrower, as applicable, must comply with certain financial covenants, including but not limited to (i) combined tangible net worth, and (ii) the ratio of combined net borrowings to combined tangible net worth.

The bank loan agreements contain standard events of default such as the occurrence of a change of control, bankruptcy and an event that has a material adverse effect. Our Directors confirm that we

FINANCIAL INFORMATION

had no material defaults in payment of bank borrowings and had not breached any finance covenants thereunder during the Track Record Period and up to the Latest Practicable Date. Our Directors also confirm that we are not subject to other material covenants under any agreements with respect to any bank loans or other borrowings.

In accordance with our loan agreements with a Chinese bank, our Controlling Shareholders and their acting in concert parties (if any) are not allowed to pledge more than 40% of their shares. Breaching such covenant may result in the acceleration of the loan. As of September 30, 2019, the total outstanding amount of the loans were RMB230.0 million, in which RMB63.7 million was due in December 2019, RMB116.3 million will be due in January 2020 and RMB50.0 million will be due in May 2020.

Lease Liabilities

Since IFRS 16 was adopted by our Group throughout the Track Record Period, we recognized right-of-use assets and the corresponding lease liabilities in respect of all leases, except for short-term leases and low value assets. The table below sets forth our lease liabilities for the period indicated:

	As of December 31,		As of	As of
	2017	2018	September 30,	November 30,
	RMB'000	RMB'000	2019	2019
	RMB'000	RMB'000	RMB'000	RMB'000
Current	28,968	30,809	31,900	34,297
Non-current	127,062	106,718	94,741	88,736
Total	156,030	137,527	126,641	123,033

During the Track Record Period, we entered into certain long-term lease contracts for office premises, manufacturing facilities, warehouses, vehicles and equipment.

During the Track Record Period, we also leased certain office premises, vehicles, tools and equipment under short-term (i.e. within 12 months) lease arrangement. We elected not to recognize right-of-use assets on these short-term lease contracts. There are no restrictions or covenants imposed on our lease liabilities.

Our total lease liabilities decreased gradually during the Track Record Period up to November 30, 2019, primarily attributable to the expiration of certain of our lease contracts the lease liabilities under which are larger than the lease liabilities incurred under our new lease contracts.

Except as discussed above, we did not have any other material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of the Latest Practicable Date.

FINANCIAL INFORMATION

CAPITAL EXPENDITURE

We regularly make capital expenditures to expand our operations, upgrade our facilities and increase our operating efficiency. The table below sets forth our capital expenditures for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,	
	2017	2018	2018	2019
	RMB'000	RMB'000	RMB'000	RMB'000
Purchases of property, plant and equipment	621,524	498,797	303,358	272,825
Purchases of other intangible assets	18,276	36,212	33,854	2,179
Investment in associates	439,120	53,550	23,800	71,507
Purchase of derivative instrument	27,154	3,534	—	34,455
Purchase of financial asset at fair value through profit or loss . . .	2,008,259	813,916	537,631	1,160,176
Purchases of equity investments designated at fair value through other comprehensive income	15,948	31,863	—	—
Increase in an amount due from a related party	43,287	—	—	—
Acquisition of a subsidiary	8,750	—	—	—
Total	3,182,318	1,437,872	898,643	1,541,142

We expect to incur capital expenditures of approximately RMB362 million and RMB337 million in 2019 and 2020, respectively. These expected capital expenditures are primarily for the expansion of our heparin API and finished doses production capacity, and our CDMO business. See “Future Plans and Use of [REDACTED]” in this document for further details. We expect to finance such capital expenditures through a combination of operating cash flows and net [REDACTED] from the [REDACTED]. We may adjust our capital expenditures for any given period according to our development plans or in light of market conditions and other factors we believe to be appropriate.

CONTRACTUAL OBLIGATIONS

Capital Commitments

As of December 31, 2017 and 2018 and September 30, 2019, we had the following capital commitments:

	As of December 31,		As of
	2017	2018	September 30,
	RMB'000	RMB'000	2019
Contracted, but not provided for:			RMB'000
Property, plant and equipment	369,671	397,317	321,109
Capital contributions payable to an investment included in financial assets at fair value through other comprehensive income	—	85,958	423
Total	369,671	483,275	321,532

Capital contributions payable to an investment included in financial assets at fair value through other comprehensive income represents our obligations to make investment in one investee.

CONTINGENT LIABILITIES

As of December 31, 2017 and 2018 and September 30, 2019, we did not have any contingent liabilities, except for the guarantees given to banks in respect of performance bonds of nil,

FINANCIAL INFORMATION

RMB10.7 million and RMB13.6 million, respectively. We confirm that as of the Latest Practicable Date, there have been no material changes or arrangements to our contingent liabilities.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

KEY FINANCIAL RATIOS

The table below sets forth the key financial ratios of our Group for the periods or as of the dates indicated:

	Year ended December 31, / As of December 31,		Nine months ended September 30, / As of September 30,	
	2017	2018	2018	2019
Gross margin ⁽¹⁾	0.30	0.39	0.38	0.34
Current ratio ⁽²⁾	1.57	1.20	N/A	1.02
Gearing ratio ⁽³⁾	0.63	0.78	N/A	0.88
Leverage ratio ⁽⁴⁾	0.43	0.55	N/A	0.53

Notes:

- (1) Gross margin equals gross profit divided by revenue for the year/period.
- (2) Current ratio equals current assets divided by current liabilities as of the end of the year/period.
- (3) Gearing ratio equals total financial indebtedness (including interest-bearing bank and other borrowings and lease liabilities) divided by total equity as of the end of the year/period.
- (4) Leverage ratio equals total liabilities divided by total assets as of the end of the year/period.

Gross Margin

The increase in gross margin from the year ended December 31, 2017 to the year ended December 31, 2018 was primarily due to the decrease in unit production cost of our finished dose pharmaceutical products and the increase in price of our API products. The decrease in gross margin from the year ended December 31, 2018 to the nine months ended September 30, 2019 was mainly attributable to the increase in cost of raw materials and increase in the volume of sales to hospitals in the EU countries which generally have a lower profit margin as compared to sales to pharmacies, and less demand for our other products.

Current Ratio

The decrease in current ratio from December 31, 2017 to December 31, 2018 was primarily due to the decrease in time deposits to pay the acquisition consideration of Topknow, and increase in liabilities due to related parties, resulting from the acquisition of Topknow. The decrease in current ratio from December 31, 2018 to September 30, 2019 was mainly attributable to the increase in the current portion of interest-bearing banking and other borrowings, which is used to supplement working capital and pay the acquisition consideration of Topknow, and the reclassification of the corporate bond issued in 2016 to current liabilities.

Gearing Ratio

The increase in gearing ratio was primarily attributable to the increase in the total amount of short-term and long-term interest-bearing bank and other borrowings in order to supplement working capital and pay the purchase amount of Topknow.

FINANCIAL INFORMATION

Leverage Ratio

The increase in leverage ratio from December 31, 2017 to December 31, 2018 was primarily attributable to RMB2.4 billion acquisition of Topknow that resulted in an decrease in equity. The leverage ratio was relatively stable from December 31, 2018 to September 30, 2019.

RELATED-PARTY TRANSACTIONS

We enter into transactions with our related parties from time to time. Our Directors are of the view that each of the related party transactions set out in note 46 to the Accountants’ Report in Appendix I to this document was conducted in the ordinary course of business and on an arm’s length basis and with normal commercial terms between the relevant parties. Our Directors are also of the view that our related party transactions during the Track Record Period would not distort our results of operations or make our historical results not reflective of our future performance.

The following table sets forth the significant related party transactions for the years and periods indicated:

	Year ended December 31,		Nine months ended September 30,	
	2017 RMB’000	2018 RMB’000	2018 RMB’000 (Unaudited)	2019 RMB’000 (Unaudited)
Revenue from sales of products				
OncoQuest	10,100	3,569	2,852	6,990
Acquisition of a subsidiary ⁽¹⁾				
Controlling shareholders	—	1,765,660	—	—
Mr. Shan	—	55,460	—	—
Shuidi Shichuan	—	33,600	—	—
	—	1,854,720	—	—

Note:

(1) The Company acquired 100% shares of Topknow from the shareholders. Further details are included in note 41 to the Accountants’ Report set out in Appendix I.

FINANCIAL INFORMATION

The following table sets forth the outstanding balances with related parties as of the dates indicated:

	As of December 31,		As of
	2017	2018	September 30,
	RMB'000	RMB'000	2019 RMB'000 (Unaudited)
<i>Due from related parties</i>			
Trade receivables (trade in nature) ⁽¹⁾			
OncoQuest ⁽²⁾	8,427	503	8,730
Other receivables (non-trade in nature)			
Controlling Shareholders ⁽³⁾	—	—	236,616
Mr. Shan ⁽³⁾	—	—	7,433
Shuidi Shichuan ⁽³⁾	—	—	4,502
Resverlogix ⁽⁴⁾	41,858	43,965	45,309
Total receivables from related parties	<u>50,285</u>	<u>44,468</u>	<u>302,590</u>
<i>Due to related parties</i>			
Controlling Shareholders ⁽⁵⁾	—	1,119,530	—
Mr. Shan ⁽⁵⁾	—	35,168	—
Shuidi Shichuan ⁽⁵⁾	—	21,302	—
Aridis	—	2,472	3,189
Deposit received (trade in nature)			
OncoQuest	2,122	2,229	2,298
Total payables to related parties	<u>2,122</u>	<u>1,180,701</u>	<u>5,487</u>

Note:

- (1) Trade receivables due from related parties are unsecured, interest-free and repayable upon request.
- (2) The receivables due from OncoQuest are from the CDMO service provided by Cytovance.
- (3) The outstanding balances of controlling shareholders, Mr. Shan and Shuidi Shichuan were due from a contingent consideration based on the achievement of the profit targets of Topknow. Further details are included in note 46 to the Accountants' Report set out in Appendix I.
- (4) The receivables due from Resverlogix are the prepayment of the licensing rights fee for RVX-208.
- (5) The payables were due from the acquisition of 100% share of Topknow. Further details are included in note 46 to the Accountants' Report set out in Appendix I.

MARKET RISK DISCLOSURE

We are exposed to a variety of financial risks, including interest rate risk, foreign currency risk, credit risk and liquidity risk, as set out below. We regularly monitor our exposure to these risks and as of the Latest Practicable Date, did not hedge or consider necessary to hedge any of these risks by the use of derivative financial instruments.

Interest Rate Risk

Our exposure to the risk of changes in market interest rates relates primarily to the interest-bearing bank with floating interest rates. Our policy is to manage our interest cost using a mix of fixed and variable rate debts. As of December 31, 2017, 2018 and September 30, 2019, approximately 70%, 56%, and 71% of our interest-bearing borrowings bore interest at fixed rates, respectively. For further details, including relevant sensitivity analysis, please see note 49 to the Accountant's Report set out in Appendix I.

FINANCIAL INFORMATION

Foreign Currency Risk

Foreign currency risk arise from sales or purchases by operating units in currencies other than the units’ functional currencies.

We have transactional currency exposures. In addition, we have currency exposures from our interest-bearing bank borrowings. We currently have a foreign currency hedging policy to mitigate our foreign currency risk and our management monitors foreign exchange exposure from time to time to adjust our hedging measures. For further details, including relevant sensitivity analysis, please see note 49 to the Accountant’s Report set out in Appendix I.

Credit Risk

We have established a policy to perform an assessment for the period beginning on or after January 1, 2017, of whether a financial instrument’s credit risk has increased significantly since initial recognition, by considering the change in the risk of default occurring over the remaining life of the financial instrument

Our management makes periodic collective assessments for financial assets included in prepayments, and deposits and other receivables as well as individual assessment on the recoverability of other receivables based on historical settlement records and past experience. We recognized allowance for financial assets included in prepayments, deposits and other receivables based on 12-month ECLs and adjusts for forward looking macroeconomic data. For further details, see note 49 to the Accountant’s Report set out in Appendix I.

Liquidity Risk

Our objective is to maintain a balance between continuity of funding and flexibility through the use of internally generated cash flows from operation and bank borrowings. We regularly review our major funding positions to ensure that it has adequate financial resources in meeting its financial obligations.. For further details, see note 49 to the Accountant’s Report set out in Appendix I.

DIVIDEND POLICY

We paid and declared dividends of RMB311.8 million, RMB56.1 million and RMB124.7 million to our then shareholders for the years ended December 31, 2017 and 2018, and the nine months ended September 30, 2019, respectively. Except as disclosed in this section, we had not made any payment of, or set any payment schedule for, dividends as of the Latest Practicable Date.

After the [REDACTED], we may declare and pay dividends mainly by cash or by stock that we consider appropriate. At the end of each financial year, distribution of dividends will be formulated by our Board, and will be subject to shareholders’ approval. Decisions to declare or to pay any dividends in the future, will depend on, among other things, the company’s profitability, operation and development plans, external financing environment, costs of capital, the company’s cash flows and other factors that our Directors may consider relevant.

Pursuant to our Dividends Distribution Plan (2018-2020) formulated by our board, we, in principle, declare and distribute our dividends once a year. The accumulated cash dividends we paid in the past three years shall be no less than 30% of the average annual distributable profit in the

FINANCIAL INFORMATION

respective period. We are also able to declare interim dividends subject to our profitability and capital requirements. When the Board considers that our stock price does not align with the total amount of our outstanding shares, or when the Boards considers appropriate, we can propose and carry out a stock dividend distribution plan, provided that the above requirements of cash dividend distribution are satisfied.

In accordance with the PRC GAAP, when a company distributes the profit after tax, the company shall allocate an amount equivalent to 10% of profit after tax to the statutory common reserve fund. When the statutory common reserve fund reaches and is maintained at or above 50% of the registered capital, no further allocation to this statutory common reserve fund will be require. Before allocating such amount of profit after tax to the statutory common reserve fund in any given year, the company shall allocate the profit after tax to recover the accumulated losses. After the company has recovered the accumulated losses and allocated the required profit after tax to the statutory common reserve fund, the company may distribute the dividends based on the amount of shares that each shareholder possesses. Any distributable profits that are not distributed in any given year will be retained and become available for distribution in subsequent years.

Our future declarations of dividends may not reflect our historical declaration of dividends and will be at the absolute discretion of our Directors. For more information, please see “Risk Factors—Risks Relating to the [REDACTED].”

DISTRIBUTABLE RESERVES

As of September 30, 2019, our reserves available for distribution to our equity holders amounted to approximately RMB1,701.9 million, subject to the allocation to the statutory common reserve fund in the year end. Please refer to “Financial Information—Dividend Policy” for more information.

[REDACTED]-RELATED EXPENSE INCURRED AND TO BE INCURRED

The total [REDACTED] expenses (including [REDACTED]) payable by our Company are estimated to be approximately HK\$[REDACTED], assuming the [REDACTED] is not exercised and based on an [REDACTED] of HK\$[REDACTED] (being the mid-point of our [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]). These [REDACTED] expenses mainly comprise legal and other professional fees paid and payable to the professional parties, [REDACTED] payable to the [REDACTED], and printing and other expenses for their services rendered in relation to the [REDACTED] and the [REDACTED].

As of September 30, 2019, the [REDACTED] expenses (excluding [REDACTED]) incurred by our Company in relation to the [REDACTED] were [REDACTED], for the nine months ended September 30, 2019. We estimate that additional [REDACTED] expenses of RMB[REDACTED] (including [REDACTED] of RMB[REDACTED], assuming the [REDACTED] is not exercised and based on the mid-point of our [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]) will be incurred by our Company, of which approximately RMB[REDACTED] is expected to be charged to our consolidated statement of profit or loss and approximately RMB[REDACTED] is expected to be charged against equity upon the [REDACTED].

FINANCIAL INFORMATION

[REDACTED]

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that up to the date of this document, there has been no material adverse change in our financial, operational or trading positions or prospects since September 30, 2019, being the date of our consolidated financial statements as set out in the Accountants’ Report included in Appendix I to this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors have confirmed that, save as disclosed in this document, as of the Latest Practicable Date, there were no circumstances that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND USE OF [REDACTED]

FUTURE PLANS

Please see the section headed “Business—Our Strategies” for a detailed description of our future plans.

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED] is exercised and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED] in this document. We intend to use the net [REDACTED] we will receive from the [REDACTED] for the following purposes, subject to changes in light of our evolving business needs and changing market conditions:

- approximately [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], for improving our capital structure and repaying existing debt, including our loan facility of RMB588 million at China Merchants Bank for the acquisition of Topknow, US\$30.7 million at Ping An Bank of China and US\$42.5 million at Bank of China, with maturity date of June 2020, February 2021 and July 2020 respectively, and interest rate of 4.785%, 3 month libor+1.5% and 3 month libor+1.3%, respectively. For more details, see “Financial Information—Indebtedness”.
- approximately [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], for our expansion of the sales and marketing network and infrastructure in the EU and other global markets.
- approximately [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], for expanding our development and manufacturing capacity and broadening our product and services offering of Cytovance.
- approximately [REDACTED]% of net [REDACTED], or approximately HK\$[REDACTED], for investment in innovative drugs.

The allocation of the [REDACTED] used for the above will be adjusted in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the estimated [REDACTED] range. If the [REDACTED] is fixed at HK\$[REDACTED] per H Share, being the high end of the stated [REDACTED] range, our net [REDACTED] will be (i) increased by approximately HK\$[REDACTED], assuming the [REDACTED] is not exercised; and (ii) increased by approximately HK\$[REDACTED], assuming the [REDACTED] is exercised in full. In such circumstances, we currently intend to use such additional [REDACTED] to increase the net [REDACTED] applied for the same purposes as set out above on a pro rata basis. If the [REDACTED] is fixed at HK\$[REDACTED] per H Share, being the low end of the stated [REDACTED] range, our net [REDACTED] will be (i) decreased by approximately HK\$[REDACTED], assuming the [REDACTED] is not exercised; and (ii) decreased by approximately HK\$[REDACTED], assuming the [REDACTED] is exercised in full. In such circumstances, we currently intend to reduce the net [REDACTED] applied for the same purposes as set out above on a pro rata basis.

If the [REDACTED] is exercised in full, the additional net [REDACTED] that we will receive will be approximately HK\$[REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per Share,

FUTURE PLANS AND USE OF [REDACTED]

being the mid-point of the proposed [REDACTED] range. The Company may be required to issue up to an aggregate of [REDACTED] additional H Shares pursuant to the [REDACTED].

To the extent that the net [REDACTED] of the [REDACTED] are not immediately required for the above purposes or if we are unable to put into effect any part of our development plan as intended, we may hold such funds in short-term deposits so long as it is deemed to be in the best interests of the Company. In such event, we will comply with the appropriate disclosure requirements under the Listing Rules.

[REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

[REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

[REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

[REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

[REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

[REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

STRUCTURE OF THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

STRUCTURE OF THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

STRUCTURE OF THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

STRUCTURE OF THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

STRUCTURE OF THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

STRUCTURE OF THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

STRUCTURE OF THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED “WARNING” ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

HOW TO APPLY FOR THE [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

The following is the text of a report, prepared for inclusion in this document, received from the independent reporting accountants of the Company, Ernst & Young, Certified Public Accountants, Hong Kong.

22/F, CITIC Tower
1 Tim Mei Avenue
Central, Hong Kong

The Directors
Shenzhen Hepalink Pharmaceutical Group Co. Ltd.
Goldman Sachs (Asia) L.L.C.
Morgan Stanley Asia Limited

Dear Sirs,

We report on the historical financial information of Shenzhen Hepalink Pharmaceutical Group Co. Ltd. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages [I-●] to [I-●], which comprises the consolidated statements of profit or loss, statements of comprehensive income, statements of changes in equity and statements of cash flows of the Group for each of the years ended 31 December 2017 and 2018, and the nine months ended 30 September 2019 (the “Relevant Periods”), and the consolidated statements of financial position of the Group as at 31 December 2017 and 2018, and 30 September 2019 and the statement of financial position of the Company as at 31 December 2017 and 2018 and 30 September 2019 and a summary of significant accounting policies and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages [I-●] to [I-●] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [DATE] (the “Document”) in connection with the [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

Directors’ responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 (“HKSIR 200”) *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical

Reporting accountants’ responsibility—continued

Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants’ report, a true and fair view of the financial position of the Group and the Company as at 31 December 2017 and 2018 and of the financial performance and cash flows of the Group for the year then ended in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

Review of interim financial information

We have reviewed the interim financial information of the Group which comprises the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 30 September 2019, and the consolidated statement of profit or loss, statement of comprehensive income, statement of changes in equity and statement of cash flows of the Group for the nine months ended 30 September 2018 and 2019 and other explanatory information (the “Interim Financial Information”).

The directors of the Company are responsible for the preparation and presentation of the Interim Financial Information in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Interim Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the HKICPA. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, which does not constitute an audit, for the purposes of this report, nothing has come to our attention that causes us to believe that the Interim Financial Information, is not prepared, in all material respects, in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

APPENDIX I

ACCOUNTANTS' REPORT

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to note 12 to the Historical Financial Information which contains information about the dividends paid by the Company in respect of the Relevant Periods.

Yours faithfully,

Certified Public Accountants

Hong Kong

[Date]

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION

Preparation of the Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The financial statements of the Group for the years ended 31 December 2017 and 2018, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing issued by the HKICPA (the “Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

	Notes	Year ended 31 December		Nine months ended 30 September	
		2017	2018	2018	2019
		RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
REVENUE	5	2,828,225	4,799,807	3,306,748	3,132,171
Cost of sales		(1,976,442)	(2,926,275)	(2,037,569)	(2,069,583)
Gross profit		851,783	1,873,532	1,269,179	1,062,588
Other income and gains	6	209,701	308,150	317,777	740,238
Selling and distribution expenses		(192,201)	(371,710)	(240,505)	(292,569)
Administrative expenses		(435,629)	(497,735)	(343,676)	(365,580)
Impairment losses on financial assets		(10,884)	(12,454)	(13,404)	(14,676)
Other expenses		(2,707)	(366)	(68)	(477)
Finance costs	8	(183,268)	(229,207)	(170,519)	(200,693)
Share of profits and losses of associates		(79,710)	(305,003)	(233,915)	(41,797)
PROFIT BEFORE TAX	7	157,085	765,207	584,869	887,034
Income tax credit/(expense)	11	83,807	(148,244)	(115,424)	(138,061)
PROFIT FOR THE YEAR/ PERIOD		<u>240,892</u>	<u>616,963</u>	<u>469,445</u>	<u>748,973</u>
Attributable to:					
Owners of the parent		238,904	640,194	479,041	763,586
Non-controlling interests		1,988	(23,231)	(9,596)	(14,613)
EARNINGS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	13				
Basic					
—for profit for the year/period		<u>RMB0.19</u>	<u>RMB0.51</u>	<u>RMB0.38</u>	<u>RMB0.61</u>
Diluted					
—for profit for the year/period		<u>RMB0.19</u>	<u>RMB0.51</u>	<u>RMB0.38</u>	<u>RMB0.61</u>

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION—continued

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

	Year ended 31 December		Nine months ended 30 September	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
PROFIT FOR THE YEAR/PERIOD	240,892	616,963	469,445	748,973
OTHER COMPREHENSIVE (LOSS)/INCOME				
Other comprehensive (loss)/ income that may be reclassified to profit or loss in subsequent periods (net of tax):				
Exchange differences on translation of foreign operations	(72,384)	73,202	78,078	82,463
Share of other comprehensive income of an associate	—	—	—	269
Net other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods	(72,384)	73,202	78,078	82,732
Other comprehensive (loss) /income that will not be reclassified to profit or loss in subsequent periods (net of tax):				
Net losses on equity investments designated at fair value through other comprehensive income	(180,501)	(190,852)	(141,210)	(40,265)
Remeasurement (losses)/gains on defined benefit pension schemes	(9,936)	5,380	6,621	(19,508)
Net other comprehensive loss that will not be reclassified to profit or loss in subsequent periods	(190,437)	(185,472)	(134,589)	(59,773)
Other comprehensive (loss)/income for the year/period, net of tax	(262,821)	(112,270)	(56,511)	22,959
Total comprehensive (loss)/ income for the year/period, net of tax	(21,929)	504,693	412,934	771,932
Attributable to:				
Owners of the parent	(21,314)	528,711	422,749	786,906
Non-controlling interests	(615)	(24,018)	(9,815)	(14,974)

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION—continued

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Notes	As at 31 December		As at
		2017	2018	30 September
		RMB’000	RMB’000	RMB’000 (Unaudited)
NON-CURRENT ASSETS				
Property, plant and equipment	14	2,080,291	2,554,239	2,627,496
Right-of-use assets	15	292,543	261,906	245,940
Goodwill	16	2,205,705	2,316,763	2,387,550
Other intangible assets	17	606,450	616,656	568,118
Investments in associates	18	641,979	562,490	1,279,809
Equity investments designated at fair value through other comprehensive income	20	550,363	608,785	649,811
Financial assets at fair value through profit or loss	21	961,863	931,367	1,259,938
Time deposits	28	490,909	127,510	—
Deferred tax assets	34	21,816	110,831	156,108
Other non-current assets	23	143,468	146,327	164,517
Total non-current assets		<u>7,995,387</u>	<u>8,236,874</u>	<u>9,339,287</u>
CURRENT ASSETS				
Inventories	24	1,353,592	1,646,559	2,175,588
Trade and bills receivables	25	703,202	1,084,489	1,054,996
Contract assets	26	11,389	17,384	21,560
Prepayments, other receivables and other assets	27	652,415	476,801	591,480
Due from related parties	46	50,285	44,468	302,590
Financial assets at fair value through profit or loss	21	293,185	266,293	343,897
Derivative financial instruments	22	43,150	77,174	6,811
Pledged deposits	28	6,141	3,837	52,027
Time deposits	28	2,369,640	464,299	127,510
Cash and cash equivalents	28	730,470	1,526,100	1,177,083
Total current assets		<u>6,213,469</u>	<u>5,607,404</u>	<u>5,853,542</u>
CURRENT LIABILITIES				
Trade and bills payables	29	162,474	205,273	253,569
Other payables and accruals	30	340,024	493,683	484,102
Contract liabilities	31	129,398	254,843	257,912
Interest-bearing bank and other borrowings	32	3,259,732	2,463,482	4,630,960
Tax payable		24,134	61,788	53,283
Due to related parties	46	2,122	1,180,701	5,487
Lease liabilities	36	28,968	30,809	31,900
Total current liabilities		<u>3,946,852</u>	<u>4,690,579</u>	<u>5,717,213</u>
NET CURRENT ASSETS		<u>2,266,617</u>	<u>916,825</u>	<u>136,329</u>
TOTAL ASSETS LESS CURRENT LIABILITIES		<u>10,262,004</u>	<u>9,153,699</u>	<u>9,475,616</u>
NON-CURRENT LIABILITIES				
Interest-bearing bank and other borrowings	32	1,824,333	2,449,442	1,729,899
Deferred income	33	42,345	31,254	21,334
Deferred tax liabilities	34	130,447	202,503	308,865
Long-term employee benefits	35	74,954	77,607	104,548
Other non-current liabilities		9,094	9,842	10,157
Lease liabilities	36	127,062	106,718	94,741
Total non-current liabilities		<u>2,208,235</u>	<u>2,877,366</u>	<u>2,269,544</u>
Net assets		<u>8,053,769</u>	<u>6,276,333</u>	<u>7,206,072</u>
EQUITY				
Equity attributable to owners of the parent				
Share capital	37	1,247,202	1,247,202	1,247,202
Reserves	38	6,584,962	4,852,410	5,834,153
Total equity attributable to owners of the parent		<u>7,832,164</u>	<u>6,099,612</u>	<u>7,081,355</u>
Non-controlling interests		221,605	176,721	124,717
Total equity		<u>8,053,769</u>	<u>6,276,333</u>	<u>7,206,072</u>

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION—continued
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to owners of the parent												
	Share capital	Share premium*	Merger reserve*	Exchange fluctuation reserve*	Share option reserve*	Fair value reserve*	Defined benefit contribution reserve*	Other reserve*	Statutory surplus reserve*	Retained profits*	Total	Non-controlling interests	Total equity
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At 1 January 2017	1,247,202	4,218,797	245,358	99,339	33,937	337,422	(9,815)	—	482,057	1,499,481	8,153,778	219,980	8,373,758
Profit for the year	—	—	—	—	—	—	—	—	—	238,904	238,904	1,988	240,892
Other comprehensive income for the year:													
Change in fair value of equity investments designated at fair value through other comprehensive income, net of tax	—	—	—	—	—	(180,501)	—	—	—	—	(180,501)	—	(180,501)
Exchange differences on translation of foreign operations	—	—	—	(69,781)	—	—	—	—	—	—	(69,781)	(2,603)	(72,384)
Remeasurement losses on defined benefit pension schemes	—	—	—	—	—	—	(9,936)	—	—	—	(9,936)	—	(9,936)
Total comprehensive income for the year	—	—	—	(69,781)	—	(180,501)	(9,936)	—	—	238,904	(21,314)	(615)	(21,929)
Capital contribution from non-controlling shareholders	—	—	—	—	—	—	—	—	—	—	—	17	17
Increase in equity interest in non-wholly owned subsidiary	—	—	—	—	—	—	—	(2,225)	—	—	(2,225)	2,225	—
Transfer from retained profits	—	—	—	—	—	—	—	—	8,228	(8,228)	—	—	—
Dividend declared to shareholders	—	—	—	—	—	—	—	—	—	(311,800)	(311,800)	(2)	(311,802)
Others	—	—	—	—	—	—	—	13,725	—	—	13,725	—	13,725
At 31 December 2017	1,247,202	4,218,797	245,358	29,558	33,937	156,921	(19,751)	11,500	490,285	1,418,357	7,832,164	221,605	8,053,769

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION—continued
 CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY—continued

Note	Attributable to owners of the parent										Total equity RMB’000		
	Share capital RMB’000 (Note 37)	Share premium* RMB’000 (Note 38)	Merger reserve* RMB’000 (Note 38)	Exchange fluctuation reserve* RMB’000 (Note 38)	Share option reserve* RMB’000 (Note 38)	Fair value reserve* RMB’000 (Note 38)	Defined contribution reserve* RMB’000 (Note 38)	Other reserve* RMB’000 (Note 38)	Statutory surplus reserve* RMB’000 (Note 38)	Retained profits* RMB’000		Total RMB’000	Non-controlling interests RMB’000
At 31 December 2017 and 1 January	1,247,202	4,218,797	245,358	29,558	33,937	156,921	(19,751)	11,500	490,285	1,418,357	7,832,164	221,605	8,053,769
2018	—	—	—	—	—	—	—	—	—	640,194	640,194	(23,231)	616,963
Profit for the year	—	—	—	—	—	—	—	—	—	—	—	—	—
Other comprehensive income for the year:	—	—	—	—	—	—	—	—	—	—	—	—	—
Change in fair value of equity investments designated at fair value through other comprehensive income, net of tax	—	—	—	—	—	(190,852)	—	—	—	—	(190,852)	—	(190,852)
Exchange differences on translation of foreign operations	—	—	—	73,989	—	—	—	—	—	—	73,989	(787)	73,202
Remeasurement gains on defined benefit pension schemes	—	—	—	—	—	—	5,380	—	—	—	5,380	—	5,380
Total comprehensive income for the year	—	—	—	73,989	—	(190,852)	5,380	—	—	640,194	528,711	(24,018)	504,693
Capital contribution from non-controlling shareholders	—	—	—	—	—	—	—	45,124	—	—	45,124	85,362	130,486
Share of other reserves of associates	—	—	—	—	—	—	—	11,813	—	—	11,813	—	11,813
Equity-settled share option arrangements	—	—	—	—	—	—	—	240	—	—	240	204	444
Acquisition of a subsidiary	—	—	(2,293,416)	—	—	—	—	—	—	(2,293,416)	(2,293,416)	(106,584)	(2,400,000)
Disposal of a subsidiary	—	—	—	—	—	—	—	—	—	—	—	152	152
Transfer of fair value reserve of equity investments at fair value through other comprehensive income	—	—	—	—	—	(14,995)	—	—	—	14,995	—	—	—
Transfer from retained profits	—	—	—	—	—	—	—	—	27,282	(27,282)	—	—	—
Dividend declared to shareholders	—	—	—	—	—	—	—	—	—	(56,124)	(56,124)	—	(56,124)
Others	—	—	—	—	—	—	—	31,100	—	—	31,100	—	31,100
At 31 December 2018	1,247,202	4,218,797	(2,048,058)	103,547	33,937	(48,926)	(14,371)	99,777	517,567	1,990,140	6,099,612	176,721	6,276,333

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION—continued
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY—continued

	Attributable to owners of the parent												
	Share capital	Share premium*	Merger reserve*	Exchange fluctuation reserve*	Share option reserve*	Fair value reserve*	Defined benefit contribution reserve*	Other reserve*	Statutory surplus reserve*	Retained profits*	Total	Non-controlling interests	Total equity
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
(Unaudited)													
At 31 December 2018 and 1 January 2019	1,247,202	4,218,797	(2,048,058)	103,547	33,937	(48,926)	(14,371)	99,777	517,567	1,990,140	6,099,612	176,721	6,276,333
Profit for the period	—	—	—	—	—	—	—	—	—	763,586	763,586	(14,613)	748,973
Other comprehensive income for the period:													
Share of other comprehensive income of an associate	—	—	—	—	—	—	—	269	—	—	269	—	269
Change in fair value of equity investments designated at fair value through other comprehensive income, net of tax	—	—	—	—	—	(40,265)	—	—	—	—	(40,265)	—	(40,265)
Exchange differences on translation of foreign operations	—	—	—	82,824	—	—	—	—	—	—	82,824	(361)	82,463
Remeasurement losses on defined benefit pension schemes	—	—	—	—	—	—	(19,508)	—	—	—	(19,508)	—	(19,508)
Total comprehensive income for the period	—	—	—	82,824	—	(40,265)	(19,508)	269	—	763,586	786,906	(14,974)	771,932
Capital contribution from non-controlling shareholders	—	—	—	—	—	—	—	6,469	—	—	6,469	8,209	14,678
Share of other reserves of associates	—	—	—	—	—	—	—	2,364	—	—	2,364	—	2,364
Equity-settled share option arrangements	—	—	—	—	—	—	—	128	—	—	128	109	237
Deemed disposal of a subsidiary	—	—	—	—	—	—	—	—	—	—	—	(45,348)	(45,348)
Transfer of fair value reserve of equity investments at fair value through other comprehensive	—	—	—	—	—	742	—	—	—	(742)	—	—	—
Other changes of investment in a subsidiary	—	—	—	—	—	—	—	248,551	—	—	248,551	—	248,551
Dividend declared to shareholders	—	—	—	—	—	—	—	—	—	(124,720)	(124,720)	—	(124,720)
Others	—	—	—	—	—	—	—	62,045	—	—	62,045	—	62,045
At 30 September 2019	1,247,202	4,218,797	(2,048,058)	186,371	33,937	(88,449)	(33,879)	419,603	517,567	2,628,264	7,081,355	124,717	7,206,072

* These reserve accounts comprise the consolidated reserves of RMB6,584,962,000, RMB4,852,410,000 and RMB5,834,153,000 in the consolidated statements of financial position as of 31 December 2017 and 2018, and 30 September 2019, respectively.

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION—continued
 CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY—continued

Note	Attributable to owners of the parent										Total equity RMB’000		
	Share capital RMB’000 (Note 37)	Share premium RMB’000 (Note 38)	Merger reserve RMB’000 (Note 38)	Exchange fluctuation reserve RMB’000 (Note 38)	Share option reserve RMB’000 (Note 38)	Fair value reserve RMB’000 (Note 38)	Defined benefit contribution reserve RMB’000 (Note 38)	Other reserve RMB’000 (Note 38)	Statutory surplus reserve RMB’000 (Note 38)	Retained profits RMB’000		Total RMB’000	Non-controlling interests RMB’000
(Unaudited)													
At 31 December 2017 and 1 January 2018	1,247,202	4,218,797	245,358	29,558	33,937	156,921	(19,751)	11,500	490,285	1,418,357	7,832,164	221,605	8,053,769
Profit for the period	—	—	—	—	—	—	—	—	—	479,041	479,041	(9,596)	469,445
Other comprehensive income for the period:													
Change in fair value of equity investments designated at fair value through other comprehensive income, net of tax	—	—	—	—	—	(141,210)	—	—	—	—	(141,210)	—	(141,210)
Exchange differences on translation of foreign operations	—	—	—	78,297	—	—	—	—	—	—	78,297	(219)	78,078
Remeasurement gains on defined benefit pension schemes	—	—	—	—	—	—	6,621	—	—	—	6,621	—	6,621
Total comprehensive income for the period	—	—	—	78,297	—	(141,210)	6,621	—	—	479,041	422,749	(9,815)	412,934
Capital contribution from non-controlling shareholders	—	—	—	—	—	—	—	—	—	—	—	100	100
Acquisition of a subsidiary 41	—	—	(2,293,416)	—	—	—	—	—	—	—	(2,293,416)	(106,584)	(2,400,000)
Disposal of a subsidiary	—	—	—	—	—	—	—	—	—	—	—	152	152
Transfer of fair value reserve of equity investments at fair value through other comprehensive income	—	—	—	—	—	(6,867)	—	—	—	6,867	—	—	—
Dividend declared to shareholders	—	—	—	—	—	—	—	—	—	(56,124)	(56,124)	—	(56,124)
Others	—	—	—	—	—	—	—	19,130	—	—	19,130	—	19,130
At 30 September 2018	1,247,202	4,218,797	(2,048,058)	107,855	33,937	8,844	(13,130)	30,630	490,285	1,848,141	5,924,503	105,458	6,029,961

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION—continued

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	Year ended 31 December		Nine months ended 30 September	
		2017	2018	2018	2019
		RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES					
Profit before tax:		157,085	765,207	584,869	887,034
Adjustments for:					
Bank interest income	6	(137,740)	(69,456)	(50,568)	(40,170)
Finance costs	8	183,268	229,207	170,519	200,693
Share of profits and losses of associates		79,710	305,003	233,915	41,797
Dividend income from financial assets at fair value through profit or loss	6	(781)	(36,823)	(25,353)	(643)
Dividend income from financial assets designated at fair value through other comprehensive income	6	—	(3,694)	—	(16,449)
Gains on disposal of financial assets at fair value through profit or loss	6	(26,363)	(13,917)	(12,385)	(1,456)
Fair value losses/(gains) on derivative instruments	6	3,728	(30,490)	(38,742)	101,241
Fair value gains on financial assets at fair value through profit or loss	6	(46,757)	(8,191)	(32,218)	(151,220)
Gain on disposal of a subsidiary	6	—	(28,766)	(28,766)	—
Gain on deemed disposal of a subsidiary	6	—	—	—	(573,865)
Losses/(gains) on disposal of items of property, plant and equipment	6	383	(2,304)	(18)	(1,792)
Depreciation of property, plant and equipment	7	139,557	157,632	116,095	146,492
Depreciation of right-of-use assets	7	37,291	41,251	27,320	29,180
Amortisation of other intangible assets	7	45,559	51,799	30,487	39,401
Impairment losses on financial assets	7	10,884	12,454	13,404	14,676
Non—cash transaction in relation to investment	43	—	(256,564)	(179,995)	(85,430)
Foreign exchange losses/(gains), net	6	49,584	(70,545)	(105,098)	(23,954)
		<u>495,408</u>	<u>1,041,803</u>	<u>703,465</u>	<u>565,535</u>
Increase in inventories		(664,334)	(292,967)	(271,308)	(529,029)
(Increase)/decrease in trade and bills receivables		(199,902)	(388,816)	(102,407)	20,985
Increase in contract assets		(11,389)	(5,995)	(4,312)	(4,175)
(Increase)/decrease in prepayments, deposits and other receivables		(288,853)	119,924	(191,966)	(197,896)
(Increase)/decrease in amounts due from related parties		(7,487)	5,817	6,217	(9,571)
Increase in trade and bills payables		60,990	42,800	98,439	48,295
Increase in other payables and accruals		149,451	85,527	56,155	29,354
Increase in amounts due to related parties		2,124	2,578	—	786
Increase in contract liabilities		87,587	95,124	95,729	3,069
Decrease in deferred income		(10,903)	(22,037)	(22,595)	(11,564)
Increase/(decrease) in net defined benefit retirement obligation		11,204	2,653	(1,214)	26,942
(Increase)/decrease in pledged deposits		(498)	2,304	5,529	(48,190)
Cash generated from operations		(376,602)	688,715	371,733	(105,459)
Bank interest income		34,810	91,952	84,571	90,939
Income tax paid		(51,682)	(107,879)	(38,796)	(96,885)
Net cash flows (used in)/from operating activities		<u>(393,474)</u>	<u>672,788</u>	<u>417,508</u>	<u>(111,405)</u>

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION—continued

CONSOLIDATED STATEMENTS OF CASH FLOWS—continued

	Year ended 31 December		Nine months ended 30 September	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
CASH FLOWS FROM INVESTING ACTIVITIES				
Dividend income from financial assets at fair value through profit or loss	238	38,994	5,394	643
Dividend income from equity investments designated at fair value through other comprehensive income	—	—	—	16,449
Dividend received from an associate	—	—	—	21,605
Gains on disposal of financial assets at fair value through profit or loss	24,377	6,685	4,589	14,274
Proceeds from financial assets at fair value through profit or loss	1,938,515	788,618	495,698	908,528
Proceeds from equity investments designated at fair value through other comprehensive income	—	31,018	10,868	16,779
Purchases of derivative instruments	(27,154)	(3,534)	—	(34,455)
Purchases of property, plant and equipment	(621,524)	(498,797)	(303,358)	(272,826)
Purchases of other intangible assets	(18,276)	(36,212)	(33,854)	(2,179)
Investments in associates	(439,120)	(53,550)	(23,800)	(71,507)
Purchase of financial assets at fair value through profit or loss	(2,008,259)	(813,916)	(537,631)	(1,160,176)
Purchases of equity investments designated at fair value through other comprehensive income	(15,948)	(31,863)	—	—
Increase in an amount due from a related party	(43,287)	—	—	—
Proceeds from disposal of items of property, plant and equipment	1,400	1,081	316	24
Acquisition of a subsidiary	(8,750)	—	—	—
Proceeds from disposal of subsidiaries	—	27,172	27,172	(75,898)
Decrease in time deposits	922,492	2,268,740	1,968,640	464,299
Interest received from time deposits	38,099	111,452	111,452	2,860
Net cash flows (used in)/from investing activities	(257,197)	1,835,888	1,725,486	(171,580)

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION—continued

CONSOLIDATED STATEMENTS OF CASH FLOWS—continued

	Notes	Year ended 31 December		Nine months ended 30 September	
		2017	2018	2018	2019
		RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
CASH FLOWS FROM FINANCING ACTIVITIES					
New bank loans and other borrowings		3,400,903	3,916,955	2,797,372	4,131,683
Repayment of bank loans and other borrowings		(2,365,726)	(4,205,169)	(2,838,712)	(2,728,080)
Interest on bank loans and other borrowings paid		(180,920)	(224,628)	(124,218)	(162,459)
Contribution from the non-controlling shareholders		17	96,861	100	14,543
Dividends paid		(311,800)	(56,124)	(12,527)	(124,720)
Acquisition of subsidiaries under common control		—	(1,224,000)	(1,224,000)	(1,176,000)
Principal and interest elements of lease payments		(39,172)	(36,370)	(26,889)	(29,314)
Net cash flows from/(used in) financing activities		503,302	(1,732,475)	(1,428,874)	(74,347)
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS					
Cash and cash equivalents at beginning of year / period		882,376	730,470	730,470	1,526,100
Effect of foreign exchange rate changes, net		(4,537)	19,429	42,431	8,315
CASH AND CASH EQUIVALENTS AT END OF YEAR / PERIOD		730,470	1,526,100	1,487,021	1,177,083
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS					
Cash and bank balances	28	529,470	1,226,000	1,487,021	852,085
Non-pledged time deposits with original maturity of less than three months	28	201,000	300,100	—	324,998
CASH AND CASH EQUIVALENTS AS STATED IN THE STATEMENT OF CASH FLOWS	28	730,470	1,526,100	1,487,021	1,177,083

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION—continued

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

	Notes	As at 31 December		As at
		2017	2018	30 September
		RMB'000	RMB'000	2019
				RMB'000
				(Unaudited)
NON-CURRENT ASSETS				
Property, plant and equipment	14	705,030	1,135,646	1,193,131
Right-of-use assets	15	114,991	111,013	123,505
Other intangible assets	17	9,788	8,782	8,255
Investments in associates		555,817	375,798	537,295
Interests in subsidiaries	19	2,620,191	3,195,069	3,249,058
Equity investments designated at fair value through other comprehensive income	20	281,583	69,423	32,143
Financial assets at fair value through profit or loss	21	246,150	303,848	450,860
Time deposits	28	490,909	127,510	—
Deferred tax assets	34	—	57,122	62,040
Other non-current assets	23	37,797	6,145	2,464
Total non-current assets		5,062,256	5,390,356	5,658,751
CURRENT ASSETS				
Inventories	24	429,866	363,369	425,624
Trade and bills receivables	25	174,840	129,741	187,512
Prepayments, other receivables and other assets	27	523,195	316,846	356,587
Due from related parties		1,207,755	2,281,000	3,011,142
Financial assets at fair value through profit or loss	21	253,005	204,004	280,406
Derivative financial instruments	22	43,150	77,174	6,811
Time deposits	28	2,369,640	463,299	127,510
Cash and cash equivalents	28	367,389	1,033,773	666,690
Total current assets		5,368,840	4,869,206	5,062,282
CURRENT LIABILITIES				
Trade and bills payables	29	6,516	13,672	6,676
Other payables and accruals	30	114,713	207,365	191,457
Contract liabilities	31	—	6,690	5,625
Interest-bearing bank and other borrowings	32	1,361,048	1,032,400	3,012,232
Tax payable		11,396	52,401	18,795
Due to related parties		120,285	1,509,833	145,488
Lease liabilities	36	1,401	2,086	4,591
Total current liabilities		1,615,359	2,824,447	3,384,864
NET CURRENT ASSETS		3,753,481	2,044,759	1,677,418
TOTAL ASSETS LESS CURRENT LIABILITIES		8,815,737	7,435,115	7,336,169
NON-CURRENT LIABILITIES				
Interest-bearing bank and other borrowings	32	992,787	1,539,888	1,185,935
Deferred income	33	10,254	4,664	4,147
Deferred tax liabilities	34	10,642	—	—
Lease liabilities	36	20,146	19,618	32,641
Total non-current liabilities		1,033,829	1,564,170	1,222,723
Net assets		7,781,908	5,870,945	6,113,446
EQUITY				
Equity attributable to owners of the parent				
Share capital	37	1,247,202	1,247,202	1,247,202
Reserves	38	6,534,706	4,623,743	4,866,244
Total equity		7,781,908	5,870,945	6,113,446

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

The Company is a joint stock company with limited liability established in the People’s Republic of China (hereafter, the “PRC”) on 21 April 1998. With the approval of the China Securities Regulatory Commission, the Company completed its initial public offering and was listed on the Shenzhen Stock Exchange (stock code: 002399.SZ) on 6 May 2010. The registered address of the office of the Company is No.21 Langshan Road, Nanshan District, Shenzhen. The Company is ultimately controlled by Mr. Li Li and Ms. Li Tan who are acting in concert.

The Company and its subsidiaries (collectively referred to as the “Group”) are principally engaged in biopharmaceutical production, biopharmaceutical services, biopharmaceutical trading and biopharmaceutical research and development in Asia, Europe, North America and Australia, and investment business in Asia and North America.

As of the date of this report, the Company had direct and indirect interests in its subsidiaries, all of which are private limited liability companies, the particulars of which are set out below:

Name	Notes	Date and place of incorporation/ registration and place of operations	Issued ordinary share/registered capital	Percentage of equity attributable to the Company		Principal activities
				Direct	Indirect	
成都深瑞畜產品有限公司 Chengdu Sunrace Co., Ltd*	(a)	PRC/Mainland China 19 November 2009	RMB 200,000,000	96%	—	Production and sale of heparin sodium
山東瑞盛生物技術有限公司 Shandong Ruisheng Biotechnology Co., Ltd*	(a)	PRC/Mainland China 15 July 2010	RMB 30,000,000	100%	—	Production and sale of heparin sodium
深圳朋和物業管理有限公司 Shenzhen Penghe Property Management Co., Ltd*	(a)	PRC/Mainland China 13 June 2011	RMB 132,000,000	55%	—	Property management operation
深圳市坪山新區海普瑞藥業有限公司 Shenzhen Pingshan New District Hepalink Pharmaceutical Co., Ltd*	(a)	PRC/Mainland China 29 July 2013	RMB 120,000,000	100%	—	Biopharmaceutical production; biopharmaceutical services; and biopharmaceutical R&D
深圳市德康投資發展有限公司 Shenzhen Dekang Investment Development Co., Ltd*	(a)	PRC/Mainland China 23 March 2015	RMB 10,000,000	100%	—	Equity investment; investment management and consulting
深圳市返璞生物技術有限公司 Shenzhen Fanpu Biotechnology Co., Ltd.*	(a)	PRC/Mainland China 25 February 2015	RMB 1,000,000	66%	—	Biopharmaceutical technology development and consulting
海普瑞（香港）有限公司 Hepalink（Hong Kong） Limited*	(b)	Hong Kong 23 November 2010	HK 330,221,445	100%	—	Investment holding; trading of medical products
Hepalink Europe AB	(g)	Sweden 1 February 2010	SEK100,000	—	100%	Investment holding

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

1. CORPORATE INFORMATION—continued

Name	Notes	Date and place of incorporation/ registration and place of operations	Issued ordinary share/registered capital	Percentage of equity attributable to the Company		Principal activities
				Direct	Indirect	
Hepalink USA INC.	(g)	USA 25 October 2013	10,000 shares	100%	—	Production and sale of active pharmaceutical ingredients
SPL Acquisition Corp. (“SPL”)	(c)	USA 13 July 2006	500,000 shares	—	100%	Production of active pharmaceutical ingredients; manufacture of pancreatin
Scientific Protein Laboratories LLC	(g)	USA 22 January 2004	1,000 shares	—	100%	Biopharmaceutical production and sales
Mobren Logistics L.L.C.	(g)	USA 22 December 2003	1 share	—	100%	Biopharmaceutical production and sales
Mobren Transport Inc.	(g)	USA 23 December 1997	1,000 shares	—	100%	Biopharmaceutical production and sales
Novahealth Biosystems, LLC	(g)	USA 24 March 2016	1 share	—	100%	Biopharmaceutical R&D
Pharma Bridge International LLC	(g)	USA 28 November 2012	1 share	—	100%	Biopharmaceutical sales
SPL Distribution Holdings LLC	(g)	USA 26 December 2017	1 share	—	100%	Biopharmaceutical sales
SPL Distribution LLC	(g)	USA 26 December 2017	1 share	—	100%	Biopharmaceutical sales
Cytovance Biologics, Inc	(c)	USA 19 September 2005	5,000 shares	—	100%	Biopharmaceutical contract manufacturing and development
深圳市北地奧科科技開發有限公司 Shenzhen Beidi Aoke Technology Development Co., Ltd.*	(a)	PRC/Mainland China 19 July 2002	RMB 10,000,000	100%	—	Biopharmaceutical technology development
深圳楓海資本股權投資基金合夥企業 (有限合夥) Shenzhen Maple Sea Capital Equity Investment Fund Partnership (Limited Partnership)*	(g)	PRC/Mainland China 10 April 2015	RMB 250,000,000	99%	—	Equity investment; venture investment; investment consulting and management
深圳昂瑞生物醫藥技術有限公司 Shenzhen OncoVent Co., Ltd.*	(a)	PRC/Mainland China 26 July 2016	USD9,259,300	54%	—	Biopharmaceutical R&D

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

1. CORPORATE INFORMATION—continued

Name	Notes	Date and place of incorporation/ registration and place of operations	Issued ordinary share/registered capital	Percentage of equity attributable to the Company		Principal activities
				Direct	Indirect	
OncoVent USA Inc.	(g)	USA 11 August 2016	20,000 shares	—	54%	Biopharmaceutical R&D
深圳市瑞迪生物醫藥有限公司 Shenzhen Arimeb Biomedical Co., Ltd.*	(d)	PRC/Mainland China 2 July 2018	USD14,117,647	51%	—	Biopharmaceutical production, sales and R&D
Arimab USA Inc.	(f)	USA 10 December 2018	100 shares	—	51%	Biopharmaceutical R&D
深圳市多普樂實業發展有限公司 Shenzhen Topknow Industrial Development Co., Ltd.*	(e)	PRC/Mainland China 7 June 2000	RMB 230,000,000	100%	—	Biopharmaceutical R&D
深圳市天道醫藥有限公司 Shenzhen Techdow Pharmaceutical Co., Ltd.*	(e)	PRC/Mainland China 29 June 2004	RMB 150,000,000	—	100%	Biopharmaceutical R&D
Techdow (Hong Kong) Limited	(b)	Hong Kong 22 May 2013	HK 233,960,000	—	100%	Investment holding; trading of medical products
Techdow Europe AB	(g)	Sweden 12 June 2014	SEK100,000	—	100%	Trading of medical products
宇科（上海）醫藥科技有限公司 Histar (Shanghai) Co., Ltd.*	(a)	PRC/Mainland China 5 March 2012	RMB1,000,000	—	100%	Provision of services on pharmaceutical related activities
Techdow Pharma Poland Sp.zo.o.	(g)	Poland 12 October 2016	PLN50,000	—	100%	Trading of medical products
Techdow Pharma Netherlands B.V.	(g)	Netherlands 6 June 2017	EUR480	—	100%	Trading of medical products
TD Pharma B.V.	(g)	Netherlands 22 November 2016	EUR480	—	100%	Investment holding
Techdow Pharma England Limited	(g)	England 6 December 2016	EUR1,000	—	100%	Trading of medical products
Techdow Pharma Spain,S.L.	(g)	Spain 23 January 2017	EUR3,000	—	100%	Trading of medical products
Techdow Pharma Germany GmbH	(g)	Germany 13 December 2016	EUR25,000	—	100%	Trading of medical products
Techdow Pharma Italy S.R.L.	(g)	Italy 4 April 2017	EUR10,000	—	100%	Trading of medical products
Techdow Pharma France SARL	(g)	France 5 June 2017	EUR5,000	—	100%	Trading of medical products
Techdow Pharma Switzerland GmbH	(g)	Switzerland 23 March 2017	CHF20,000	—	100%	Trading of medical products

* The English names of these subsidiaries registered in the PRC represent the translated names of these companies as no English names have been registered.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

1. CORPORATE INFORMATION—continued

Notes:

- (a) The statutory financial statements of these entities for the years ended 31 December 2017 and 2018 prepared in accordance with PRC accounting principles and regulations were audited by RuiHua Certified Public Accountants, a certified public accounting firm registered in the PRC.
- (b) The statutory financial statements of these entities for the years ended 31 December 2017 and 2018 prepared in accordance with Hong Kong Financial Reporting Standards were audited by CH CPA & Co., a certified public accounting firm registered in Hong Kong.
- (c) The statutory financial statements of SPL Acquisition Corp. and Cytovance Biologics, Inc. for the years ended 31 December 2017 and 2018 prepared in accordance with the accounting principles generally accepted in the United States of America (the “US GAAP”) were audited by RSM US LLP, a certified public accountant registered in the USA.
- (d) The entity was established in 2018. The statutory financial statements for the period from their respective dates of establishment to 31 December 2018 prepared in accordance with PRC accounting principles and regulations were audited by RuiHua Certified Public Accountants, a certified public accounting firm registered in the PRC.
- (e) These entities have not appointed an auditor to issue statutory financial statements for the year ended 31 December 2017. The statutory financial statements of these entities for the year ended 31 December 2018 prepared in accordance with PRC accounting principles and regulations were audited by RuiHua Certified Public Accountants, a certified public accounting firm registered in the PRC.
- (f) The entity was established in 2018 and the entity has not appointed an auditor to issue statutory financial statements for the year ended 31 December 2018.
- (g) These entities have not appointed auditors to issue statutory financial statements for the years ended 31 December 2017 and 2018.

The changes in the Company’s subsidiaries during the Relevant Periods are as follows:

The following companies were disposed/deem disposed and cancelled by the Group during the Relevant Periods. Details in relation to the disposal are set out in note 42 and note 18 to the Historical Financial Information. The financial results of these companies were included in the Group’s consolidated financial statements until the date of disposal.

Name	Date and place of incorporation/ registration and place of operations	Issued ordinary share/registered capital	Percentage of equity attributable to the Company		Principal activities
			Direct	Indirect	
成都市海通藥業有限公司 Chengdu Hepatunn Pharmaceutical Co., Ltd*	Mainland China 7 December 2010	RMB 40,000,000	85%	—	Biopharmaceutical production, sales and R&D
Hightide Therapeutics, Inc	Cayman Islands 28 February 2018	USD 50,000	55%	—	Biopharmaceutical R&D
Hightide Therapeutics (Hong Kong) Limited	Hong Kong 9 April 2018	1 share	—	55%	Biopharmaceutical R&D
Hightide Therapeutics	British Virgin Islands 16 March 2018	100 shares	—	55%	Biopharmaceutical R&D
深圳君聖泰生物技術有限公司 Shenzhen Hightide Biopharmaceutical Co., Ltd*	Mainland China 15 November 2011	RMB 42,000,000	—	55%	Biopharmaceutical R&D
上海君聖泰生物技術有限公司 Shanghai Hightide Biopharmaceutical Co., Ltd*	Mainland China 14 March 2014	RMB 5,000,000	—	55%	Biopharmaceutical R&D
Hightide Biopharma Pty Ltd.	Australia 11 June 2015	AUD 1,000	—	55%	Biopharmaceutical R&D
深圳君聖康生物技術有限公司 Shenzhen Junshengkang Biopharmaceutical Co., Ltd.*	Mainland China 21 July 2015	RMB 5,000,000	—	55%	Biopharmaceutical R&D

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

1. CORPORATE INFORMATION—continued

<u>Name</u>	<u>Date and place of incorporation/ registration and place of operations</u>	<u>Issued ordinary share/registered capital</u>	<u>Percentage of equity attributable to the Company</u>		<u>Principal activities</u>
			<u>Direct</u>	<u>Indirect</u>	
H3 Life Science Corporation	USA 27 September 2011	100 shares	—	100%	Biopharmaceutical production, sales and R&D
Histar PTE. Ltd.	Singapore 11 October 2011	SGD 200,000	100%	—	Biopharmaceutical sales and R&D

* The English names of these subsidiaries registered in the PRC represent the translated names of these companies as no English names have been registered.

2.1 BASIS OF PREPARATION

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (the “IASB”).

All IFRSs effective for the accounting period commencing on/before 1 January 2019, including IFRS 9 *Financial Instruments*, IFRS 15 *Revenue from Contracts with Customers*, and IFRS 16 *Leases*, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods and in the period covered by the Interim Financial Information.

The Historical Financial Information has been prepared under the historical cost convention, except for equity investments designated at fair value through other comprehensive income, derivative financial instruments and financial assets at fair value through profit or loss which have been measured at fair value.

Basis of consolidation

The consolidated financial statements include the financial statements of the Group for the Relevant Periods. A subsidiary is an entity directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

When the Company has, directly or indirectly, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group’s voting rights and potential voting rights.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.1 BASIS OF PREPARATION—continued

Basis of consolidation—continued

The financial statements of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognizes (i) the assets (including goodwill) and liabilities of the subsidiary, (ii) the carrying amount of any non-controlling interest and (iii) the cumulative translation differences recorded in equity; and recognizes (i) the fair value of the consideration received, (ii) the fair value of any investment retained and (iii) any resulting surplus or deficit in profit or loss. The Group’s share of components previously recognized in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

On 31 May 2018, the Group acquired the entire equity interest in Shenzhen Topknow Industrial Development Co., Ltd. As both the Company and Shenzhen Topknow Industrial Development Co., Ltd. are ultimately controlled by Mr. Li Li and Ms. Li Tan, the Company applied the pooling of interests method, which involves incorporating the financial statement items of the combining entities or businesses which underwent the business combination under common control as if they had been combined from the date when the combining entities or businesses first came under the control of the controlling party. Accordingly, the consolidated financial statements are prepared as if Shenzhen Topknow Industrial Development Co., Ltd. had been combined throughout the Relevant Periods. The business combination is further detailed in note 41 to the Historical Financial Information.

2.2 ISSUED BUT NOT YET EFFECTIVE HONG KONG FINANCIAL REPORTING STANDARDS

The Group has not applied the following new and revised IFRSs that have been issued but are not yet effective, in the Historical Financial Information.

Amendments to IFRS 3	<i>Definition of a Business</i> ¹
Amendments to IFRS 10 and IAS 28 (2011)	<i>Sale or Contribution of Assets between an Investor and its Associate or and IAS 28 (2011) Joint Venture</i> ³
IFRS 17	<i>Insurance Contracts</i> ²
Amendments to IAS 1 and IAS 8	<i>Definition of Material</i> ¹

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.2 ISSUED BUT NOT YET EFFECTIVE HONG KONG FINANCIAL REPORTING STANDARDS—continued

- 1 Effective for annual periods beginning on or after 1 January 2020
- 2 Effective for annual periods beginning on or after 1 January 2021
- 3 No mandatory effective date yet determined but available for adoption

The Group is in the process of making an assessment of the impact of these new and revised IFRSs upon initial application. So far, the Group has expected that these standards will not have significant effect on the Group’s financial performance and financial position.

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Investments in associates

An associate is an entity in which the Group has a long-term interest of generally but not necessary not less than 20% of the equity voting rights and over which it is in a position to exercise significant influence. Significant influence is the power to participate in the financial and operating policy decisions of the investee, but is not control over those policies.

The Group’s investments in associates are stated in the consolidated statements of financial position at the Group’s share of net assets under the equity method of accounting, less any impairment losses. Adjustments are made to bring into line any dissimilar accounting policies that may exist.

The Group’s share of the post-acquisition results and other comprehensive income of associates is included in the consolidated statements of profit or loss and consolidated statements of comprehensive income, respectively. In addition, when there has been a change recognized directly in the equity of the associate, the Group recognizes its share of any changes, when applicable, in the consolidated statements of changes in equity. Unrealised gains and losses resulting from transactions between the Group and its associates are eliminated to the extent of the Group’s investments in the associates, except where unrealised losses provide evidence of an impairment of the assets transferred. Goodwill arising from the acquisition of associates is included as part of the Group’s investments in associates.

Upon loss of significant influence over the associates, the Group measures and recognizes any retained investments at their fair values. Any difference between the carrying amounts and the fair values of the retained investment and proceeds from disposal is recognized in profit or loss.

When an investment in an associate is classified as held for sale, it is accounted for in accordance with IFRS 5 *Non-current Assets Held for Sale and Discontinued Operation*.

Business combinations and goodwill

Business combinations are accounted for using the acquisition method except for business combination under common control. The consideration transferred is measured at the acquisition date fair value which is the sum of the acquisition date fair values of assets transferred by the Group, liabilities assumed by the Group to the former owners of the acquiree and the equity interests issued by the Group in exchange for control of the acquiree. For each business combination, the Group elects whether to measure the non-controlling interests in the acquiree that are present ownership interests

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Business combinations and goodwill—continued

and entitle their holders to a proportionate share of net assets in the event of liquidation at fair value or at the proportionate share of the acquiree’s identifiable net assets. All other components of non-controlling interests are measured at fair value. Acquisition-related costs are expensed as incurred.

When the Group acquires a business, it assesses the financial assets and liabilities assumed for appropriate classification and designation in accordance with the contractual terms, economic circumstances and pertinent conditions as at the acquisition date. This includes the separation of embedded derivatives in host contracts of the acquiree.

If the business combination is achieved in stages, the previously held equity interest is remeasured at its acquisition date fair value and any resulting gain or loss is recognized in profit or loss.

Any contingent consideration to be transferred by the acquirer is recognized at fair value at the acquisition date. Contingent consideration classified as an asset or liability is measured at fair value with changes in fair value recognized in profit or loss. Contingent consideration that is classified as equity is not remeasured and subsequent settlement is accounted for within equity.

An acquisition of a business which is a business combination under common control is accounted for in a manner similar to a uniting of interests whereby the assets and liabilities acquired are accounted for at carryover predecessor values to the other party to the business combination within all periods presented as if the operations of the Group and the business acquired have always been combined. The difference between the consideration paid by the Group and the net assets or liabilities of the business acquired is adjusted against equity. Contingent consideration from the business combination under common control is recognised in equity.

Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred, the amount recognized for non-controlling interests and any fair value of the Group’s previously held equity interests in the acquiree over the identifiable net assets acquired and liabilities assumed. If the sum of this consideration and other items is lower than the fair value of the net assets acquired, the difference is, after reassessment, recognized in profit or loss as a gain on bargain purchase.

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. Goodwill is tested for impairment annually or more frequently if events or changes in circumstances indicate that the carrying value may be impaired. The Group performs its annual impairment test of goodwill as at 31 December. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the Group’s cash-generating units, or groups of cash-generating units, that are expected to benefit from the synergies of the combination, irrespective of whether other assets or liabilities of the Group are assigned to those units or groups of units.

Impairment is determined by assessing the recoverable amount of the cash-generating unit (group of cash-generating units) to which the goodwill relates. Where the recoverable amount of the

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Business combinations and goodwill—continued

cash-generating unit (group of cash-generating units) is less than the carrying amount, an impairment loss is recognized. An impairment loss recognized for goodwill is not reversed in a subsequent period.

Where goodwill has been allocated to a cash-generating unit (or group of cash-generating units) and part of the operation within that unit is disposed of, the goodwill associated with the operation disposed of is included in the carrying amount of the operation when determining the gain or loss on the disposal. Goodwill disposed of in these circumstances is measured based on the relative value of the operation disposed of and the portion of the cash-generating unit retained.

Fair value measurement

The Group measures its equity investments designated at fair value through other comprehensive income, derivative financial instruments and financial assets at fair value through profit or loss at the end of each Relevant Period. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
- Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognized in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Relevant Periods.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than inventories, construction contract assets and financial assets), the asset's recoverable amount is estimated. An asset's recoverable amount is the higher of the asset's or cash-generating unit's value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case, the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognized only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to the statements of profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each of the Relevant Periods as to whether there is an indication that previously recognized impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognized impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortization) had no impairment loss been recognized for the asset in prior years. A reversal of such an impairment loss is credited to the statement of profit or loss in the period in which it arises.

Related parties

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person's family and that person
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or of a parent of the Group;

or

- (b) the party is an entity where any of the following conditions applies:
 - (i) the entity and the Group are members of the same group;
 - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);
 - (iii) the entity and the Group are joint ventures of the same third party;
 - (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Related parties—continued

- (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
- (vi) the entity is controlled or jointly controlled by a person identified in (a);
- (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
- (viii) the entity, or any member of a group of which it is a part, provides key management personal services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to the statement of profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalized in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognizes such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Buildings	2.375%-4.75%
Machine equipment	19%-9.5%
Motor vehicles	19%-9.5%
Other equipment	19%-9.5%
Leasehold improvements	2.5%-33.3%

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation method are reviewed, and adjusted if appropriate, at least at each financial year end.

An item of property, plant and equipment including any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognized in the statement of profit or loss in the year the asset is derecognized is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents a building under construction, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of construction and

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Property, plant and equipment and depreciation—continued

capitalised borrowing costs on related borrowed funds during the period of construction. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

Other intangible assets (other than goodwill)

Other intangible assets acquired separately are measured on initial recognition at cost. The cost of other intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of other intangible assets are assessed to be either finite or indefinite. Other intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the other intangible assets may be impaired. The amortization period and the amortization method for other intangible assets with a finite useful life are reviewed at least at each financial year end.

Other intangible assets with indefinite useful lives are tested for impairment annually either individually or at the cash-generating unit level. Such other intangible assets are not amortized. The useful life of other intangible assets with an indefinite life is reviewed annually to determine whether the indefinite life assessment continues to be supportable. If not, the change in the useful life assessment from indefinite to finite is accounted for on a prospective basis.

Patents and licences

Purchased patents and licences are stated at cost less any impairment losses and are amortized on the straight-line basis over their estimated useful lives of 10 to 15 years.

Computer software

Acquired computer software is stated at historical cost less amortization. Acquired computer software is capitalized on the basis of the costs incurred to acquire and bring to use the specific software, and is amortized on a straight-line basis over the useful life of 5 years.

Trademarks

Trademarks are initially recognized and measured at costs incurred to register. The costs are amortized on the straight-line basis over their estimated useful lives of 5 years.

Proprietary technologies

Proprietary technologies invested by minority shareholders are recognized at fair values assessed at the investment day or cost of getting the medicine licences from the related authorities. Proprietary technologies are amortised on the straight-line basis over the respective estimated useful lives of 20-30 years, and the useful lives of the proprietary technologies are assessed by the Group after considering the useful lives of similar technologies and the market condition.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Other intangible assets (other than goodwill)—continued

Brands

Brands acquired in a business combination are recognized at fair value at the acquisition date. The brands have a finite useful life and are carried at cost less accumulated amortization. Amortization is calculated using the straight-line method over the expected life of 15 years for the brands.

Customer relationships

Customer relationships acquired in a business combination are recognized at fair value at the acquisition date. The contractual customer relationships have a finite useful life and are carried at cost less accumulated amortization. Amortization is calculated using the straight-line method over the expected life of 15 years for the customer relationships.

Research and development costs

All research costs are charged to the statement of profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalized and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the Group’s ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Leases

Right-of-use assets

The Group recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term. Right-of-use assets are subject to impairment.

Lease liabilities

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for terminating a lease, if the lease term reflects the Group exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognized as an expense in the period in which the event or condition that triggers the payment occurs.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Leases—continued

Lease liabilities—continued

In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases that are considered of low value (i.e., below US\$5,000). Lease payments on short-term leases and leases of low-value assets are recognized as an expense on a straight-line basis over the lease terms.

Determining the lease term of contracts with renewal options

The Group determines the lease term as the non-cancellable term of the lease, together with any periods covered by an option to extend the lease if it is reasonably certain to be exercised, or any periods covered by an option to terminate the lease, if it is reasonably certain not to be exercised.

The Group applies judgement in evaluating whether it is reasonably certain to exercise the option to renew. That is, it considers all relevant factors that create an economic incentive for it to exercise the renewal. After the commencement date, the Group reassesses the lease term if there is a significant event or change in circumstances that is within its control and affects its ability to exercise (or not to exercise) the option to renew (e.g., a change in business strategy).

Financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortized cost, fair value through other comprehensive income and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient, the Group initially measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Financial assets—continued

Initial recognition and measurement—continued

In order for a financial asset to be classified and measured at amortized cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“SPPI”) on the principal amount outstanding.

The Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both.

All regular way purchases and sales of financial assets are recognized on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortized cost (debt instruments)

The Group measures financial assets at amortized cost if both of the following conditions are met:

- The financial asset is held within a business model with the objective to hold financial assets in order to collect contractual cash flows.
- The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets at amortized cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognized in the statement of profit or loss when the asset is derecognized, modified or impaired.

Financial assets designated at fair value through other comprehensive income (equity investments)

Upon initial recognition, the Group can elect to classify irrevocably its equity investments as equity investments designated at fair value through other comprehensive income when they meet the definition of equity under IAS 32 *Financial Instruments: Presentation* and are not held for trading. The classification is determined on an instrument-by-instrument basis.

Gains and losses on these financial assets are never recycled to the statement of profit or loss. Dividends are recognized as other income in the statement of profit or loss when the right of payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably, except when the Group benefits from such proceeds as a recovery of part of the cost of the financial asset, in which case, such gains are recorded in other comprehensive income. Equity investments designated at fair value through other comprehensive income are not subject to impairment assessment.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Financial assets—continued

Financial assets at fair value through profit or loss

Financial assets at fair value through profit or loss include financial assets held for trading, financial assets designated upon initial recognition at fair value through profit or loss, or financial assets mandatorily required to be measured at fair value. Financial assets are classified as held for trading if they are acquired for the purpose of selling or repurchasing in the near term. Derivatives, including separated embedded derivatives, are also classified as held for trading unless they are designated as effective hedging instruments. Financial assets with cash flows that are not solely payments of principal and interest are classified and measured at fair value through profit or loss, irrespective of the business model. Notwithstanding the criteria for debt instruments to be classified at amortized cost or at fair value through other comprehensive income, as described above, debt instruments may be designated at fair value through profit or loss on initial recognition if doing so eliminates, or significantly reduces, an accounting mismatch.

Financial assets at fair value through profit or loss are carried in the statement of financial position at fair value with net changes in fair value recognized in the statement of profit or loss.

This category includes derivative instruments and equity investments which the Group had not irrevocably elected to classify at fair value through other comprehensive income. Dividends on equity investments classified as financial assets at fair value through profit or loss are also recognized as other income in the statement of profit or loss when the right of payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably.

A derivative embedded in a hybrid contract, with a financial liability or non-financial host, is separated from the host and accounted for as a separate derivative if the economic characteristics and risks are not closely related to the host; a separate instrument with the same terms as the embedded derivative would meet the definition of a derivative; and the hybrid contract is not measured at fair value through profit or loss. Embedded derivatives are measured at fair value with changes in fair value recognized in the statement of profit or loss. Reassessment only occurs if there is either a change in the terms of the contract that significantly modifies the cash flows that would otherwise be required or a reclassification of a financial asset out of the fair value through profit or loss category.

A derivative embedded within a hybrid contract containing a financial asset host is not accounted for separately. The financial asset host together with the embedded derivative is required to be classified in its entirety as a financial asset at fair value through profit or loss.

Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognized (i.e., removed from the Group’s consolidated statement of financial position) when:

- The rights to receive cash flows from the asset have expired; or

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Derecognition of financial assets—continued

- The Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a ‘pass-through’ arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset, nor transferred control of the asset, the Group continues to recognize the transferred asset to the extent of its continuing involvement. In that case, the Group also recognizes an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognizes an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

General approach

ECLs are recognized in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At each reporting date, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information.

The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Impairment of financial assets—continued

General approach—continued

external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial assets at amortized cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables which apply the simplified approach as detailed below.

Stage 1 – Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs

Stage 2 – Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs

Stage 3 – Financial assets that are credit-impaired at the reporting date (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs

Simplified approach

For trade receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group’s financial liabilities include trade and bills payables, other payables, interest-bearing bank and other borrowings, amounts due to related parties and lease liabilities.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Financial liabilities—continued

Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

(i) Loans and borrowings

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost, using the effective interest rate method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognized in the statement of profit or loss when the liabilities are derecognized as well as through the effective interest rate amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortization is included in finance costs in the statement of profit or loss.

(ii) Financial guarantee contracts

Financial guarantee contracts issued by the Group are those contracts that require a payment to be made to reimburse the holder for a loss it incurs because the specified debtor fails to make a payment when due in accordance with the terms of a debt instrument. A financial guarantee contract is recognized initially as a liability at its fair value, adjusted for transaction costs that are directly attributable to the issuance of the guarantee. Subsequent to initial recognition, the Group measures the financial guarantee contracts at the higher of: (i) the ECL allowance determined in accordance with the policy as set out in “Impairment of financial assets”; and (ii) the amount initially recognized less, when appropriate, the cumulative amount of income recognized.

Derecognition of financial liabilities

A financial liability is derecognized when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognized in the statement of profit or loss.

Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognized amounts and there is an intention to settle on a net basis, or to realise the assets and settle the liabilities simultaneously.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Derivative financial instruments

Initial recognition and subsequent measurement

The Group uses derivative financial instruments, such as warrants. Such derivative financial instruments are initially recognized at fair value on the date on which a derivative contract is entered into and are subsequently remeasured at fair value. Derivatives are carried as assets when the fair value is positive and as liabilities when the fair value is negative.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the first-in, first-out basis and, in the case of work in progress and finished goods, comprises direct materials, direct labour and an appropriate proportion of overheads. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Cash and cash equivalents

For the purpose of the consolidated statements of cash flows, cash and cash equivalents comprise cash on hand and demand deposits, and short term highly liquid investments that are readily convertible into known amounts of cash, are subject to an insignificant risk of changes in value, and have a short maturity of generally within three months when acquired, less bank overdrafts which are repayable on demand and form an integral part of the Group’s cash management.

For the purpose of the consolidated statements of financial position, cash and cash equivalents comprise cash on hand and at banks, including term deposits, and assets similar in nature to cash, which are not restricted as to use.

Provisions

A provision is recognized when a present obligation (legal or constructive) has arisen as a result of a past event and it is probable that a future outflow of resources will be required to settle the obligation, provided that a reliable estimate can be made of the amount of the obligation.

When the effect of discounting is material, the amount recognized for a provision is the present value at the end of the reporting period of the future expenditures expected to be required to settle the obligation. The increase in the discounted present value amount arising from the passage of time is included in finance costs in the statement of profit or loss.

Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognized outside profit or loss is recognized outside profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods, taking into consideration interpretations and practices prevailing in the countries in which the Group operates.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Income tax—continued

Deferred tax is provided, using the liability method, on all temporary differences at the end of each of the Relevant Periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries and associates, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of deductible temporary differences associated with investments in subsidiaries and associates, deferred tax assets are only recognized to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each of the Relevant Periods and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognized deferred tax assets are reassessed at the end of each of the Relevant Periods and are recognized to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Government grants

Government grants are recognized at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the costs, which it is intended to compensate, are expensed.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset by equal annual instalments or deducted from the carrying amount of the asset and released to profit or loss by way of a reduced depreciation charge.

Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

When the contract contains a financing component which provides the customer a significant benefit of financing the transfer of goods or services to the customer for more than one year, revenue is measured at the present value of the amount receivable, discounted using the discount rate that would be reflected in a separate financing transaction between the Group and the customer at contract inception. When the contract contains a financing component which provides the Group a significant financial benefit for more than one year, revenue recognized under the contract includes the interest expense accreted on the contract liability under the effective interest method. For a contract where the period between the payment by the customer and the transfer of the promised goods or services is one year or less, the transaction price is not adjusted for the effects of a significant financing component, using the practical expedient in IFRS 15.

(a) Sale of products

Revenue from the sale of products is recognized at the point in time when control of the asset is transferred to the customer, generally on delivery of the products.

Some contracts for the sale of products provide customers with rights of return. The rights of return give rise to variable consideration.

(b) Contract development and manufacturing organization (“CDMO”) services

The Group earns revenues by providing research services to its customers through Fee-for-service (“FFS”) contracts. Contract duration ranges from a few months to years. Under the

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Revenue recognition—continued

Revenue from contracts with customers—continued

FFS model, the contracts usually have multiple task units, which are generally in the form of technical laboratory reports and/or samples, each of which is with an individual selling price specified within the contract. The Group identifies each task unit as a separate performance obligation. The revenue is recognized over time, as the Group’s performance has created an asset with no alternative use and the Group has an enforceable right for payments for performance completed to date. The selection of the method to measure progress towards completion requires judgement and is based on the nature of the products or services to be provided. Depending on which better depicts the transfer of value to the customer, the Group generally measures its progress using cost-to-cost (input method).

Under the input method, the Group uses the known cost measure of progress when it best depicts the transfer of value to the customer which occurs as the Group incurs costs on its contract, under the cost-to-cost measure of progress, the extent of progress towards completion is measured based on the ratio of costs incurred to date to the total estimated costs at completion of the performance obligation. Revenue is recorded proportionally as costs are incurred.

The Group also engages in contracts by the commercial manufacture and sale of products under customers’ specific order. The Group recognised revenue at a point in time upon acceptance of the deliverable products under customers’ specific order.

Other income

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Dividend income is recognized when the shareholders’ right to receive payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably.

Contract liabilities

A contract liability is the obligation to transfer goods or services to a customer for which the Group has received a consideration (or an amount of consideration that is due) from the customer. If a customer pays the consideration before the Group transfers goods or services to the customer, a contract liability is recognized when the payment is made or the payment is due (whichever is earlier). Contract liabilities are recognized as revenue when the Group performs under the contract.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Employee Benefits

Share-based payments

The Company operates share award scheme for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. Employees (including directors) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (“equity-settled transactions”).

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date on which they are granted. The fair value is computed based on their most recent post-money valuations. The cost of equity-settled transactions is recognized in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of each of the Relevant Periods until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will ultimately vest. The charge or credit to the consolidated statement of profit or loss for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period.

Cash-settled scheme

The cost of cash-settled transactions is measured initially at the best estimate of the settlement amounts at the settlement date, taking into account the terms and conditions upon which the instruments were granted (note 35). The best estimate of the settlement amounts is expensed over the period until the vesting date with recognition of a corresponding liability. The liability should be spread on a straight-line basis over the full vesting period. The cumulative expense recognized for cash-settled transactions at the end of each reporting period until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of awards that will ultimately vest. The liability is measured at the end of each reporting period up to and including the settlement date, with changes in best estimate of the settlement amounts at the settlement date recognized in the statement of profit or loss.

Pension scheme

The employees of the Group’s subsidiaries which operates in Mainland China are required to participate in a central pension scheme operated by the local municipal government. These subsidiaries are required to contribute a certain percentage of its payroll costs to the central pension scheme. The contributions are charged to the statement of profit or loss as they become payable in accordance with the rules of the central pension scheme.

The Group contributes on a monthly basis to various defined contribution plans organized by the relevant governmental authorities in various areas other than Mainland China. The Group’s liability in respect of these plans is limited to the contributions payable at the end of each period. Contributions to these plans are expensed as incurred.

Housing fund—Mainland China

The Group contributes on a monthly basis to a defined contribution housing fund plan operated by the local municipal government. Contributions to this plan by the Group are expensed as incurred.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Employee Benefits—continued

Defined benefit retirement plan obligations

The Group’s net obligation in respect of defined benefit retirement plans is calculated separately for each plan by estimating the amount of future benefit that employees have earned in return for their services in the current and prior periods; that benefit is discounted to determine the present value, and the fair value of any plan assets is deducted. The calculation is performed by a qualified actuary using the projected unit credit method. When the calculation results in a benefit to the Group, the recognized asset is limited to the present value of economic benefits available in the form of any future refunds from the plan or reductions in future contributions to the plan.

Service cost and net interest expense/(income) on the net defined benefit liability/(asset) are recognized in profit or loss and allocated by function as part of “cost of sales”, “selling and distribution expenses” or “administrative expenses”. Current service cost is measured as the increase in the present value of the defined benefit obligation resulting from employee service in the current period. When the benefits of a plan are changed, or when a plan is curtailed, the portion of the changed benefit related to the past service provided by employees, or the gain or loss on curtailment, is recognized as an expense in profit or loss at the earlier of when the plan amendment or curtailment occurs and when related restructuring costs or termination benefits are recognized. Net interest expense/(income) for the period is determined by applying the discount rate used to measure the defined benefit obligation at the beginning of the reporting period on high quality corporate bonds that have maturity dates approximating the terms of the Group’s obligations.

Remeasurements arising from defined benefit retirement plans are recognized in other comprehensive income. Remeasurements comprise actuarial gains and losses, the return on plan assets (excluding amounts included in net interest on the net defined benefit liability/(asset)) and any change in the effect of the asset ceiling (excluding amounts included in net interest on the net defined benefit liability/(asset)).

Borrowing costs

Borrowing costs directly attributable to the acquisition, construction or production of qualifying assets, i.e., assets that necessarily take a substantial period of time to get ready for their intended use or sale, are capitalized as part of the cost of those assets. The capitalization of such borrowing costs ceases when the assets are substantially ready for their intended use or sale. Investment income earned on the temporary investment of specific borrowings pending their expenditure on qualifying assets is deducted from the borrowing costs capitalized. All other borrowing costs are expensed in the period in which they are incurred. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

Dividends

Final dividends are recognized as a liability when they are approved by the shareholders in a general meeting. Proposed final dividends are disclosed in note 12 to the Historical Financial Information.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES—continued

Foreign currencies

The Historical Financial Information is presented in RMB, which is the Company’s functional currency. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of the reporting period. Differences arising on settlement or translation of monetary items are recognized in the statement of profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognized in other comprehensive income or profit or loss is also recognized in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognizes the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

The functional currencies of certain overseas subsidiaries and associates are currencies other than the RMB. As at the end of the reporting period, the assets and liabilities of these entities are translated into the presentation currency of the Company at the exchange rates prevailing at the end of the reporting period and their statements of profit or loss are translated into RMB at the weighted average exchange rates for the year.

The resulting exchange differences are recognized in other comprehensive income and accumulated in the exchange fluctuation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognized in the statement of profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising on acquisition are treated as assets and liabilities of the foreign operation and translated at the closing rate.

For the purpose of the consolidated statement of cash flows, the cash flows of overseas subsidiaries are translated into RMB at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of overseas subsidiaries which arise throughout the year are translated into RMB at the weighted average exchange rates for the year.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group’s Historical Financial Information requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Judgements

In the process of applying the Group’s accounting policies, management has made the following judgements, apart from those involving estimations, which have the most significant effect on the amounts recognized in the Historical Financial Information:

Determining the timing of satisfaction of performance obligations

The Group has different contractual arrangements with different customers. In determining the timing of satisfaction of performance obligations, management reviews the contract terms of each individual contract.

For certain types of revenue under the FFS model, the directors of the Company have determined that performance obligations are satisfied over time. Significant judgement is required in determining whether the terms of the Group’s contracts with customers in relation to certain types of revenue under the FFS model create an enforceable right to payment for the Group.

Determining the method for measuring progress towards complete satisfaction of performance obligations

Depending on which better depicts the transfer of value to the customer, the directors of the Company make judgement to measure the progress of the projects using input method.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each of the Relevant Periods, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are discussed below.

Impairment of goodwill

The Group determines whether goodwill is impaired at least on an annual basis. This requires an estimation of the value in use of the cash-generating units to which the goodwill is allocated. Estimating the value in use requires the Group to make an estimate of the expected future cash flows from the cash-generating units and also to choose a suitable discount rate in order to calculate the present value of those cash flows. The carrying amounts of goodwill at 31 December 2017, 2018 and 30 September 2019 were RMB2,205,705,000, RMB2,316,763,000, and RMB2,387,550,000, respectively. Further details are given in note 16 to the Historical Financial Information.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES—continued

Estimation uncertainty—continued

Post-employment benefit obligations

The present value of the pension obligations depends on a number of factors that are determined on an actuarial basis using a number of assumptions. Discount rate is one of the assumptions used in determining the net cost (income) for pensions. Any changes in these assumptions will impact the carrying amount of pension obligations.

The Group determines the appropriate discount rate at the end of each year. This is the interest rate that should be used to determine the present value of estimated future cash outflows expected to be required to settle the pension obligations. In determining the appropriate discount rate, the Group considers using market yields at the end of each of the Relevant Period on high quality United States corporate bonds for SPL Acquisition Corp., which is also the currency that benefits will be paid, and make sure terms of corporate bonds will match the estimated term of defined benefit plan.

Other key assumptions for pension obligations are partially based on current market conditions.

Provision for expected credit losses of trade and other receivables

The Group uses a provision matrix to calculate ECLs for trade receivables. The provision rates are based on days past due for groupings of various customer segments that have similar loss patterns (i.e., by geography, product type, customer type and rating, and coverage by letters of credit and other forms of credit insurance).

The provision matrix is initially based on the Group’s historical observed default rates. The Group will calibrate the matrix to adjust the historical credit loss experience with forward-looking information. For instance, if forecast economic conditions (i.e., gross domestic products) are expected to deteriorate over the next year which can lead to an increased number of defaults in the manufacturing sector, the historical default rates are adjusted. At each reporting date, the historical observed default rates are updated and changes in the forward-looking estimates are analysed.

The assessment of the correlation among historical observed default rates, forecast economic conditions and ECLs is a significant estimate. The amount of ECLs is sensitive to changes in circumstances and forecast economic conditions. The Group’s historical credit loss experience and forecast of economic conditions may also not be representative of customer’s actual default in the future. The information about the ECLs on the Group’s trade receivables and other receivables is disclosed in notes 25 and 27 to the Historical Financial Information, respectively.

Deferred tax assets

Deferred tax assets are recognized for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Significant management judgement is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and level of future taxable profits together with future tax planning strategies. The carrying values of deferred tax assets relating to recognized tax losses at 31 December 2017 and 2018 and 30 September 2019 were RMB76,694,000, RMB26,079,000, and RMB17,587,000,

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES—continued

Estimation uncertainty—continued

Deferred tax assets—continued

respectively. The amounts of unrecognized tax losses at 31 December 2017 and 2018 and 30 September 2019 were RMB224,864,000, RMB336,923,000, and RMB551,750,000, respectively. Further details are given in note 34 to the Historical Financial Information.

Fair value of unlisted equity investments

The unlisted equity investments have been valued based on a market-based valuation technique as detailed in note 48 to the Historical Financial Information. The valuation requires the Group to determine the comparable public companies (peers) and select the price multiple. In addition, the Group makes estimates about the discount for illiquidity and size differences. The Group classifies the fair value of these investments as Level I, II and III. The fair values of the unlisted equity investments at 31 December 2017, 2018 and 30 September 2019 were RMB1,012,563,000, RMB1,435,730,000 and RMB1,867,654,000, respectively. Further details are given in note 20 and 21 to the Historical Financial Information.

Development costs

Development costs are capitalized in accordance with the accounting policy for research and development costs as detailed in note 2.3 to the Historical Financial Information. Determining the amounts to be capitalized requires management to make assumptions regarding the expected future cash generation of the assets, the discount rates to be applied and the expected period of benefits. The best estimates of the carrying amount of capitalised development costs at 31 December 2017 and 2018 and 30 September 2019 were RMB12,644,000, RMB15,376,000 and RMB2,233,000, respectively.

4. OPERATING SEGMENT INFORMATION

For management purposes, the Group is organized into business units based on their products and services and has four reportable operating segments as follows:

- (a) The finished dose pharmaceutical products segment includes enoxaparin sodium injection and standard heparin sodium injection.
- (b) The active pharmaceutical ingredients segment includes standard heparin sodium active pharmaceutical ingredients, and enoxaparin sodium active pharmaceutical ingredients.
- (c) The CDMO segment includes R&D, manufacturing, quality management and program management.
- (d) The “others” segment.

Management monitors the results of the Group’s operating segments separately for the purpose of making decisions about resource allocation and performance assessment. Segment performance is evaluated based on reportable segment profit/loss, which is a measure of adjusted profit/loss before tax from continuing operations. The adjusted profit/loss before tax from continuing operations is measured

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

4. OPERATING SEGMENT INFORMATION—continued

consistently with the Group’s profit before tax except that other income and gains, selling and distribution expenses, administrative expenses, impairment losses on financial assets, other expenses, finance costs and share of profits and losses of associates are excluded from such measurement. No analysis of segment assets and liabilities is presented as management does not regularly review such information for the purposes of resource allocation and performance assessment. Therefore, only segment revenue and segment results are presented.

Intersegment sales and transfers are transacted with reference to the selling prices used for sales made to third parties at the then prevailing market prices.

Segment revenue and results

The following is an analysis of the Group’s revenue and results by reportable segments.

For the year ended 31 December 2017

<u>Segments</u>	<u>Finished dose pharmaceutical products</u> RMB’000	<u>Active pharmaceutical ingredients</u> RMB’000	<u>CDMO</u> RMB’000	<u>Others</u> RMB’000	<u>Total</u> RMB’000
Segment revenue:					
Sales to external customers	381,197	1,846,129	324,308	276,591	2,828,225
Intersegment sales	211,666	382,852	—	102,431	696,949
	592,863	2,228,981	324,308	379,022	3,525,174
<u>Reconciliation:</u>					
Elimination of intersegment sales					(696,949)
Revenue from contracts with customers					2,828,225
Segment results:	250,245	683,293	43,530	(40,258)	936,810
<u>Reconciliation:</u>					
Elimination of intersegment results					(85,027)
Other income and gains					209,701
Selling and distribution expenses					(192,201)
Administrative expenses					(435,629)
Impairment losses on financial assets					(10,884)
Other expenses					(2,707)
Finance costs					(183,268)
Share of profits and losses of associates					(79,710)
Group’s profit before tax					157,085

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

4. OPERATING SEGMENT INFORMATION—continued

Segment revenue and results—continued

For the year ended 31 December 2018

<u>Segments</u>	<u>Finished dose pharmaceutical products</u> RMB’000	<u>Active pharmaceutical ingredients</u> RMB’000	<u>CDMO</u> RMB’000	<u>Others</u> RMB’000	<u>Total</u> RMB’000
Segment revenue:					
Sales to external customers	1,045,643	2,752,386	548,469	453,309	4,799,807
Intersegment sales	396,369	1,352,093	—	283,861	2,032,323
	<u>1,442,012</u>	<u>4,104,479</u>	<u>548,469</u>	<u>737,170</u>	<u>6,832,130</u>
Reconciliation:					
Elimination of intersegment sales					(2,032,323)
Revenue from contracts with customers					<u>4,799,807</u>
Segment results:	<u>576,476</u>	<u>1,230,950</u>	<u>75,051</u>	<u>173,889</u>	<u>2,056,366</u>
Reconciliation:					
Elimination of intersegment results . . .					(182,834)
Other income and gains					308,150
Selling and distribution expenses					(371,710)
Administrative expenses					(497,735)
Impairment losses on financial assets					(12,454)
Other expenses					(366)
Finance costs					(229,207)
Share of profits and losses of associates					<u>(305,003)</u>
Group’s profit before tax					<u><u>765,207</u></u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

4. OPERATING SEGMENT INFORMATION—continued

Segment revenue and results—continued

For the nine months ended 30 September 2019 (unaudited)

<u>Segments</u>	<u>Finished dose pharmaceutical products</u>	<u>Active pharmaceutical ingredients</u>	<u>CDMO</u>	<u>Others</u>	<u>Total</u>
	<u>RMB’000</u> (Unaudited)	<u>RMB’000</u> (Unaudited)	<u>RMB’000</u> (Unaudited)	<u>RMB’000</u> (Unaudited)	<u>RMB’000</u> (Unaudited)
Segment revenue:					
Sales to external customers	720,891	1,690,020	503,161	218,099	3,132,171
Intersegment sales	<u>709,748</u>	<u>769,446</u>	<u>4,110</u>	<u>179,151</u>	<u>1,662,455</u>
	1,430,639	2,459,466	507,271	397,250	4,794,626
<u>Reconciliation:</u>					
Elimination of intersegment sales					<u>(1,662,455)</u>
Revenue from contracts with customers					<u>3,132,171</u>
Segment results:	<u>344,153</u>	<u>646,753</u>	<u>132,447</u>	<u>24,438</u>	<u>1,147,791</u>
<u>Reconciliation:</u>					
Elimination of intersegment results					(85,203)
Other income and gains					740,238
Selling and distribution expenses					(292,569)
Administrative expenses					(365,580)
Impairment losses on financial assets					(14,676)
Other expenses					(477)
Finance costs					(200,693)
Share of profits and losses of associates					<u>(41,797)</u>
Group’s profit before tax					<u><u>887,034</u></u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

4. OPERATING SEGMENT INFORMATION—continued

Segment revenue and results—continued

For the nine months ended 30 September 2018 (unaudited)

Segments	Finished dose pharmaceutical products	Active pharmaceutical ingredients	CDMO	Others	Total
	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Segment revenue:					
Sales to external customers	605,142	2,003,884	356,542	341,180	3,306,748
Intersegment sales	231,196	981,764	—	146,258	1,359,218
	836,338	2,985,648	356,542	487,438	4,665,966
Reconciliation:					
Elimination of intersegment sales					(1,359,218)
Revenue from contracts with customers					3,306,748
Segment results:	<u>366,818</u>	<u>877,568</u>	<u>33,453</u>	<u>118,128</u>	<u>1,395,967</u>
Reconciliation:					
Elimination of intersegment results					(126,788)
Other income and gains					317,777
Selling and distribution expenses					(240,505)
Administrative expenses					(343,676)
Impairment losses on financial assets					(13,404)
Other expenses					(68)
Finance costs					(170,519)
Share of profits and losses of associates					(233,915)
Group’s profit before tax					<u>584,869</u>

Geographical information

(a) Revenue from external customers

	Year ended 31 December		Nine months ended 30 September	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Hong Kong	6,651	34,909	18,566	11,441
United States of America	403,055	804,715	575,327	668,655
Europe	1,636,938	2,937,707	2,066,840	1,896,382
Mainland China	352,443	442,599	292,992	257,501
Other countries/regions	429,138	579,877	353,023	298,192
	<u>2,828,225</u>	<u>4,799,807</u>	<u>3,306,748</u>	<u>3,132,171</u>

The revenue information above is based on the locations of the customers.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

4. OPERATING SEGMENT INFORMATION—continued

Geographical information—continued

(b) *Non-current assets*

	As at 31 December 2017	As at 31 December 2018	As at 30 September 2019
	RMB’000	RMB’000	RMB’000 (Unaudited)
Mainland China	2,246,708	2,594,544	3,351,440
United States of America	3,548,982	3,667,148	3,726,523
Europe	172,217	188,928	183,228

The non-current asset information above is based on the locations of the assets and excludes financial instruments and deferred tax assets.

Information about major customers

During the year ended 31 December 2017, revenue of approximately RMB1,126,899,000 derived from a single external customer accounted for more than 10% of the total revenue.

During the year ended 31 December 2018, revenue of approximately RMB1,804,652,000 derived from a single external customer accounted for more than 10% of the total revenue.

During the nine months ended 30 September 2018, revenue of approximately RMB1,304,004,000 derived from a single external customer accounted for more than 10% of the total revenue.

During the nine months ended 30 September 2019, revenue of approximately RMB896,310,000 derived from a single external customer accounted for more than 10% of the total revenue.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

5. REVENUE

An analysis of revenue is as follows:

Revenue from contracts with customers

(i) Disaggregated revenue information

For the year ended 31 December 2017

<u>Segments</u>	<u>Finished dose pharmaceutical products</u>	<u>Active pharmaceutical ingredients</u>	<u>CDMO</u>	<u>Others</u>	<u>Total</u>
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Type of goods or services					
Sale of products	381,197	1,846,129	—	217,124	2,444,450
CDMO services	—	—	324,308	—	324,308
Others	—	—	—	59,467	59,467
Total revenue from contracts with customers	<u>381,197</u>	<u>1,846,129</u>	<u>324,308</u>	<u>276,591</u>	<u>2,828,225</u>
Geographical markets					
Hong Kong	141	6,510	—	—	6,651
United States of America	—	80,505	250,735	71,815	403,055
Europe	227,249	1,373,681	—	36,008	1,636,938
Mainland China	150,176	33,499	—	168,768	352,443
Other countries/regions	3,631	351,934	73,573	—	429,138
Total revenue from contracts with customers	<u>381,197</u>	<u>1,846,129</u>	<u>324,308</u>	<u>276,591</u>	<u>2,828,225</u>
Timing of revenue recognition					
Products transferred at a point in time	381,197	1,846,129	—	217,124	2,444,450
Services transferred at a point in time	—	—	—	23,459	23,459
Services transferred over time	—	—	324,308	36,008	360,316
Total revenue from contracts with customers	<u>381,197</u>	<u>1,846,129</u>	<u>324,308</u>	<u>276,591</u>	<u>2,828,225</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

5. REVENUE—continued

Revenue from contracts with customers—continued

(i) Disaggregated revenue information—continued

For the year ended 31 December 2018

Segments	Finished dose pharmaceutical products	Active pharmaceutical ingredients	CDMO	Others	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Type of goods or services					
Sale of products	1,045,643	2,752,386	—	385,403	4,183,432
CDMO services	—	—	548,469	—	548,469
Others	—	—	—	67,906	67,906
Total revenue from contracts with customers	<u>1,045,643</u>	<u>2,752,386</u>	<u>548,469</u>	<u>453,309</u>	<u>4,799,807</u>
Geographical markets					
Hong Kong	2,187	32,722	—	—	34,909
United States of America	—	24,190	512,596	267,929	804,715
Europe	754,660	2,153,640	—	29,407	2,937,707
Mainland China	269,880	23,277	—	149,442	442,599
Other countries/regions	18,916	518,557	35,873	6,531	579,877
Total revenue from contracts with customers	<u>1,045,643</u>	<u>2,752,386</u>	<u>548,469</u>	<u>453,309</u>	<u>4,799,807</u>
Timing of revenue recognition					
Products transferred at a point in time	1,045,643	2,752,386	—	385,403	4,183,432
Services transferred at a point in time	—	—	2,783	26,172	28,955
Services transferred over time	—	—	545,686	41,734	587,420
Total revenue from contracts with customers	<u>1,045,643</u>	<u>2,752,386</u>	<u>548,469</u>	<u>453,309</u>	<u>4,799,807</u>

For the nine months ended 30 September 2019

Segments	Finished dose pharmaceutical products	Active pharmaceutical ingredients	CDMO	Others	Total
	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Type of goods or services					
Sale of products	720,891	1,690,020	—	193,398	2,604,309
CDMO services	—	—	503,161	—	503,161
Others	—	—	—	24,701	24,701
Total revenue from contracts with customers	<u>720,891</u>	<u>1,690,020</u>	<u>503,161</u>	<u>218,099</u>	<u>3,132,171</u>
Geographical markets					
Hong Kong	729	10,712	—	—	11,441
United States of America	—	85,085	464,788	118,782	668,655
Europe	561,198	1,310,337	—	24,847	1,896,382
Mainland China	142,609	55,727	—	59,165	257,501
Other countries /regions	16,355	228,159	38,373	15,305	298,192
Total revenue from contracts with customers	<u>720,891</u>	<u>1,690,020</u>	<u>503,161</u>	<u>218,099</u>	<u>3,132,171</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

5. REVENUE—continued

Revenue from contracts with customers—continued

(i) Disaggregated revenue information—continued

Segments	Finished dose pharmaceutical products	Active pharmaceutical ingredients	CDMO	Others	Total
	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Timing of revenue recognition					
Products transferred at a point in time	720,891	1,690,020	—	193,398	2,604,309
Services transferred at a point in time	—	—	17,088	5,184	22,272
Services transferred over time	—	—	486,073	19,517	505,590
Total revenue from contracts with customers	<u>720,891</u>	<u>1,690,020</u>	<u>503,161</u>	<u>218,099</u>	<u>3,132,171</u>

For the nine months ended 30 September 2018

Segments	Finished dose pharmaceutical products	Active pharmaceutical ingredients	CDMO	Others	Total
	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Type of goods or services					
Sale of products	605,142	2,003,884	—	310,762	2,919,788
CDMO services	—	—	356,542	—	356,542
Others	—	—	—	30,418	30,418
Total revenue from contracts with customers	<u>605,142</u>	<u>2,003,884</u>	<u>356,542</u>	<u>341,180</u>	<u>3,306,748</u>
Geographical markets					
Hong Kong	2,187	16,379	—	—	18,566
United States of America	—	39,195	325,705	210,427	575,327
Europe	414,053	1,622,369	—	30,418	2,066,840
Mainland China	174,386	26,701	—	91,905	292,992
Other countries /regions	14,516	299,240	30,837	8,430	353,023
Total revenue from contracts with customers	<u>605,142</u>	<u>2,003,884</u>	<u>356,542</u>	<u>341,180</u>	<u>3,306,748</u>
Timing of revenue recognition					
Products transferred at a point in time	605,142	2,003,884	—	310,762	2,919,788
Services transferred at a point in time	—	—	6,555	1,710	8,265
Services transferred over time	—	—	349,987	28,708	378,695
Total revenue from contracts with customers	<u>605,142</u>	<u>2,003,884</u>	<u>356,542</u>	<u>341,180</u>	<u>3,306,748</u>

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

5. REVENUE—continued

Revenue from contracts with customers—continued

(i) Disaggregated revenue information—continued

The following table shows the amounts of revenue recognized during the Relevant Periods and nine months ended 30 September 2018 that were included in the contract liabilities at the beginning of each reporting period and recognized from performance obligations satisfied in previous periods:

	Year ended 31 December		Nine months ended 30 September	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Revenue recognized that was included in the contract liabilities balance at the beginning of year/period:				
Sale of products	7,503	12,730	11,803	9,177
CDMO services	97,414	108,346	106,899	208,418
	<u>104,917</u>	<u>121,076</u>	<u>118,702</u>	<u>217,595</u>

(ii) Performance obligations

Sale of products

The performance obligation is satisfied upon delivery of the products and payment is generally due within 30 to 180 days from delivery, except for PRC customers of the finished dose pharmaceutical products, where payment in advance is normally required.

CDMO services

For services under the FFS model, revenue is recognised over time and the performance obligation is part of a contract that has an original expected duration of one year or less. Therefore, under practical expedients allowed by IFRS 15, the Group does not disclose the value of unsatisfied performance obligations under the FFS model.

For certain CDMO services, the directors of the Company have determined that performance obligations are satisfied upon acceptance of the deliverable products under customers’ specific orders, and therefore, the performance obligation is recognised as revenue at a point in time.

The transaction prices allocated to the remaining performance obligations (unsatisfied or partially unsatisfied) as at the end of each of the Relevant Periods are as follows:

	As at 31 December		As at 30 September	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Within one year	<u>24,884</u>	<u>47,852</u>	<u>213,090</u>	<u>249,495</u>

All the performance obligations are expected to be recognised within one year. The amounts disclosed above do not include variable consideration which is constrained.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

6. OTHER INCOME AND GAINS

	Year ended 31 December		Nine months ended 30 September	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Other income				
Bank interest income	137,740	69,456	50,568	40,170
Government grants related to				
-Assets*	2,298	2,242	1,690	1,588
-Income**	40,190	31,581	19,641	26,433
Dividend income from financial assets at fair value through profit or loss	781	36,823	25,353	643
Dividend income from financial assets designated at fair value through other comprehensive income	—	3,694	—	16,449
	<u>181,009</u>	<u>143,796</u>	<u>97,252</u>	<u>85,283</u>
Other gains				
Foreign exchange gain/(losses), net	(49,584)	70,545	105,098	23,954
Gains on disposal of financial assets at fair value through profit or loss	26,363	13,917	12,385	1,456
Fair value gains, net:	43,029	38,681	70,960	49,979
Fair value gains/(losses) on derivative instruments (note 22)	(3,728)	30,490	38,742	(101,241)
Fair value gains on financial assets at fair value through profit or loss (note 21)	46,757	8,191	32,218	151,220
Gain on disposal of a subsidiary (note 42)	—	28,766	28,766	—
Gain on deemed disposal of a subsidiary (note 42)	—	—	—	573,865
Gains/(losses) on disposal of items of property, plant and equipment	(383)	2,304	18	1,792
Others	9,267	10,141	3,298	3,909
	<u>28,692</u>	<u>164,354</u>	<u>220,525</u>	<u>654,955</u>
	<u>209,701</u>	<u>308,150</u>	<u>317,777</u>	<u>740,238</u>

* The Group has received certain government grants related to assets to invest in laboratory equipment and plant. The grants related to assets were recognized in profit or loss over the useful lives of the relevant assets. Details of these grants related to assets are set out in note 33.

** The government grants and subsidies related to income have been received to compensate for the Group’s research and development costs. Some of the grants related to income have future related costs expected to be incurred and require the Group to comply with conditions attached to the grants and the government to acknowledge the compliance of these conditions. These grants related to income are recognized in the statement of profit or loss on a systematic basis over the periods that the costs, which it is intended to compensate, are expensed. Details of these grants are set out in note 33.

Other government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period in which they become receivable.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

7. PROFIT BEFORE TAX

The Group’s profit before tax is arrived at after charging/(crediting):

	Year ended 31 December		Nine months ended	
	2017	2018	30 September	2019
	RMB’000	RMB’000	RMB’000	RMB’000
			(Unaudited)	(Unaudited)
Cost of inventories sold	1,683,221	2,436,552	1,713,705	1,698,918
Cost of services provided	293,221	489,723	323,864	370,665
Depreciation of property, plant and equipment	139,557	157,632	116,095	146,492
Depreciation of right-of-use assets	37,291	41,251	27,320	29,180
Amortisation of other intangible assets	45,559	51,799	30,487	39,401
Research and development costs*	93,541	186,853	116,546	112,881
Auditor’s remuneration	3,465	2,743	2,743	2,940
Employee benefit expense (including directors’ and supervisors’ remuneration):				
Salaries and other benefits	457,809	605,527	435,821	518,272
Pension scheme contributions, social welfare and other welfare	72,444	118,025	75,861	88,417
Rental expenses from short-term leases	1,087	1,089	817	1,495
Bank interest income	(137,740)	(69,456)	(50,568)	(40,170)
Finance costs	183,268	229,207	170,519	200,693
Dividend income from financial assets at fair value through profit or loss	(781)	(36,823)	(25,352)	(643)
Dividend income from financial assets at fair value through other comprehensive income	—	(3,694)	—	(16,449)
Foreign exchange losses/(gains), net	49,584	(70,545)	(105,098)	(23,954)
Gains on disposal of financial assets at fair value through profit or loss	(26,363)	(13,917)	(12,385)	(1,456)
Fair value losses/(gains) on derivative instruments	3,728	(30,490)	(38,742)	101,241
Fair value gains on financial assets at fair value through profit or loss	(46,757)	(8,191)	(32,218)	(151,220)
Gain on disposal of a subsidiary	—	(28,766)	(28,766)	—
Gain on deemed disposal of a subsidiary	—	—	—	(573,865)
Losses/(gains) on disposal of items of property, plant and equipment	383	(2,304)	(18)	(1,792)
Impairment losses on financial assets	10,884	12,454	13,404	14,676

* Research and development costs are included in “Administrative expenses” in the consolidated statements of profit or loss.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

8. FINANCE COSTS

An analysis of finance costs is as follows:

	Year ended 31 December		Nine months ended 30 September	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Interest expenses on:				
Bank borrowings	118,923	165,968	117,539	139,586
Corporate bonds	33,661	33,721	25,285	44,051
Lease liabilities	9,246	7,193	5,754	4,568
Other finance cost	26,028	24,609	24,195	12,488
Less : Interest capitalised	(4,590)	(2,284)	(2,254)	—
	<u>183,268</u>	<u>229,207</u>	<u>170,519</u>	<u>200,693</u>

9. DIRECTORS’ AND SUPERVISORS’ REMUNERATION

The remuneration of each director and supervisor as recorded during each of the Relevant Periods and the nine months ended 30 September 2018 is set out below:

	Year ended 31 December		Nine months ended 30 September	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Fees	300	300	225	225
Other emoluments:				
Salaries, allowances and benefits in kind	5,774	7,088	2,903	2,957
Performance related bonuses*	—	2,011	—	—
Pension scheme contributions	211	231	172	154
	<u>6,285</u>	<u>9,630</u>	<u>3,300</u>	<u>3,336</u>

* Certain executive directors and supervisors of the Company are entitled to bonus payments which are determined as a percentage of the profit after tax of the Group.

(a) Independent non-executive directors

The fees paid to independent non-executive directors during the Relevant Periods and the nine months ended 30 September 2018 were as follows:

	Year ended 31 December		Nine months ended 30 September	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Mr. Zhang Rongqing	100	100	75	75
Mr. Chen Junfa	50	100	75	75
Mr. Wang Zhaohui	33	100	75	75
Mr. Ha Jiming (note (a))	17	—	—	—
Mr. Jie Dong (note (b))	50	—	—	—
Mr. Xu Bin (note (c))	50	—	—	—
	<u>300</u>	<u>300</u>	<u>225</u>	<u>225</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

9. DIRECTORS’ AND SUPERVISORS’ REMUNERATION—continued

(b) Executive directors and supervisors

	<u>Year ended 31 December 2017</u>	<u>Salaries, allowances and benefits in kind</u> RMB’000	<u>Performance related bonuses</u> RMB’000	<u>Pension scheme contributions</u> RMB’000	<u>Total remuneration</u> RMB’000
Executive directors					
Mr. Li Li		1,414	—	36	1,450
Ms. Li Tan		905	—	36	941
Mr. Shan Yu		2,130	—	36	2,166
Mr. Bu Haihua		723	—	36	759
Supervisors					
Mr. Zheng Zehui		100	—	—	100
Mr. Tang Haijun		307	—	36	343
Ms. Su Jilan		195	—	31	226
		<u>5,774</u>	<u>—</u>	<u>211</u>	<u>5,985</u>

	<u>Year ended 31 December 2018</u>	<u>Salaries, allowances and benefits in kind</u> RMB’000	<u>Performance related bonuses</u> RMB’000	<u>Pension scheme contributions</u> RMB’000	<u>Total remuneration</u> RMB’000
Executive directors					
Mr. Li Li		2,495	965	40	3,500
Ms. Li Tan		1,808	263	40	2,111
Mr. Shan Yu		1,214	447	40	1,701
Mr. Bu Haihua		912	289	40	1,241
Supervisors					
Mr. Zheng Zehui		100	—	—	100
Mr. Tang Haijun		320	26	40	386
Ms. Su Jilan		239	21	31	291
		<u>7,088</u>	<u>2,011</u>	<u>231</u>	<u>9,330</u>

	<u>Nine months ended 30 September 2018</u>	<u>Salaries, allowances and benefits in kind</u> RMB’000 (Unaudited)	<u>Performance related bonuses</u> RMB’000 (Unaudited)	<u>Pension scheme contributions</u> RMB’000 (Unaudited)	<u>Total remuneration</u> RMB’000 (Unaudited)
Executive directors					
Mr. Li Li		858	—	30	888
Ms. Li Tan		510	—	30	540
Mr. Shan Yu		556	—	30	586
Mr. Bu Haihua		538	—	30	568
Supervisors					
Mr. Zheng Zehui		75	—	—	75
Mr. Tang Haijun		215	—	29	244
Ms. Su Jilan		151	—	23	174
		<u>2,903</u>	<u>—</u>	<u>172</u>	<u>3,075</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

9. DIRECTORS’ AND SUPERVISORS’ REMUNERATION—continued

(b) Executive directors and supervisors—continued

	<u>Nine months ended 30 September 2019</u>	Salaries, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Total remuneration
		RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Executive directors					
Mr. Li Li		910	—	26	936
Ms. Li Tan		562	—	26	588
Mr. Shan Yu		545	—	26	571
Mr. Bu Haihua		464	—	26	490
Supervisors					
Mr. Zheng Zehui		75	—	—	75
Mr. Tang Haijun		223	—	27	250
Ms. Su Jilan		178	—	23	201
		<u>2,957</u>	<u>—</u>	<u>154</u>	<u>3,111</u>

Note:

- (a) Mr. Ha Jiming was appointed as independent non- executive director of the Company with effect from 23 May 2017 and resigned on 21 July 2017.
- (b) Mr. Jie Dong was appointed as independent non- executive director of the Company with effect from 16 February 2011 and resigned on 23 May 2017.
- (c) Mr. Xu Bin was appointed as independent non- executive director of the Company with effect from 16 February 2011 and resigned on 23 May 2017.

There was no arrangement under which a director or a supervisor waived or agreed to waive any remuneration during the Relevant Periods and nine months ended 30 September 2018.

10. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees of the Group during the Relevant Periods and nine months ended 30 September 2018 included 0,1,1,0 director, respectively, details of whose remuneration are set out in note 9 above. Details of the remuneration of the 5,4,4,5 highest paid employees who are neither a director of the Group during the Relevant Periods and nine months ended 30 September 2018 are as follows:

	<u>Year ended 31 December</u>		<u>Nine months ended 30 September</u>	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Salaries, allowances and benefits in kind	21,787	14,470	7,835	11,174
Performance related bonuses	—	1,631	—	—
Pension scheme contributions	198	737	569	653
	<u>21,985</u>	<u>16,838</u>	<u>8,404</u>	<u>11,827</u>

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

10. FIVE HIGHEST PAID EMPLOYEES—continued

The number of non-director and highest paid employees whose remuneration fell within the following band is as follows:

	Year ended 31 December 2017	2018	Nine months ended 30 September 2018	2019
			(Unaudited)	(Unaudited)
Nil to HK\$1,000,000	—	—	—	—
HK\$1,000,001 to HK\$1,500,000	—	—	—	—
HK\$1,500,001 to HK\$2,000,000	—	—	1	—
HK\$2,000,001 to HK\$2,500,000	—	—	1	2
HK\$2,500,001 to HK\$3,000,000	—	—	1	1
HK\$3,000,001 to HK\$3,500,000	1	—	1	2
HK\$3,500,001 to HK\$4,000,000	—	1	—	—
HK\$4,000,001 to HK\$4,500,000	1	—	—	—
HK\$4,500,001 to HK\$5,000,000	—	1	—	—
HK\$5,000,001 to HK\$5,500,000	1	1	—	—
HK\$5,500,001 to HK\$6,000,000	1	—	—	—
HK\$6,000,001 to HK\$6,500,000	—	1	—	—
HK\$6,500,001 to HK\$7,000,000	—	—	—	—
HK\$7,000,001 to HK\$7,500,000	1	—	—	—
	<u>5</u>	<u>4</u>	<u>4</u>	<u>5</u>

During the Relevant Periods and nine months ended 30 September 2018, no highest paid employees waived or agreed to waive any remuneration and no remuneration was paid by the Group to any of the five highest paid employees as an inducement to join or upon joining the Group or as compensation for loss of office.

11. INCOME TAX

The Group is subject to income tax on an entity basis on profit arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

Under the Law of the PRC on Enterprise Income Tax (the “EIT Law”) and Implementation Regulation of the EIT Law, the EIT rate of the PRC subsidiaries is 25% unless these subject to tax exemption set out below.

The Company was accredited as a “High and New Technology Enterprise” in 2015 which was subsequently renewed in 2018, and therefore the Company was entitled to a preferential CIT rate of 15% for the Relevant Periods. This qualification is subject to review by the relevant tax authority in the PRC for every three years.

Shenzhen Techdow Pharmaceutical Co., Ltd was accredited as a “High and New Technology Enterprise” in 2014 which was subsequently renewed in 2017, and therefore Shenzhen Techdow Pharmaceutical Co., Ltd was entitled to a preferential CIT rate of 15% for the Relevant Periods. This qualification is subject to review by the relevant tax authority in the PRC for every three years.

The group entities incorporated in USA are subject to the federal corporate tax rate at a range from 15%-39% for the years ended 31 December 2017. On 22 December 2017, the 2017 Tax Cuts and

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

11. INCOME TAX—continued

Jobs Act was enacted, which reduces the federal corporate tax rate to 21% from the range of 15%-39% and is effective on 1 January 2018. The state income tax rate remains at a range from 1% to 9.5% during the Relevant Periods and nine months ended 30 September 2018.

The group entity incorporated in Singapore is subject to the corporate income tax rate of 17% during the Relevant Periods and nine months ended 30 September 2018.

The group entities incorporated in Sweden are subject to the corporate income tax rate of 22% during the Relevant Periods and nine months ended 30 September 2018.

On 21 March 2018 the Hong Kong Legislative Council passed the Inland Revenue (Amendment) (No. 7) Bill 2017 (the “Bill”) which introduces the two-tiered profits tax rates regime. The Bill was signed into law on 28 March 2018 and was gazetted on the following day. Under the two-tiered profits tax rates regime, the first HK\$2 million of profits of the qualifying group entity will be taxed at 8.25%, and profits above HK\$2 million will be taxed at 16.5%. The profits of the group entities not qualifying for the two-tiered profits tax rates regime will continue to be taxed at a flat rate of 16.5%.

The group entity incorporated in Poland is subject to the corporate income tax rate of 19% during the Relevant Periods and nine months ended 30 September 2018.

The group entities incorporated in Netherland are subject to the corporate income tax rate of 20% for taxable income that do not exceed the amount of EUR 200,000 and if the taxable income excess the amount of EUR 200,000, the tax rate of 25% should apply to the part that excess the amount of EUR 200,000 during the Relevant Periods and nine months ended 30 September 2018.

The group entity incorporated in the United Kingdom is entitled to the tax rate at 20% before 1 April 2017. The tax rate reduced from 20% to 19% from April 2017. The tax rate remains at 19% during the remaining Relevant Periods and nine months ended 30 September 2018.

The group entity incorporated in Spain is subject to the corporate income tax rate of 25% during the Relevant Periods and nine months ended 30 September 2018.

The group entity incorporated in Italy is subject to the corporate income tax rate of 24% and Imposta regionale sulle attività produttive (“IRAP”) tax rate of 3.9% during the Relevant Periods and the nine months ended 30 September 2018.

The group entity incorporated in France is subject to the corporate income tax rate of 28% for taxable income that do not exceed the amount of EUR500,000 and if the taxable income excesses the amount of EUR500,000 the tax rate of 33.33% should apply to the part that excess the amount of EUR500,000 during the Relevant Periods and the nine months ended 30 September 2018.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

11. INCOME TAX—continued

The major components of the income tax expense for the year/period are as follows:

	Year ended 31 December		Nine months ended	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)	RMB’000 (Unaudited)
Current Tax Expense				
PRC	53,543	131,718	120,377	66,827
USA	—	—	—	14,414
Elsewhere	659	366	199	87
(Overprovision)/Underprovision in prior years from the PRC	(1,220)	(1,571)	(304)	133
Total	<u>52,982</u>	<u>130,513</u>	<u>120,272</u>	<u>81,461</u>
Deferred Tax Expense				
PRC	(24,088)	(36,936)	(47,935)	54,431
USA	(112,701)	67,959	43,649	9,763
Elsewhere	—	(13,292)	(562)	(7,594)
Total	<u>(136,789)</u>	<u>17,731</u>	<u>(4,848)</u>	<u>56,600</u>
Total tax (credit)/charge for the year/period	<u>(83,807)</u>	<u>148,244</u>	<u>115,424</u>	<u>138,061</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

11. INCOME TAX—continued

A reconciliation of the tax expense applicable to profit before tax at the statutory rates for the jurisdictions in which the Company and the majority of its subsidiaries are domiciled to the tax expense at the effective tax rates, and a reconciliation of the statutory tax rates to the effective tax rates, are as follows:

	Year ended 31 December 2017		Year ended 31 December 2018		Nine months ended 30 September 2018		Nine months ended 30 September 2019	
	RMB’000	%	RMB’000	%	RMB’000 (Unaudited)	%	RMB’000 (Unaudited)	%
Profit before tax	157,085		765,207		584,869		887,034	
Tax at the statutory tax rate	25,713	16%	173,945	23%	132,661	23%	200,049	23%
Lower tax rate for specific provinces or enacted by local authority	(38,174)	(24%)	(62,117)	(8%)	(53,095)	(9%)	(89,258)	(10%)
Effect on opening deferred tax of decrease in rates	(89,727)	(57%)	—	—	—	—	—	—
Adjustments in respect of current tax of previous periods	(1,220)	(1%)	(1,571)	0%	(304)	0%	133	0%
Income not subject to tax	—	—	(7,224)	(1%)	(4,219)	(1%)	—	—
Expenses not deductible for tax	945	1%	335	0%	264	0%	724	0%
Utilization of previously unrecognized tax losses	(4,818)	(3%)	(3,538)	0%	(229)	0%	(28,909)	(3%)
Tax losses and temporary difference not recognized	28,173	18%	54,151	7%	42,439	7%	67,297	8%
Super deduction for research and development expenses	(4,699)	(3%)	(7,986)	(1%)	(3,123)	(1%)	(9,573)	(1%)
Others	—	—	2,249	0%	1,030	0%	(2,402)	0%
Tax (credit)/charge at the Group’s effective rate	(83,807)	(53%)	148,244	19%	115,424	20%	138,061	16%

12. DIVIDENDS

	Year ended 31 December 2017		Year ended 31 December 2018		Nine months ended 30 September 2018		Nine months ended 30 September 2019	
	RMB’000		RMB’000		RMB’000 (Unaudited)		RMB’000 (Unaudited)	
Dividends declared by the Company	311,800		56,124		56,124		124,720	

On 23 May 2017, the Company’s shareholders approved the 2016 profit distribution plan at an annual general meeting, pursuant to which an aggregate amount of RMB 311,800,000 (inclusive of tax) were subsequently paid in June 2017 to the shareholders of the Company on the record date for determining the shareholders’ entitlement to the 2016 profit distribution plan, which amounted to a dividend of RMB2.5 (inclusive of tax) for every 10 shares of the Company.

On 16 May 2018, the Company’s shareholders approved the 2017 profit distribution plan at an annual general meeting, pursuant to which an aggregate amount of RMB 56,124,000 (inclusive of tax)

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

12. DIVIDENDS—continued

were subsequently paid in June 2018 to the shareholders of the Company on the record date for determining the shareholders’ entitlement to the 2017 profit distribution plan, which amounted to a dividend of RMB0.45 (inclusive of tax) for every 10 shares of the Company.

On 21 May 2019, the Company’s shareholders approved the 2018 profit distribution plan at an annual general meeting, pursuant to which an aggregate amount of RMB 124,720,170 (inclusive of tax) were subsequently paid in September 2019 to the shareholders of the Company on the record date for determining the shareholders’ entitlement to the 2018 profit distribution plan, which amounted to a dividend of RMB1 (inclusive of tax) for every 10 shares of the Company.

13. EARNINGS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic earnings per share amounts is based on the profit attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares in issue during the Relevant Periods and the nine months ended 30 September 2018 as adjusted to reflect the subsequent changes in capital at nil consideration.

The Group had no potentially dilutive ordinary shares in issue during the Relevant Periods and the nine months ended 30 September 2018.

The calculation of basic earnings per share is based on:

	Year ended 31 December		Nine months ended 30 September	
	2017	2018	2018	2019
	RMB’000	RMB’000	RMB’00 (Unaudited)	RMB’00 (Unaudited)
<u>Earnings</u>				
Profit attributable to ordinary equity holders of the parent	238,904	640,194	479,041	763,586
Number of shares				
	Year ended 31 December		Nine months ended 30 September	
	2017	2018	2018	2019
			(Unaudited)	(Unaudited)
<u>Number of shares</u>				
Weighted average number of ordinary shares in issue during the year/ period, used in the basic earnings per share calculation	1,247,201,704	1,247,201,704	1,247,201,704	1,247,201,704

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

14. PROPERTY, PLANT AND EQUIPMENT

Group

	Buildings RMB’000	Machine equipment RMB’000	Motor vehicles RMB’000	Other equipment RMB’000	Land RMB’000	Leasehold improvements RMB’000	Construction in progress RMB’000	Total RMB’000
31 December 2017								
At 1 January 2017:								
Cost	736,930	738,180	41,900	55,190	30,154	118,915	388,856	2,110,125
Accumulated depreciation	(121,729)	(228,848)	(24,152)	(26,667)	—	(17,626)	—	(419,022)
Net carrying amount	615,201	509,332	17,748	28,523	30,154	101,289	388,856	1,691,103
At 1 January 2017, net of accumulated depreciation	615,201	509,332	17,748	28,523	30,154	101,289	388,856	1,691,103
Additions	4,721	33,815	12	1,949	3,249	2,416	521,436	567,598
Disposals	(485)	(361)	(642)	(190)	(181)	—	—	(1,859)
Depreciation provided during the year	(29,454)	(88,070)	(4,246)	(11,058)	—	(6,729)	—	(139,557)
Transfers	56,712	56,324	8,003	6,695	—	—	(127,734)	—
Exchange realignment	(7,136)	(10,958)	(1,135)	(358)	(1,855)	—	(15,552)	(36,994)
At 31 December 2017, net of accumulated depreciation	639,559	500,082	19,740	25,561	31,367	96,976	767,006	2,080,291
At 31 December 2017:								
Cost	789,241	804,758	40,424	59,973	31,367	121,331	767,006	2,614,100
Accumulated depreciation	(149,682)	(304,676)	(20,684)	(34,412)	—	(24,355)	—	(533,809)
Net carrying amount	639,559	500,082	19,740	25,561	31,367	96,976	767,006	2,080,291

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

14. PROPERTY, PLANT AND EQUIPMENT—continued

	Buildings RMB’000	Machine equipment RMB’000	Motor vehicles RMB’000	Other equipment RMB’000	Land RMB’000	Leasehold improvements RMB’000	Construction in progress RMB’000	Total RMB’000
31 December 2018								
At 1 January 2018:								
Cost	789,241	804,758	40,424	59,973	31,367	121,331	767,006	2,614,100
Accumulated depreciation	(149,682)	(304,676)	(20,684)	(34,412)	—	(24,355)	—	(533,809)
Net carrying amount	639,559	500,082	19,740	25,561	31,367	96,976	767,006	2,080,291
At 1 January 2018, net of accumulated depreciation	639,559	500,082	19,740	25,561	31,367	96,976	767,006	2,080,291
Additions	—	1,903	871	958	—	9,571	596,641	609,944
Disposals	—	(331)	(20)	(114)	—	—	—	(465)
Disposal of a subsidiary	(314)	(9,005)	(38)	(189)	—	(2,339)	—	(11,885)
Depreciation provided during the year	(40,357)	(93,472)	(4,362)	(12,165)	—	(7,276)	—	(157,632)
Transfers	481,818	134,237	5,682	10,273	—	—	(632,010)	—
Exchange realignment	6,535	10,823	970	471	1,579	2	13,606	33,986
At 31 December 2018, net of accumulated depreciation	1,087,241	544,237	22,843	24,795	32,946	96,934	745,243	2,554,239
At 31 December 2018:								
Cost	1,278,723	940,353	48,110	70,912	32,946	127,013	745,243	3,243,300
Accumulated depreciation	(191,482)	(396,116)	(25,267)	(46,117)	—	(30,079)	—	(689,061)
Net carrying amount	1,087,241	544,237	22,843	24,795	32,946	96,934	745,243	2,554,239

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

14. PROPERTY, PLANT AND EQUIPMENT—continued

	Buildings RMB’000	Machine equipment RMB’000	Motor vehicles RMB’000	Other equipment RMB’000	Land RMB’000	Leasehold improvements RMB’000	Construction in progress RMB’000	Total RMB’000
(Unaudited)								
30 September 2019								
At 1 January 2019:								
Cost	1,278,723	940,353	48,110	70,912	32,946	127,013	745,243	3,243,300
Accumulated depreciation	(191,482)	(396,116)	(25,267)	(46,117)	—	(30,079)	—	(689,061)
Net carrying amount	1,087,241	544,237	22,843	24,795	32,946	96,934	745,243	2,554,239
At 1 January 2019, net of accumulated depreciation	1,087,241	544,237	22,843	24,795	32,946	96,934	745,243	2,554,239
Additions	17,418	3,426	—	719	—	68	182,964	204,595
Disposals	—	(79)	—	(288)	—	—	—	(367)
Disposal of a subsidiary	—	(2,062)	—	(286)	—	(1,997)	(2,017)	(6,362)
Depreciation provided during the period	(39,820)	(90,369)	(3,037)	(8,197)	—	(5,069)	—	(146,492)
Transfers	59,603	197,627	378	5,564	—	—	(263,172)	—
Exchange realignment	5,654	10,543	560	429	1,007	(5)	3,695	21,883
At 30 September 2019, net of accumulated depreciation	1,130,096	663,323	20,744	22,736	33,953	89,931	666,713	2,627,496
At 30 September 2019:								
Cost	1,362,727	1,149,152	49,255	77,017	33,953	124,190	666,713	3,463,007
Accumulated depreciation	(232,631)	(485,829)	(28,511)	(54,281)	—	(34,259)	—	(835,511)
Net carrying amount	1,130,096	663,323	20,744	22,736	33,953	89,931	666,713	2,627,496

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

14. PROPERTY, PLANT AND EQUIPMENT—continued

Company

31 December 2017

At 1 January 2017:

	Buildings RMB’000	Machine equipment RMB’000	Motor vehicles RMB’000	Other equipment RMB’000	Leasehold improvements RMB’000	Construction in progress RMB’000	Total RMB’000
Cost	80,911	206,396	14,983	24,104	114,737	159,116	600,247
Accumulated depreciation	(18,896)	(87,298)	(13,390)	(15,197)	(16,793)	—	(151,574)
Net carrying amount	62,015	119,098	1,593	8,907	97,944	159,116	448,673
At 1 January 2017, net of accumulated depreciation	62,015	119,098	1,593	8,907	97,944	159,116	448,673
Additions	230	1,107	—	325	155	284,936	286,753
Disposals	—	(153)	(218)	(87)	—	—	(458)
Depreciation provided during the year	(3,021)	(17,075)	(231)	(3,417)	(6,194)	—	(29,938)
Transfers	5,182	2,243	—	674	—	(8,099)	—
At 31 December 2017, net of accumulated depreciation	64,406	105,220	1,144	6,402	91,905	435,953	705,030
At 31 December 2017:							
Cost	86,323	206,690	10,618	23,477	114,892	435,953	877,953
Accumulated depreciation	(21,917)	(101,470)	(9,474)	(17,075)	(22,987)	—	(172,923)
Net carrying amount	64,406	105,220	1,144	6,402	91,905	435,953	705,030

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

14. PROPERTY, PLANT AND EQUIPMENT—continued

	Buildings RMB’000	Machine equipment RMB’000	Motor vehicles RMB’000	Other equipment RMB’000	Leasehold improvements RMB’000	Construction in progress RMB’000	Total RMB’000
31 December 2018							
At 1 January 2018:							
Cost	86,323	206,690	10,618	23,477	114,892	435,953	877,953
Accumulated depreciation	(21,917)	(101,470)	(9,474)	(17,075)	(22,987)	—	(172,923)
Net carrying amount	64,406	105,220	1,144	6,402	91,905	435,953	705,030
At 1 January 2018, net of accumulated depreciation	64,406	105,220	1,144	6,402	91,905	435,953	705,030
Additions	—	—	—	—	8,178	460,066	468,244
Disposals	—	(206)	—	(6)	—	—	(212)
Depreciation provided during the year	(11,557)	(16,795)	(231)	(2,686)	(6,147)	—	(37,416)
Transfers	454,326	2,815	—	682	—	(457,823)	—
At 31 December 2018, net of accumulated depreciation	507,175	91,034	913	4,392	93,936	438,196	1,135,646
At 31 December 2018:							
Cost	540,650	209,023	10,618	24,095	122,615	438,196	1,345,197
Accumulated depreciation	(33,475)	(117,989)	(9,705)	(19,703)	(28,679)	—	(209,551)
Net carrying amount	507,175	91,034	913	4,392	93,936	438,196	1,135,646

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

14. PROPERTY, PLANT AND EQUIPMENT—continued

	Buildings RMB’000	Machine equipment RMB’000	Motor vehicles RMB’000	Other equipment RMB’000	Leasehold improvements RMB’000	Construction in progress RMB’000	Total RMB’000
(Unaudited)							
30 September 2019							
At 1 January 2019:							
Cost	540,650	209,023	10,618	24,095	122,615	438,196	1,345,197
Accumulated depreciation	(33,475)	(117,989)	(9,705)	(19,703)	(28,679)	—	(209,551)
Net carrying amount	507,175	91,034	913	4,392	93,936	438,196	1,135,646
At 1 January 2019, net of accumulated depreciation	507,175	91,034	913	4,392	93,936	438,196	1,135,646
Additions	—	1,132	—	170	—	89,458	90,760
Disposals	—	—	—	(14)	—	—	(14)
Depreciation provided during the period	(15,183)	(12,419)	(157)	(899)	(4,603)	—	(33,261)
Transfers	—	—	—	5	—	(5)	—
At 30 September 2019, net of accumulated depreciation	491,992	79,747	756	3,654	89,333	527,649	1,193,131
At 30 September 2019:							
Cost	540,650	210,153	10,618	24,135	122,615	527,649	1,435,820
Accumulated depreciation	(48,658)	(130,406)	(9,862)	(20,481)	(33,282)	—	(242,689)
Net carrying amount	491,992	79,747	756	3,654	89,333	527,649	1,193,131

The information about the pledged assets is disclosed in note 45 to the Historical Financial Information.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

15. RIGHT-OF-USE ASSETS

Group

	<u>Properties</u> RMB’000	<u>Equipment</u> RMB’000	<u>Motor vehicles</u> RMB’000	<u>Land use rights</u> RMB’000	<u>Total</u> RMB’000
31 December 2017					
At 1 January 2017:					
Cost	108,716	32,746	266	163,960	305,688
Accumulated depreciation	—	(7,577)	—	(25,488)	(33,065)
Net carrying amount	<u>108,716</u>	<u>25,169</u>	<u>266</u>	<u>138,472</u>	<u>272,623</u>
At 1 January 2017, net of accumulated					
depreciation	108,716	25,169	266	138,472	272,623
Additions	58,748	2,213	3,392	—	64,353
Depreciation provided during the year	(22,061)	(9,957)	(319)	(4,954)	(37,291)
Exchange realignment	(6,025)	(1,205)	88	—	(7,142)
At 31 December 2017, net of accumulated					
depreciation	<u>139,378</u>	<u>16,220</u>	<u>3,427</u>	<u>133,518</u>	<u>292,543</u>
At 31 December 2017:					
Cost	160,845	32,985	3,753	163,960	361,543
Accumulated depreciation	(21,467)	(16,765)	(326)	(30,442)	(69,000)
Net carrying amount	<u>139,378</u>	<u>16,220</u>	<u>3,427</u>	<u>133,518</u>	<u>292,543</u>
	<u>Properties</u> RMB’000	<u>Equipment</u> RMB’000	<u>Motor vehicles</u> RMB’000	<u>Land use rights</u> RMB’000	<u>Total</u> RMB’000
31 December 2018					
At 1 January 2018:					
Cost	160,845	32,985	3,753	163,960	361,543
Accumulated depreciation	(21,467)	(16,765)	(326)	(30,442)	(69,000)
Net carrying amount	<u>139,378</u>	<u>16,220</u>	<u>3,427</u>	<u>133,518</u>	<u>292,543</u>
At 1 January 2018, net of accumulated					
depreciation	139,378	16,220	3,427	133,518	292,543
Additions	2,078	—	3,188	—	5,266
Depreciation provided during the year	(26,633)	(8,390)	(1,274)	(4,954)	(41,251)
Exchange realignment	4,774	517	57	—	5,348
At 31 December 2018, net of accumulated					
depreciation	<u>119,597</u>	<u>8,347</u>	<u>5,398</u>	<u>128,564</u>	<u>261,906</u>
At 31 December 2018:					
Cost	169,306	34,646	7,015	163,960	374,927
Accumulated depreciation	(49,709)	(26,299)	(1,617)	(35,396)	(113,021)
Net carrying amount	<u>119,597</u>	<u>8,347</u>	<u>5,398</u>	<u>128,564</u>	<u>261,906</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

15. RIGHT-OF-USE ASSETS—continued

	<u>Properties</u> RMB’000	<u>Equipment</u> RMB’000	<u>Motor vehicles</u> RMB’000	<u>Land use rights</u> RMB’000	<u>Total</u> RMB’000
(Unaudited)					
30 September 2019					
At 1 January 2019:					
Cost	169,306	34,646	7,015	163,960	374,927
Accumulated depreciation	(49,709)	(26,299)	(1,617)	(35,396)	(113,021)
Net carrying amount	<u>119,597</u>	<u>8,347</u>	<u>5,398</u>	<u>128,564</u>	<u>261,906</u>
At 1 January 2019, net of accumulated					
depreciation	119,597	8,347	5,398	128,564	261,906
Additions	6,373	2,965	2,296	—	11,634
Depreciation provided during the period	(20,432)	(3,423)	(1,609)	(3,716)	(29,180)
Disposals	(982)	—	—	—	(982)
Exchange realignment	2,379	241	(58)	—	2,562
At 30 September 2019, net of accumulated					
depreciation	<u>106,935</u>	<u>8,130</u>	<u>6,027</u>	<u>124,848</u>	<u>245,940</u>
At 30 September 2019:					
Cost	174,700	38,764	9,249	163,960	386,673
Accumulated depreciation	(67,765)	(30,634)	(3,222)	(39,112)	(140,733)
Net carrying amount	<u>106,935</u>	<u>8,130</u>	<u>6,027</u>	<u>124,848</u>	<u>245,940</u>

Company

	<u>Properties</u> RMB’000	<u>Land use rights</u> RMB’000	<u>Total</u> RMB’000
31 December 2017			
At 1 January 2017:			
Cost	23,499	114,191	137,690
Accumulated depreciation	—	(16,569)	(16,569)
Net carrying amount	<u>23,499</u>	<u>97,622</u>	<u>121,121</u>
At 1 January 2017, net of accumulated depreciation			
Depreciation provided during the year	(2,387)	(3,743)	(6,130)
At 31 December 2017, net of accumulated depreciation			
	<u>21,112</u>	<u>93,879</u>	<u>114,991</u>
At 31 December 2017:			
Cost	23,499	114,191	137,690
Accumulated depreciation	(2,387)	(20,312)	(22,699)
Net carrying amount	<u>21,112</u>	<u>93,879</u>	<u>114,991</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

15. RIGHT-OF-USE ASSETS—continued

	<u>Properties</u> <u>RMB’000</u>	<u>Land use</u> <u>rights</u> <u>RMB’000</u>	<u>Total</u> <u>RMB’000</u>
31 December 2018			
At 1 January 2018:			
Cost	23,499	114,191	137,690
Accumulated depreciation	(2,387)	(20,312)	(22,699)
Net carrying amount	<u>21,112</u>	<u>93,879</u>	<u>114,991</u>
At 1 January 2018, net of accumulated depreciation	21,112	93,879	114,991
Additions	2,170	—	2,170
Depreciation provided during the year	(2,406)	(3,742)	(6,148)
At 31 December 2018, net of accumulated depreciation	<u>20,876</u>	<u>90,137</u>	<u>111,013</u>
At 31 December 2018:			
Cost	25,669	114,191	139,860
Accumulated depreciation	(4,793)	(24,054)	(28,847)
Net carrying amount	<u>20,876</u>	<u>90,137</u>	<u>111,013</u>
	<u>Properties</u> <u>RMB’000</u>	<u>Land use</u> <u>rights</u> <u>RMB’000</u>	<u>Total</u> <u>RMB’000</u>
(Unaudited)			
30 September 2019			
At 1 January 2019:			
Cost	25,669	114,191	139,860
Accumulated depreciation	(4,793)	(24,054)	(28,847)
Net carrying amount	<u>20,876</u>	<u>90,137</u>	<u>111,013</u>
At 1 January 2019, net of accumulated depreciation	20,876	90,137	111,013
Additions	17,311	—	17,311
Depreciation provided during the period	(2,012)	(2,807)	(4,819)
At 30 September 2019, net of accumulated depreciation	<u>36,175</u>	<u>87,330</u>	<u>123,505</u>
At 30 September 2019:			
Cost	42,980	114,191	157,171
Accumulated depreciation	(6,805)	(26,861)	(33,666)
Net carrying amount	<u>36,175</u>	<u>87,330</u>	<u>123,505</u>

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

16. GOODWILL

	RMB’000
At 1 January 2017:	
Cost	2,341,675
Accumulated impairment	—
Net carrying amount	<u>2,341,675</u>
Cost at 1 January 2017, net of accumulated impairment	2,341,675
Impairment during the year	—
Exchange realignment	(135,970)
Cost and net carrying amount at 31 December 2017	<u>2,205,705</u>
At 31 December 2017:	
Cost	2,205,705
Accumulated impairment	—
Net carrying amount	<u>2,205,705</u>
Cost at 1 January 2018, net of accumulated impairment	2,205,705
Impairment during the year	—
Exchange realignment	111,058
Cost and net carrying amount at 31 December 2018	<u>2,316,763</u>
At 31 December 2018:	
Cost	2,316,763
Accumulated impairment	—
Net carrying amount	<u>2,316,763</u>
Cost at 1 January 2019, net of accumulated impairment	2,316,763
Impairment during the period	—
Exchange realignment	70,787
Cost and net carrying amount at 30 September 2019 (unaudited)	<u>2,387,550</u>
At 30 September 2019:	
Cost	2,387,550
Accumulated impairment	—
Net carrying amount	<u>2,387,550</u>

Impairment testing of goodwill

On 9 April 2014, goodwill arising from the acquisition of SPL Acquisition Corp. amounted to RMB1,297,621,000.

On 5 October 2015, goodwill arising from the acquisition of Cytovance Biologics Inc. amounted to RMB814,940,000.

Goodwill is allocated to Heparin SPL cash-generating unit and CDMO cash-generating unit (collectively of the two above, the “CGUs”) for impairment testing. The recoverable amount of the CGUs has been determined based on fair value less costs of disposal using combination of the income approach and the market approach, each receiving an equal weighting of 50 percent.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

16. GOODWILL—continued

Impairment testing of goodwill—continued

The respective recoverable amount and the carrying value of the CGUs as at 31 December 2017 and 31 December 2018 are as follows:

Heparin SPL CGU

	As at 31 December	
	2017	2018
	RMB’000	RMB’000
Recoverable amount	3,789,836	2,885,976
Carrying value including allocated goodwill	2,373,226	2,451,764

CDMO CGU

	As at 31 December	
	2017	2018
	RMB’000	RMB’000
Recoverable amount	1,503,193	1,642,021
Carrying value including allocated goodwill	1,472,574	1,585,716

Pursuant to IAS 36 *Impairment of Assets*, the Group performs impairment test for goodwill on an annual basis. During the nine months ended 30 September 2019, operations of the above two CGUs were ongoing as schedule and there were no indicators showing any significant adverse changes to the market circumstances. As such, in consideration of those circumstances around the CGUs and the Group’s accounting policies to assess goodwill impairment annually, as at 30 September 2019, there was no impairment test performed for the goodwill arising from the above two CGUs.

For income approach, the pre-tax discount rates applied to the cash flow projections, the forecasted growth rates and earnings before interest, taxes, depreciation and amortization (“EBITDA”) margin used to extrapolate cash flow projections and terminal growth rates are as follows:

Heparin SPL CGU

	As at 31 December	
	2017	2018
Revenue growth rates	7%-65%	-5%-31%
EBITDA margin	33%-44%	22%-29%
Pre-tax discount rate	21.5%	17.9%
Terminal revenue growth rate	3%	3%

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

16. GOODWILL—continued

Impairment testing of goodwill—continued

CDMO CGU

	As at 31 December	
	2017	2018
Revenue growth rates*	9%-44%	6%-36%
EBITDA margin*	8%-26%	20%-27%
Pre-tax discount rate	13.9%	15.1%
Terminal revenue growth rate	3%	3%

* A period longer than five years can be used if it is justifiable, and the management used a seven-year period in 2017. The expected annual growth rates over the seven-year forecast period are based on the past performance and management’s expectation of future market and business developments.

Assumptions were used in the FVLCD of the CGUs for 31 December 2017 and 31 December 2018. The revenue growth rate beyond the five or seven-year period had been projected as 3.0%. The following describes each key assumption on which management has based its cash flow projections to undertake impairment testing of goodwill:

Revenue growth rate—The revenue growth rate is based on the average growth achieved in the past years and the expected revenue from sales of heparin and pancreatin.

Budgeted EBITDA margins—The basis used to determine the value assigned to the budgeted gross margins is the EBITDA margins achieved in the past years and the expectation for market development.

Discount rate—The discount rate used is before tax and reflects specific risks relating to the relevant unit.

The values assigned to the key assumptions on market development and discount rate are consistent with external information sources.

For market approach, fair value was determined based on ratios of enterprise value (“EV”) divided by revenue and EBITDA of several comparable public companies for specific historical and/or forecasted years. Multiples were selected for the respective time periods and multiplied by the revenue and EBITDA of the related CGU resulting in an implied EV of the CGU, on a minority, marketable basis. Weightings were applied to the implied indications of value and a control premium was added to arrive at an EV on a controlling, marketable basis. The guideline companies were selected based on a comprehensive search of publicly-listed companies in the CGU’s industry, such that the guideline companies had similar or comparable operations and likely exposed to similar risks as the CGU. The selected multiples and control premium are as follows:

Heparin SPL CGU

	As at 31 December	
	2017	2018
Revenue multiples	n/a	n/a
EBITDA multiples	8.5x	6.0x-8.8x
Control premium	5.0%	5.0%

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

16. GOODWILL—continued

Impairment testing of goodwill—continued

CDMO CGU

	As at 31 December	
	2017	2018
Revenue multiples	2.0x-3.0x	2.3x-3.0x
EBITDA multiples	9.0x	11.0x
Control premium	15.0%	10.0%

Assumptions were used in the FVLCD of the CGUs for 31 December 2017 and 31 December 2018. The following describes each key assumption on which management has based to undertake impairment testing of goodwill:

Revenue multiples—The revenue multiples are based on the CGU’s historical and forecasted performance compared to the guideline companies, as well as how the business has performed relative to plan for that period.

EBITDA multiples—The basis used to determine the value of EBITDA multiples is the CGU’s historical and forecasted profitability performance compared to the guideline companies, as well as relative to plan, and initiatives driving profitability.

Control Premium—The control premium is based on review of recent transactions in the industry and the comparability of the transactions to the respective CGU’s.

Sensitivity analysis

For Heparin SPL CGU, the estimated recoverable amounts exceeded its carrying values by RMB1,416,610,000 and RMB434,212,000 as at 31 December 2017 and 31 December 2018, respectively. The directors of the Company believed that no reasonably possible change in any of the above key assumptions would cause the carrying value of the Heparin SPL CGU to exceed its recoverable amount.

The changes in the following table to assumptions used in the impairment review would have, in isolation, led to the Heparin SPL CGU’s recoverable amount to be equal to its carrying value as at 31 December 2017 and 31 December 2018.

	Change required for carrying value to equal recoverable amount	
	As at 31 December	
	2017	2018
Revenue growth rates	(54.0%)	(10.4%)
EBITDA margin	(27.1%)	(7.1%)
Pre-tax discount rate	58.8%	6.6%

For CDMO CGU, the estimated recoverable amounts exceeded its carrying values by RMB30,619,000 and RMB56,305,000 as at 31 December 2017 and 31 December 2018, respectively, any significant adverse change in key assumptions would, in isolation, cause an impairment loss to be recognized.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

16. GOODWILL—continued

Sensitivity analysis—continued

The changes in the following table to assumptions used in the impairment review would have, in isolation, led to CDMO CGU’s recoverable amount to be equal to its carrying value as at 31 December 2017 and 31 December 2018.

	Change required for carrying value to equal recoverable amount	
	As at 31 December	
	2017	2018
Revenue growth rates	(0.7%)	(2.0%)
EBITDA margin	(0.7%)	(1.3%)
Pre-tax discount rate	0.3%	0.9%

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

17. OTHER INTANGIBLE ASSETS

Group

31 December 2017

	Software RMB’000	Trademarks RMB’000	Patent RMB’000	Proprietary technology RMB’000	Brands RMB’000	Customer relationships RMB’000	Development costs RMB’000	Total RMB’000
Cost at 1 January 2017, net of accumulated amortization	8,263	7,434	755	12,529	121,577	411,051	10,469	572,078
Additions—internal development	—	20	951	—	—	—	(971)	—
Additions—acquired	5,481	—	—	95,982	—	—	3,146	104,609
Amortization provided during the year	(2,753)	(1,263)	(116)	(3,725)	(8,606)	(29,096)	—	(45,559)
Exchange realignment	(33)	—	—	5,037	(6,775)	(22,907)	—	(24,678)
At 31 December 2017	10,958	6,191	1,590	109,823	106,196	359,048	12,644	606,450
At 31 December 2017:								
Cost	16,906	13,624	2,076	117,583	124,823	422,024	12,644	709,680
Accumulated amortization	(5,948)	(7,433)	(486)	(7,760)	(18,627)	(62,976)	—	(103,230)
Net carrying amount	10,958	6,191	1,590	109,823	106,196	359,048	12,644	606,450

31 December 2018

	Software RMB’000	Trademarks RMB’000	Patent RMB’000	Proprietary technology RMB’000	Brands RMB’000	Customer relationships RMB’000	Development costs RMB’000	Total RMB’000
Cost at 1 January 2018, net of accumulated amortization	10,958	6,191	1,590	109,823	106,196	359,048	12,644	606,450
Additions—internal development	—	—	5	—	—	—	(5)	—
Additions—acquired	904	—	47	41,049	—	—	2,737	44,737
Disposals	(176)	—	—	—	—	—	—	(176)
Disposal of a subsidiary	(12)	(5,032)	(29)	(2)	—	—	—	(5,075)
Amortization provided during the year	(2,220)	(715)	(162)	(11,733)	(8,438)	(28,531)	—	(51,799)
Exchange realignment	108	—	—	308	5,045	17,058	—	22,519
At 31 December 2018	9,562	444	1,451	139,445	102,803	347,575	15,376	616,656
At 31 December 2018:								
Cost	17,797	862	2,067	158,980	131,108	443,273	15,376	769,463
Accumulated amortization	(8,235)	(418)	(616)	(19,535)	(28,305)	(95,698)	—	(152,807)
Net carrying amount	9,562	444	1,451	139,445	102,803	347,575	15,376	616,656

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

17. OTHER INTANGIBLE ASSETS—continued

(Unaudited)

30 September 2019

	Software RMB'000	Trademarks RMB'000	Patent RMB'000	Proprietary technology RMB'000	Brands RMB'000	Customer relationships RMB'000	Development costs RMB'000	Total RMB'000
Cost at 1 January 2019, net of accumulated amortization	9,562	444	1,451	139,445	102,803	347,575	15,376	616,656
Additions—acquired	898	163	16	1,606	—	—	2,111	4,794
Disposals	(21)	—	—	—	—	—	—	(21)
Disposal of subsidiaries	—	(26)	(851)	(9,556)	—	—	(15,254)	(25,687)
Amortization provided during the period	(2,263)	(69)	(74)	(8,320)	(6,546)	(22,129)	—	(39,401)
Exchange realignment	(4)	—	—	(1,059)	2,932	9,908	—	11,777
At 30 September 2019	8,172	512	542	122,116	99,189	335,354	2,233	568,118
At 30 September 2019:								
Cost	18,751	986	1,132	144,319	135,114	456,817	2,233	759,352
Accumulated amortization	(10,579)	(474)	(590)	(22,203)	(35,925)	(121,463)	—	(191,234)
Net carrying amount	8,172	512	542	122,116	99,189	335,354	2,233	568,118

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

17. OTHER INTANGIBLE ASSETS—continued

Company

	<u>Software</u> RMB’000	<u>Patent</u> RMB’000	<u>Development costs</u> RMB’000	<u>Total</u> RMB’000
31 December 2017				
Cost at 1 January 2017, net of accumulated amortization	7,848	634	74	8,556
Additions—acquired	2,527	—	2	2,529
Amortization provided during the year	<u>(1,246)</u>	<u>(51)</u>	<u>—</u>	<u>(1,297)</u>
At 31 December 2017	<u>9,129</u>	<u>583</u>	<u>76</u>	<u>9,788</u>
At 31 December 2017:				
Cost	13,013	791	76	13,880
Accumulated amortization	<u>(3,884)</u>	<u>(208)</u>	<u>—</u>	<u>(4,092)</u>
Net carrying amount	<u>9,129</u>	<u>583</u>	<u>76</u>	<u>9,788</u>
31 December 2018				
Cost at 1 January 2018, net of accumulated amortization	9,129	583	76	9,788
Additions—internal development	—	5	(5)	—
Additions—acquired	364	—	210	574
Disposals	(176)	—	—	(176)
Amortization provided during the year	<u>(1,354)</u>	<u>(50)</u>	<u>—</u>	<u>(1,404)</u>
At 31 December 2018	<u>7,963</u>	<u>538</u>	<u>281</u>	<u>8,782</u>
At 31 December 2018:				
Cost	13,181	796	281	14,258
Accumulated amortization	<u>(5,218)</u>	<u>(258)</u>	<u>—</u>	<u>(5,476)</u>
Net carrying amount	<u>7,963</u>	<u>538</u>	<u>281</u>	<u>8,782</u>
	<u>Software</u> RMB’000	<u>Patent</u> RMB’000	<u>Development costs</u> RMB’000	<u>Total</u> RMB’000
(Unaudited)				
30 September 2019				
Cost at 1 January 2019, net of accumulated amortization	7,963	538	281	8,782
Additions—acquired	270	—	261	531
Amortization provided during the period	<u>(1,020)</u>	<u>(38)</u>	<u>—</u>	<u>(1,058)</u>
At 30 September 2019	<u>7,213</u>	<u>500</u>	<u>542</u>	<u>8,255</u>
At 30 September 2019:				
Cost	13,450	796	542	14,788
Accumulated amortization	<u>(6,237)</u>	<u>(296)</u>	<u>—</u>	<u>(6,533)</u>
Net carrying amount	<u>7,213</u>	<u>500</u>	<u>542</u>	<u>8,255</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

18. INVESTMENTS IN ASSOCIATES

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Share of net assets	12,040	(93,073)	263,870
Goodwill on acquisition	629,939	655,563	1,015,939
	641,979	562,490	1,279,809
Provision for impairment	—	—	—
	641,979	562,490	1,279,809

Particulars of the Group’s associates are as follows:

Name	Particulars of issued shares held	Place of registration and business	Percentage of ownership interest attributable to the Group			Principal activities
			31 December		30 September	
			2017	2018	2019	
Resverlogix Corp.(a)	Ordinary shares	Canada	42.86%	38.86%	39.02%	Biopharmaceutical R&D
Quest PharmaTech Inc. (b)	Ordinary shares	Canada	14.96%	14.94%	14.94%	Biopharmaceutical R&D
OncoQuest Inc. (c)	Ordinary shares	Canada	39.16%	39.16%	38.74%	Biopharmaceutical R&D
Shanghai Taiyi Venture Capital Partnership (limited partnership) (d)	Limited partnership	PRC	49.9975%	49.9975%	49.9975%	Investment Management
Shenzhen Asia Pacific Health Management Co., Ltd. (e)	Ordinary shares	PRC	—	27.43%	27.43%	Health management consulting
Hightide Therap Eutics, Inc. (hereafter, the “HighTide”) (f)	Ordinary shares	Cayman Islands	—	—	47.02%	Biopharmaceutical R&D

- (a) Investment in Resverlogix Corp. was acquired in 2015 at a consideration of CAD35,431,000.
- (b) Investment in Quest PharmaTech Inc. was acquired in 2015 at a consideration of CAD2,000,000.
- (c) Investment in OncoQuest Inc. was acquired in 2015 at a consideration of USD13,000,000, of which, USD9,000,000 was paid in 2015 and USD4,000,000 was paid in 2016.
- (d) Investment in Shanghai Taiyi Venture Capital Partnership (limited partnership) was acquired in 2016 at a consideration of RMB120,000,000, of which, RMB18,000,000 was paid in 2016, RMB48,000,000 was paid in 2017 and RMB54,000,000 was paid in 2018.
- (e) Investment in Shenzhen Asia Pacific Health Management Co., Ltd. was acquired in 2018 at a consideration of RMB120,000,000.
- (f) On 25 March 2019, HighTide’s shareholding was diluted to 48.74% as a result of the addition of new shareholders and HighTide became an associate of the Group, On 12 August 2019, the equity interests held by the Group was further diluted to 47.02% as the result of the capital injection of other shareholders. Further details are included in note 42 to the Historical Financial Information.

Resverlogix Corp., and Hightide Therap Eutics, Inc, which are considered as material associates of the Group, are strategic partners of the Group and are accounted for using the equity method.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

18. INVESTMENTS IN ASSOCIATES—continued

The following table illustrates the summarized financial information in respect of Hightide Therap Eutics, Inc. adjusted for any differences in accounting policies and reconciled to the carrying amount in the consolidated financial statements:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
Current assets	—	—	73,666
Non-current assets, excluding goodwill	—	—	527,332
Current liabilities	—	—	(9,732)
Non-current liabilities	—	—	(11,924)
Net assets, excluding goodwill	—	—	579,342
Reconciliation to the Group’s interest in the associate:			
Proportion of the Group’s ownership	—	—	47.02%
Group’s share of net assets of the associate, excluding goodwill	—	—	272,407
Goodwill on acquisition	—	—	344,118
Carrying amount of the investment	—	—	616,525
	For the year ended		Nine months
	31 December		ended
	2017	2018	30 September
	RMB’000	RMB’000	2019
Revenue	—	—	—
Loss for the year/period	—	—	(90,410)
Total comprehensive loss for the year/period	—	—	(90,410)

The following table illustrates the summarized financial information of the Group’s associates that are not individually material to the Group:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
Share of the associates’ losses for the relevant period	(19,525)	(1,340)	(24,841)
Share of the associate’s other comprehensive interest for the relevant period	1,263	(201)	—
Carrying amount of the Group’s investment in the associates	147,123	330,188	307,788

The Group tested its investments in associates for impairment by comparing the recoverable amounts with the carrying amounts. In determining the recoverable amount of the investments in the associates, the Group estimates its shares of present value of estimated future cash flows expected to generate from the operations of the associates. The Group tested its investments in associates for impairment annually or more frequently if events or changes in circumstances indicated that they might be impaired. During the Relevant Periods, the estimated recoverable amounts of the investments in associates were greater than the carrying values and therefore no impairment was recorded.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

19. INTERESTS IN SUBSIDIARIES

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Unlisted shares, at cost	1,811,366	2,233,535	2,199,238
Amounts due from subsidiaries*	808,825	961,534	1,049,820
	<u>2,620,191</u>	<u>3,195,069</u>	<u>3,249,058</u>

* The balances with subsidiaries are unsecured, interest-bearing and have no fixed terms of repayment. The balances are expected to be recovered after more than one year.

20. EQUITY INVESTMENTS DESIGNATED AT FAIR VALUE THROUGH OTHER COMPREHENSIVE INCOME

Group

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Equity investments designated at fair value through other comprehensive income			
Listed equity investment, at fair value:			
Prometic Life Sciences Inc.(a)	281,583	37,560	280
Aridis Pharmaceuticals, Inc.(b)	71,876	66,862	41,815
	<u>353,459</u>	<u>104,422</u>	<u>42,095</u>
Unlisted equity investments, at fair value:			
Cantex Pharmaceuticals, Inc.(c)	196,027	205,896	212,187
Curemark, LLC(d)	—	297,608	393,889
Other	877	859	1,640
	<u>196,904</u>	<u>504,363</u>	<u>607,716</u>
	<u>550,363</u>	<u>608,785</u>	<u>649,811</u>

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Equity investments designated at fair value through other comprehensive income			
Listed equity investment, at fair value:			
Prometic Life Sciences Inc.(a)	281,583	37,560	280
Unlisted equity investments, at fair value			
Curemark, LLC(d)	—	31,863	31,863
	<u>281,583</u>	<u>69,423</u>	<u>32,143</u>

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

20. EQUITY INVESTMENTS DESIGNATED AT FAIR VALUE THROUGH OTHER COMPREHENSIVE INCOME—continued

The above equity investments were irrevocably designated at fair value through other comprehensive income as the Group considers these investments to be strategic in nature.

- (a) The Group acquired 48,147,053 issued shares of Prometic Life Sciences Inc. (“PLI”) with a consideration of USD9,999,999 in 2013. PLI is a company listed on the Canada Stock Exchange. The Group disposed certain shares during the Relevant Periods and the remaining shares were 3,800 as at 30 September 2019.
- (b) The Group acquired 5,365,854 issued shares of Aridis Pharmaceuticals, Inc. (“Aridis”) with a consideration of USD11,000,000 in 2017. Aridis is a company listed on the National Association of Securities Dealers Automated Quotations (NASDAQ: ARDS). The fair value of the investment in Aridis was RMB71,876,000, RMB66,862,000, RMB41,815,000 as at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.
- (c) The Group totally acquired 31,123,560 issued shares of Cantex Pharmaceuticals, Inc. (“Cantex”) with a consideration of USD30,000,000 during years ended 31 December 2014 and 2015. The fair value of the investment in Cantex was RMB196,027,000, RMB205,896,000, and RMB212,187,000 as at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.
- (d) The Group acquired 14,428 common shares of Curemark, LLC (“Curemark”) with cash consideration of USD5,000,000 and 111,740 common shares of Curemark by providing products of USD51,185,000 during the year ended 31 December 2018 and nine months ended 30 September 2019. The fair value of the investment in Curemark was RMB297,608,000 and RMB393,889,000 as at 31 December 2018 and 30 September 2019, respectively.

The information about the pledged assets is disclosed in note 45 to the Historical Financial Information.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

21. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

Group

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Current assets			
Wealth management products	293,185	266,293	343,897
Non-current assets			
Unlisted equity investments and convertible loan, at fair value			
Kymab Group Limited(a)	241,766	259,427	320,934
TPG Biotechnology Partners IV, L.P.(b)	104,983	89,744	77,260
TPG Biotechnology Partners V, L.P.(c)	116,613	181,109	337,432
ORI Healthcare Fund, L.P.(d)	190,890	221,873	279,710
Convertible loan(e)	146,204	—	—
Shenzhen Top Dental Medical Co., Ltd.(f)	90,400	104,500	123,400
Labway Clinical Laboratory Co., Ltd.(g)	33,915	36,500	40,700
Hejia Hongli (Hang Zhou) Venture Investment Partnership (L.P.)(h)	24,554	32,995	36,168
CDH Avatar, L.P.(i)	12,076	4,730	3,608
Others	462	489	40,726
	<u>961,863</u>	<u>931,367</u>	<u>1,259,938</u>
	<u>1,255,048</u>	<u>1,197,660</u>	<u>1,603,835</u>

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Current assets			
Wealth management products	253,005	204,004	280,406
Non-current assets			
Unlisted equity investments, at fair value			
TPG Biotechnology Partners IV, L.P.(b)	104,983	89,744	77,260
TPG Biotechnology Partners V, L.P.(c)	116,613	181,109	337,432
Hejia Hongli (Hang Zhou) Venture Investment Partnership (L.P.) (h)	24,554	32,995	36,168
	<u>246,150</u>	<u>303,848</u>	<u>450,860</u>
	<u>499,155</u>	<u>507,852</u>	<u>731,266</u>

(1) Wealth management products

The Group entered into contracts in respect to wealth management products from banks and other financial institutions with an expected but not guaranteed rates of return ranging from 2.00% to 5.80% per annum during the Relevant Periods and nine months ended 30 September 2018. The Group managed and evaluated the performance of the investments on a fair value basis, in accordance with the Group’s risk management and investment strategy and thus designated at fair value through profit or loss as at 31 December 2017, 2018 and 30 September 2019.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

21. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS—continued

(2) Unlisted equity investments, at fair value

Unlisted equity investments represented the Group’s certain minority interests in private companies. The Group elected the fair value method at the date of initial recognition and carried these investments subsequently at fair value. The balance of the Group’s unlisted equity investments comprised a number of individual investments, of which the following investments are material to the Group:

- (a) The Group acquired 8,487,385 Series C preference shares of Kymab Group Limited (“Kymab”) with a consideration of USD36,500,000 in 2017. The fair value of the investment in Kymab was RMB241,766,000, RMB259,427,000 and RMB320,943,000 as at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.
- (b) The Company entered into a purchase and sale agreement to purchase a limited partnership interest in TPG Biotechnology Partners IV, L.P. (“TPG IV”) in 2014. The fair value of the investment in TPG IV was RMB104,983,000, RMB89,744,000 and RMB77,260,000 as at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.
- (c) The Company entered into a purchase and sale agreement to purchase a limited partnership interest in TPG Biotechnology Partners V, L.P. (“TPG V”) in 2016. The fair value of the investment in TPG V was RMB116,613,000, RMB181,109,000, and RMB337,432,000 as at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.
- (d) The Group entered into two share purchase agreements to purchase a limited partnership interest in ORI Healthcare Fund, L.P (“ORI”) in 2016. The fair value of the investment in ORI was RMB190,890,000, RMB221,873,000 and RMB279,710,000 as at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.
- (e) According to the terms and conditions of the convertible loan with Shenzhen Moshi Jianye Investment Center (limited partnership) (“Moshi Jianye”), the Group is entitled to convert the convertible loan into equity capital of the relevant medical developing company at its own discretion before the maturity of the convertible loan. The convertible loan was classified as financial assets at fair value through profit or loss. In July 2018, the Group exercised the convertible option.
- (f) The Group entered into a share purchase agreement with Shenzhen Top Dental Medical Co., Ltd. (“Top Dental”), pursuant to which the Group agreed to acquire 14% of shares of Top Dental with a consideration of RMB35,000,000 in 2016. The Group entered into a share purchase agreement with Top Dental, pursuant to which the Group agreed to acquire additional 0.62% of the issued shares of Top Dental with the consideration of RMB10,000,000 in 2018. The fair value of the investment in Top Dental was RMB90,400,000, RMB104,500,000 and RMB123,400,000 as at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.
- (g) The Group entered into a share purchase agreement with Shanghai Labway Clinical Laboratory Co., Ltd. (“Labway”) with a consideration of RMB29,964,000 in 2016. The

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

21. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS—continued

fair value of the investment in Labway was RMB33,915,000, RMB36,500,000 and RMB40,700,000 as at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.

- (h) The Group entered into a purchase agreement to purchase a limited partnership interest in Hejia Hongli (Hang Zhou) Venture Investment Partnership (L.P.) (“Hejia Hongli”) with a consideration of RMB20,000,000, in 2015. The fair value of the investment in Hejia Hongli was RMB24,554,000, RMB32,996,000, and RMB36,167,000 as at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.
- (i) The Group entered into a purchase agreement to purchase a limited partnership interest in CDH Avatar, L.P. (“CDH”) with a consideration of USD1,500,000 in 2015. The fair value of the investment in CDH was RMB12,076,000, RMB4,730,000 and RMB3,608,000 as at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.

22. DERIVATIVE FINANCIAL INSTRUMENTS

Group and Company

	<u>As at 31 December</u>		<u>As at</u>
	<u>2017</u>	<u>2018</u>	<u>30 September</u>
	<u>RMB’000</u>	<u>RMB’000</u>	<u>2019</u>
			<u>RMB’000</u>
			<u>(Unaudited)</u>
Current assets			
Warrants	<u>43,150</u>	<u>77,174</u>	<u>6,811</u>

The Group entered into share purchase agreements with Resverlogix Corp., pursuant to which each purchased unit is comprised of one common share and common share purchase warrants. Warrants are not designated for hedge purposes and are measured at fair value through profit or loss. The changes in the fair value of the warrants were charged to the statement of profit or loss during the Relevant Periods.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

23. OTHER NON-CURRENT ASSETS

Group

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
Prepayment for purchase of property plant and equipment	60,534	38,808	55,593
Prepayment for marketing authorisation	80,405	99,758	96,685
Long-term interest receivables	2,529	7,761	12,239
	<u>143,468</u>	<u>146,327</u>	<u>164,517</u>

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
Prepayment for purchase of property plant and equipment	37,797	6,145	2,464

24. INVENTORIES

Group

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
Raw materials and consumables	406,034	559,116	622,507
Work in progress	296,829	298,875	355,520
Finished goods	650,729	788,568	1,197,561
	<u>1,353,592</u>	<u>1,646,559</u>	<u>2,175,588</u>

The inventories are net of a write-down of approximately RMB86,493,000, RMB100,004,000 and RMB128,081,000 as at 31 December 2017, 2018 and the period ended 30 September 2019, respectively.

The information about the pledged assets is disclosed in note 45 to the Historical Financial Information.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

24. INVENTORIES—continued

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000 (Unaudited)
Raw materials	129,471	130,521	145,037
Work in progress	186,161	138,193	164,947
Finished goods	114,234	94,655	115,640
	<u>429,866</u>	<u>363,369</u>	<u>425,624</u>

The inventories are net of a write-down of approximately RMB557,000, RMB974,000 and RMB241,000 as at 31 December 2017, 2018 and the period ended 30 September 2019, respectively.

25. TRADE AND BILLS RECEIVABLES

Group

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000 (Unaudited)
Trade receivables	710,738	1,109,381	1,067,262
Bills receivable	11,097	1,270	22,404
Allowance for expected credit losses	(18,633)	(26,162)	(34,670)
	<u>703,202</u>	<u>1,084,489</u>	<u>1,054,996</u>

The Group’s trading terms with its customers are mainly on credit. The credit period is generally from one month to three months. The Group seeks to maintain strict control over its outstanding receivables to minimize credit risk. Overdue balances are reviewed regularly by senior management. The Group does not hold any collateral or other credit enhancements over its trade receivable balances. The balances of trade receivables are non-interest-bearing.

An aging analysis of the trade receivables as at the end of each of the Relevant Periods, based on the billing date and net of allowance for expected credit losses, is as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000 (Unaudited)
Within 90 days	642,198	1,019,880	955,481
90 to 180 days	13,858	33,962	61,226
180 days to 1 year	24,784	11,125	16,361
1 year to 2 years	19,486	14,845	16,299
Over 2 years	2,876	4,677	5,629
	<u>703,202</u>	<u>1,084,489</u>	<u>1,054,996</u>

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

25. TRADE AND BILLS RECEIVABLES—continued

The movements in the allowance for expected credit losses of trade receivables are as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
At beginning of year/period	15,044	18,633	26,162
Impairment losses, net	6,600	10,133	9,101
Write-off	(1,649)	(2,926)	(1,213)
Exchange realignment	(1,362)	322	620
	<u>18,633</u>	<u>26,162</u>	<u>34,670</u>

The Group applies the simplified approach to providing for expected credit losses prescribed by IFRS 9, which permits the use of the lifetime expected credit loss provision for all trade receivables.

An impairment analysis is performed at the end of each of the Relevant Periods using a provision matrix to measure expected credit losses. The provision rates are based on days past due for groupings of various customer segments with similar loss patterns. The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the end of each of the Relevant Periods about past events, current conditions and forecasts of future economic conditions. Generally, trade receivables are written off when there is information indicating that the counterparty is in severe financial difficulty and there is no realistic prospect of recovery, e.g. when the counterparty has been placed under liquidation or has entered into bankruptcy proceedings.

Set out below is the information during the Relevant Periods about the credit risk exposure on the Group’s trade receivables using a provision matrix:

	As at 31 December 2017		
	Amount	Expected loss rate	Impairment
	RMB’000	%	RMB’000
Current	536,482	0.50	2,682
Past due less than 3 months	98,196	0.91	896
Past due 3 to 6 months	13,987	0.91	128
Past due 6 to 12 months	25,012	0.91	228
Past due 1 to 2 years	27,927	30.23	8,441
Past due over 2 years	9,134	68.51	6,258
	<u>710,738</u>		<u>18,633</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

25. TRADE AND BILLS RECEIVABLES—continued

	As at 31 December 2018		
	Amount	Expected loss rate	Impairment
	RMB’000	%	RMB’000
Current	869,530	0.50	4,347
Past due less than 3 months	154,839	0.91	1,412
Past due 3 to 6 months	34,275	0.91	313
Past due 6 to 12 months	11,227	0.91	102
Past due 1 to 2 years	21,345	30.45	6,500
Past due over 2 years	18,165	74.25	13,488
	<u>1,109,381</u>		<u>26,162</u>

	As at 30 September 2019		
	Amount	Expected loss rate	Impairment
	RMB’000	%	RMB’000
(Unaudited)			
Current	746,866	0.50	3,734
Past due less than 3 months	191,647	0.89	1,702
Past due 3 to 6 months	61,778	0.89	552
Past due 6 to 12 months	16,509	0.89	147
Past due 1 to 2 years	23,405	30.36	7,107
Past due over 2 years	27,057	79.20	21,428
	<u>1,067,262</u>		<u>34,670</u>

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000
Trade receivables	167,719	134,298	172,395
Bills receivable	11,063	1,270	21,757
Allowance for expected credit losses	(3,942)	(5,827)	(6,640)
	<u>174,840</u>	<u>129,741</u>	<u>187,512</u>

The movements in the allowance for expected credit losses of trade receivables are as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000
At beginning of year/period	1,229	3,942	5,827
Impairment losses, net	2,713	3,772	813
Write-off	—	(1,887)	—
	<u>3,942</u>	<u>5,827</u>	<u>6,640</u>

The Company applies the simplified approach to provide for expected credit losses prescribed by IFRS 9.

The information about the pledged assets is disclosed in note 45 to the Historical Financial Information.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

26. CONTRACT ASSETS

Group

	As at 31 December		As at 30 September
	2017	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)
Contract assets arising from service	<u>11,389</u>	<u>17,384</u>	<u>21,560</u>

The contract assets relate to the Group’s right to consideration for work completed and not billed.

27. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

Group

	As at 31 December		As at 30 September
	2017	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)
Prepayments	252,935	206,628	352,508
Deposits and other receivables*	56,239	57,725	52,490
Interest receivables	202,849	68,902	15,273
Export drawback receivable	43,334	48,582	31,752
VAT recoverable	91,609	83,645	77,035
Prepaid tax	203	459	38,045
Prepaid expenses	13,356	20,945	40,038
Less: Impairment**	<u>(8,110)</u>	<u>(10,085)</u>	<u>(15,661)</u>
	<u>652,415</u>	<u>476,801</u>	<u>591,480</u>

* Deposits and other receivables are unsecured, non-interest-bearing and repayable on demand.

** As at 31 December 2017, 31 December 2018 and 30 September 2019, the impairment of the financial assets included in prepayments, other receivables and other assets were measured based on 12-month expected credit loss if they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, they were measured based on lifetime expected credit loss.

The information about the credit exposure is disclosed in note 49 to the Historical Financial Information.

Company

	As at 31 December		As at 30 September
	2017	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)
Prepayments	238,230	175,439	312,197
Deposits and other receivables*	39,162	35,333	28,997
Interest receivables	202,849	68,902	15,272
Export drawback receivable	19,053	12,121	—
VAT recoverable	26,457	24,616	4,576
Prepaid expenses	—	4,223	4,111
Less: Impairment	<u>(2,556)</u>	<u>(3,788)</u>	<u>(8,566)</u>
	<u>523,195</u>	<u>316,846</u>	<u>356,587</u>

* Deposits and other receivables are unsecured, non-interest-bearing and repayable on demand.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

28. CASH AND CASH EQUIVALENTS AND PLEDGED DEPOSITS—continued

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Cash and bank balances	167,389	733,673	401,690
Time deposits	3,060,549	890,909	392,510
	<u>3,227,938</u>	<u>1,624,582</u>	<u>794,200</u>
Less:			
Time deposit with original maturity over three months:			
—non-current	490,909	127,510	—
—current	2,369,640	463,299	127,510
Cash and cash equivalents	<u>367,389</u>	<u>1,033,773</u>	<u>666,690</u>

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Cash and cash equivalents and time deposit			
Denominated in			
—RMB	3,227,217	1,550,549	703,885
—USD	691	73,945	88,496
—EUR	30	88	56
—Others	—	—	1,763
	<u>3,227,938</u>	<u>1,624,582</u>	<u>794,200</u>

29. TRADE AND BILLS PAYABLES

Group

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Bills payable	3,344	—	—
Trade payables	159,130	205,273	253,569
	<u>162,474</u>	<u>205,273</u>	<u>253,569</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

29. TRADE AND BILLS PAYABLES—continued

An aging analysis of the trade and bills payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Within 1 year	161,562	203,668	250,609
1 year to 2 years	225	778	2,375
2 years to 3 years	62	194	367
Over 3 years	625	633	218
	<u>162,474</u>	<u>205,273</u>	<u>253,569</u>

The trade payables are non-interest-bearing and are normally settled on terms of 90 days.

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Trade payables	<u>6,516</u>	<u>13,672</u>	<u>6,676</u>

An aging analysis of the trade payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Within 1 year	6,516	13,465	6,676
1 year to 2 years	—	207	—
	<u>6,516</u>	<u>13,672</u>	<u>6,676</u>

The trade payables are non-interest-bearing and are normally settled on terms of 30 days.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

30. OTHER PAYABLES AND ACCRUALS

Group

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Other payables	46,908	68,842	93,338
Accruals	72,260	80,142	89,772
Payables for purchase of property, plant and equipment	41,395	132,251	68,787
Payables for purchase of other intangible assets	29,259	14,717	—
Interest payables	15,877	19,826	59,071
Salary payables	125,773	157,292	148,767
Other tax payables	8,552	20,613	24,367
	<u>340,024</u>	<u>493,683</u>	<u>484,102</u>

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Other payables	9,003	5,175	3,881
Accruals	16,556	7,771	3,921
Payables for purchase of property plant and equipment	23,888	124,830	50,334
Interest payables	7,080	10,672	54,857
Salary payables	57,727	58,620	62,628
Financial guarantee contracts	—	—	15,765
Other tax payables	459	297	71
	<u>114,713</u>	<u>207,365</u>	<u>191,457</u>

Other payables are unsecured, non-interest-bearing and repayable on demand. The fair values of other payables at the end of each of the Relevant Periods approximated to their corresponding carrying amounts.

31. CONTRACT LIABILITIES

Group

The Group recognized the following revenue-related contract liabilities:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Sale of products	93,611	140,409	172,785
CDMO services	35,787	84,112	55,094
Others	—	30,322	30,033
	<u>129,398</u>	<u>254,843</u>	<u>257,912</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

31. CONTRACT LIABILITIES—continued

Company

The Company recognized the following revenue-related contract liabilities:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000
Sale of products	—	6,690	5,625
	<u> </u>	<u> </u>	<u> </u>

The Group and Company receive payments from customers based on billing schedules as established in the sales contracts. Payments are usually received in advance of the performance under the contracts which are mainly from customers.

The Group also receives payments from customers based on billing schedules as established in the CDMO service contracts. Payments are usually received in advance of the performance under the contracts which are mainly from CDMO services for clients.

All the obligations are expected to be recognized within one year. The amounts disclosed above do not include variable consideration which is constrained.

32. INTEREST-BEARING BANK AND OTHER BORROWINGS

Group

31 December 2017

	As at 31 December 2017		
	Effective interest rate per annum	Maturity	RMB’000
Current			
Bank loans—secured ^(a)	2.5%-5.6%	2018	326,246
Bank loans—unsecured	2.3%-5.7%	2018	1,741,500
Current portion of long-term bank loans—secured ^(a)	2.2%-5.0%, LIBOR+150BP-200BP	2018	211,246
Current portion of long-term bank loans—unsecured	3MLIBOR+130BP, LIBOR+150BP	2018	900,740
Other borrowings—unsecured ^(b)	5.8%	2018	80,000
			<u>3,259,732</u>
Non-current			
Bank loans—secured ^(a)	4.4%	2019	4,970
Bank loans—unsecured	LIBOR+150BP, 3MLIBOR+130BP	2019-2020	826,576
Corporate bonds—unsecured ^(c)	3.4%	2021	992,787
			<u>1,824,333</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

32. INTEREST-BEARING BANK AND OTHER BORROWINGS—continued

31 December 2018

	As at 31 December 2018		
	Effective interest rate per annum	Maturity	RMB’000
Current			
Bank loans—secured ^(a)	2.5%-6.3%	2019	91,389
Bank loans—unsecured	2.6%-6.3%, 3MLIBOR+130BP	2019	1,612,392
Current portion of long—term bank loans— secured ^(a)	4.4%	2019	4,999
Current portion of long—term bank loans— unsecured	LIBOR+150BP	2019	476,992
Other borrowings—unsecured ^(b)	3.5%-5.4%	2019	277,710
			<u>2,463,482</u>
Non-current			
Bank loans—secured ^(a)	6.5%, LIBOR+Applicable margin(1.3%-1.9%)	2023	862,319
Bank loans—unsecured	3MLIBOR+130BP-150BP	2020-2021	592,515
Corporate bonds—unsecured ^(c)	3.4%	2021	994,608
			<u>2,449,442</u>

30 September 2019

	As at 30 September 2019		
	Effective interest rate per annum	Maturity	RMB’000
Current			
Bank loans—secured ^(a)	4.8%-5.7%	2019-2020	598,000
Bank loans—unsecured	1.1%-4.9%, 3MLIBOR+130BP	2019-2020	1,861,038
Current portion of long—term bank loans— secured ^(a)	4.4%-6.5%	2019-2020	59,304
Current portion of long—term bank loans— unsecured	3MLIBOR+130BP	2020	392,066
Other borrowings—unsecured ^(b)	2.9%-4.5%	2019-2020	730,410
Current portion of corporate bonds—unsecured ^(c)	3.4%	2019	990,142
			<u>4,630,960</u>
Non-current			
Bank loans—secured ^(a)	6.5%, LIBOR+APPLICABLE MARGIN (1.3-1.9%)	2023	817,577
Bank loans—unsecured	3MLIBOR+150BP	2021	217,139
Corporate bonds—secured ^(c)	5.9%	2024	689,310
Corporate bonds—unsecured	6.0%	2021	5,873
			<u>1,729,899</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

32. INTEREST-BEARING BANK AND OTHER BORROWINGS—continued

Analyzed into:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
Repayable:			RMB’000
Within one year	3,259,732	2,463,482	4,630,960
In the second year	459,097	380,442	217,139
In the third to fifth years, inclusive	1,365,236	2,069,000	1,512,760
	<u>5,084,065</u>	<u>4,912,924</u>	<u>6,360,859</u>

Company

31 December 2017

	As at 31 December 2017		
	Effective interest rate per annum	Maturity	RMB’000
Current			
Bank loans—unsecured	2.3%-5.7%	2018	1,281,048
Other borrowings—unsecured	5.8%	2018	80,000
			<u>1,361,048</u>
Non-current			
Corporate bonds—unsecured	3.4%	2021	<u>992,787</u>

31 December 2018

	As at 31 December 2018		
	Effective interest rate per annum	Maturity	RMB’000
Current			
Bank loans—unsecured	2.6%-5.7%	2019	937,400
Other borrowings—unsecured	3.5%-5.4%	2019	95,000
			<u>1,032,400</u>
Non-current			
Bank loans—secured	6.5%	2023	545,280
Corporate bonds—unsecured	3.4%	2021	994,608
			<u>1,539,888</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

32. INTEREST-BEARING BANK AND OTHER BORROWINGS—continued

30 September 2019

	As at 30 September 2019		
	Effective interest rate per annum	Maturity	RMB’000
Current			
Bank loans—secured	4.8%	2020	588,000
Bank loans—unsecured	2.6%-4.9%	2019-2020	934,562
Current portion of long-term bank loans—secured	6.5%	2020	54,528
Other borrowings—unsecured	2.9%-4.5%	2019-2020	445,000
Current portion of corporate bonds—unsecured	3.4%	2019	990,142
			<u>3,012,232</u>
Non-current			
Bank loans—secured	6.5%	2023	490,752
Corporate bonds—secured	5.9%	2024	689,310
Corporate bonds—unsecured	6.0%	2021	5,873
			<u>1,185,935</u>

Analyzed into:

	As at 31 December		As at 30 September
	2017	2018	2019
	RMB’000	RMB’000	RMB’000
Repayable:			
Within one year	1,361,048	1,032,400	3,012,232
In the second year	—	54,528	—
In the third to fifth years, inclusive	992,787	1,485,360	1,185,935
	<u>2,353,835</u>	<u>2,572,288</u>	<u>4,198,167</u>

- (a) As at 31 December 2017 and 2018 and 30 September 2019, the mortgaged and guaranteed bank loans with the amounts of RMB159,242,000, RMB317,039,000 and RMB326,824,000 were secured by the total assets owned by SPL, respectively. As at 31 December 2017 and 2018 and 30 September 2019, the pledged assets have a net carrying amount of approximately RMB1,189,647,000, RMB1,485,333,000 and RMB1,541,747,000, respectively.

As at 31 December 2017 and 2018 and 30 September 2019, Mr. Li Li and Shenzhen Doppler Industrial Development Co., Ltd has guaranteed certain of the Group’s bank loans of up to RMB383,221,000, RMB96,388,000 and RMB14,776,000, respectively.

As at 31 December 2018 and 30 September 2019, the pledged bank loans with the amounts of RMB545,280,000 and RMB1,133,280,000 were secured by the pledge of 100% of shares of Shenzhen Topknow Industrial Development Co., Ltd, Mr. Li Li and Ms. Li Tan respectively.

- (b) As at 31 December 2017 and 2018 and 30 September 2019, other borrowings included discounted notes receivable of RMB80,000,000, RMB95,000,000 and RMB445,000,000, and letters of credit of nil, RMB182,710,000 and RMB285,410,000, respectively.

- (c) On 8 November 2016, the Company issued a domestic corporate bond at a par value of RMB1,000,000,000 in the PRC (the “16 Hepalink”). The 16 Hepalink will mature in five years from the issue date. Upon the third anniversary of the issue date, the Company shall be entitled to adjust the coupon rate and the bond holders shall be entitled to sell back the whole or partial 16 Hepalink at par. The 16 Hepalink was listed on 8 November 2016 on the Shenzhen Stock Exchange and bears interest at the rate of 3.19% per annum, payable annually in arrears or on the business day nearest to 8 November of each year, starting from 8 November 2017. On 7 November 2019, the Company paid the bond with a principal of RMB994,103,000 and the corresponding interests.

On 23 April 2019, the Company issued a non-publicly issued bond at a par value of RMB700,000,000 in the PRC (the “19 Hepalink”). The 19 Hepalink will mature in five years from the issue date. Upon the third anniversary of the issue date, the Company shall be entitled to adjust the coupon rate and the bond holders shall be entitled to sell back the whole or partial 19 Hepalink at par. The 19 Hepalink bears interest at the rate of 5.50% per annum, payable annually in arrears or on the business day nearest to 23 April of each year, starting from 23 April 2019.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

33. DEFERRED INCOME

Group

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
Government grants	42,345	31,254	RMB’000 (Unaudited) 21,334

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
Government grants	10,254	4,664	RMB’000 (Unaudited) 4,147

Government grants received for compensate for the Group’s research and development costs which has not yet been undertaken are included in deferred income and recognised as income on a systematic basis of over the periods that the cost, which it is intended to compensate, are expensed. Government grants received relates to assets invested in laboratory equipment and plant were credited to deferred income and are recognised as income over the expected useful lives of the relevant assets.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

34. DEFERRED TAX

Group

The movements in deferred tax assets during the Relevant Periods are as follows:

	Deferred tax assets										Total		
	Fair value adjustments of financial assets at fair value through other comprehensive income	Fair value adjustments of financial assets at fair value through profit and loss	Fair value loss on derivative instruments	Impairment of assets	Adjustment of share of profits and losses of associates	Accrued interest expenses	Unrealised profits from intercompany transactions	Accrued bonus	Accrued pension	Tax losses		Amortization of customer relationships and trade marks	Others
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At 1 January 2017:	4,091	1,268	—	3,015	9,332	38,858	6,013	4,385	11,832	119,076	13,894	7,863	219,627
Deferred tax credit/(charged) to the statement of profit or loss during the year	—	2,507	—	1,773	10,317	(8,251)	12,094	(43)	—	(44,429)	(6,787)	(770)	(33,589)
Deferred tax credit/(charged) to other comprehensive income during the year	6,677	—	—	—	(2,191)	—	—	—	(1,923)	—	—	—	2,563
Exchange differences	(458)	—	—	(120)	657	(1,985)	—	(254)	(623)	2,047	(582)	(147)	(1,465)
At 31 December 2017:	10,310	3,775	—	4,668	18,115	28,622	18,107	4,088	9,286	76,694	6,525	6,946	187,136
At 1 January 2018	10,310	3,775	—	4,668	18,115	28,622	18,107	4,088	9,286	76,694	6,525	6,946	187,136
Deferred tax (charged)/credit to the statement of profit or loss during the year	—	(3,775)	—	2,294	42,013	3,737	23,970	(411)	—	(53,337)	(1,787)	3,682	16,386
Deferred tax credit/(charged) to other comprehensive income during the year	14,174	—	—	—	—	—	—	—	(1,653)	—	—	—	12,521
Exchange differences	614	—	—	157	(1,347)	1,576	—	191	408	2,722	263	245	4,829
At 31 December 2018:	25,098	—	—	7,119	58,781	33,935	42,077	3,868	8,041	26,079	5,001	10,873	220,872

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

34. DEFERRED TAX—continued

Group

The movements in deferred tax assets during the Relevant Periods are as follows—(continued):

	Deferred tax assets												
	Fair value adjustments of financial assets at fair value through other comprehensive income	Fair value adjustments of financial assets at fair value through profit and loss	Fair value loss on derivative instruments	Impairment of assets	Adjustment of share of profits and losses of associates	Accrued interest expenses	Unrealised profits from intercompany transactions	Accrued bonus	Accrued pension	Tax losses	Amortization of customer relationships and trademarks	Others	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At 1 January 2019	25,098	—	—	7,119	58,781	33,935	42,077	3,868	8,041	26,079	5,001	10,873	220,872
Deferred tax credit/ (charged) to the statement of profit or loss during the period	—	—	7,520	5,052	6,329	—	31,907	—	—	(8,467)	—	1,295	43,636
Deferred tax credit/ (charged) to other comprehensive income during the period	4,876	—	—	—	(8,000)	—	—	—	5,480	—	—	—	2,356
Exchange differences	541	—	—	266	200	1,037	—	118	421	(25)	152	206	2,916
At 30 September 2019 (Unaudited)	30,515	—	7,520	12,437	57,310	34,972	73,984	3,986	13,942	17,587	5,153	12,374	269,780

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

34. DEFERRED TAX—continued

Group

The movements in deferred tax liabilities during the Relevant Periods are as follows :

	Fair value adjustments of financial assets at fair value through other comprehensive income	Fair value gain on derivative instruments	Fair value adjustment arising from acquisition of subsidiaries	Adjustment of amortization of goodwill	Depreciation allowance in excess of related depreciation	Disposal of a subsidiary	Fair value adjustments of financial assets at fair value through profit and loss	Others	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At 1 January 2017	60,407	1,937	241,038	157,325	52,601	—	127	2,522	515,957
Deferred tax credited to the statement of profit or loss during the year	—	(148)	(98,844)	(47,381)	(22,912)	—	(127)	(966)	(170,378)
Deferred tax credited to other comprehensive income during the year	(29,535)	—	—	—	—	—	—	—	(29,535)
Exchange differences	—	—	(10,333)	(7,571)	(2,258)	—	—	(115)	(20,277)
At 31 December 2017	30,872	1,789	131,861	102,373	27,431	—	—	1,441	295,767
At 1 January 2018	30,872	1,789	131,861	102,373	27,431	—	—	1,441	295,767
Deferred tax charged/(credited) to the statement of profit or loss during the year	—	5,104	(11,767)	9,935	21,438	—	9,181	226	34,117
Deferred tax credited to other comprehensive income during the year	(30,872)	—	—	—	—	—	—	—	(30,872)
Exchange differences	—	—	5,898	5,509	2,042	—	—	83	13,532
At 31 December 2018	—	6,893	125,992	117,817	50,911	—	9,181	1,750	312,544
At 1 January 2019	—	6,893	125,992	117,817	50,911	—	9,181	1,750	312,544
Deferred tax (credited)/charged to the statement of profit or loss during the period	—	(6,893)	(651)	—	1,229	88,816	17,735	—	100,236
Deferred tax charged to other comprehensive income during the period	1,035	—	—	—	—	—	—	—	1,035
Exchange differences	(60)	—	3,650	3,600	1,480	—	—	52	8,722
At 30 September 2019 (Unaudited)	975	—	128,991	121,417	53,620	88,816	26,916	1,802	422,537

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

34. DEFERRED TAX—continued

Group

For presentation purposes, certain deferred tax assets and liabilities with the amounts of RMB165,320,000, RMB110,041,000 and RMB113,672,000 as at 31 December 2017 and 2018 and 30 September 2019, respectively, have been offset in the statement of financial position. The following is an analysis of the deferred tax balances of the Group for financial reporting purposes:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Net deferred tax assets recognised in the consolidated statement of financial position	<u>21,816</u>	<u>110,831</u>	<u>156,108</u>
Net deferred tax liabilities recognised in the consolidated statement of financial position	<u>130,447</u>	<u>202,503</u>	<u>308,865</u>

Deferred income tax assets are recognised for tax losses carried forward to the extent that the realisation of the related tax benefits through future taxable profits is probable. Deferred tax assets have not been recognised in respect of losses arisen in subsidiaries that have been loss-making for some time and it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

Deferred tax assets have not been recognized in respect of the following item:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
Tax losses	<u>224,864</u>	<u>336,923</u>	<u>551,750</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

34. DEFERRED TAX—continued

Company

The movements in deferred tax assets during the Relevant Periods are as follows:

	Deferred tax assets						Total RMB'000
	Fair value adjustments of financial assets at fair value through profit and loss RMB'000	Fair value adjustments of financial assets at fair value through profit and loss RMB'000	Fair value loss on derivative instruments RMB'000	Impairment of assets RMB'000	Adjustment of share of profits and losses of associates RMB'000	Others RMB'000	
At 1 January 2017	—	—	—	265	6,742	3,635	10,642
Deferred tax credited/(charged) to the statement of profit or loss during the year	—	2,254	—	371	9,360	(955)	11,030
At 31 December 2017	—	2,254	—	636	16,102	2,680	21,672
At 1 January 2018	—	2,254	—	636	16,102	2,680	21,672
Deferred tax (charged)/credited to the statement of profit or loss during the year	—	(2,254)	—	1,359	34,089	(538)	32,656
Deferred tax credit to other comprehensive income during the year	10,579	—	—	—	1,863	—	12,442
At 31 December 2018	10,579	—	—	1,995	52,054	2,142	66,770
At 1 January 2019	10,579	—	—	1,995	52,054	2,142	66,770
Deferred tax credit to the statement of profit or loss during the period	—	—	7,519	100	5,598	175	13,392
Deferred tax charged to other comprehensive income during the period	(2,095)	—	—	—	(7,053)	—	(9,148)
At 30 September 2019 (Unaudited)	8,484	—	7,519	2,095	50,599	2,317	71,014

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

34. DEFERRED TAX—continued

Company

The movements in deferred tax liabilities during the Relevant Periods are as follows:

	Deferred tax liabilities			Total RMB’000
	Fair Value adjustments of finance assets at fair value through other comprehensive income RMB’000	Fair value gain on derivative instruments RMB’000	Fair value adjustments of financial assets at fair value through profit and loss	
At 1 January 2017	60,360	1,937	127	62,424
Deferred tax charged to the statement of profit or loss during the year	—	(148)	(127)	(275)
Deferred tax credited to other comprehensive income during the year	(29,835)	—	—	(29,835)
At 31 December 2017	30,525	1,789	—	32,314
At 1 January 2018	30,525	1,789	—	32,314
Deferred tax charged to the statement of profit or loss during the year	—	5,105	2,754	7,859
Deferred tax credited to other comprehensive income during the year	(30,525)	—	—	(30,525)
At 31 December 2018	—	6,894	2,754	9,648
At 1 January 2019	—	6,894	2,754	9,648
Deferred tax credited to the statement of profit or loss during the period	—	(6,894)	6,220	(674)
At 30 September 2019 (Unaudited)	—	—	8,974	8,974

For presentation purposes, certain deferred tax assets and liabilities with the amounts of RMB21,672,000, RMB9,648,000 and RMB8,974,000 as at 31 December 2017 and 2018 and 30 September 2019, respectively, have been offset in the statement of financial position. The following is an analysis of the deferred tax balances of the Company for financial reporting purposes:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Net deferred tax assets recognized in the consolidated statement of financial position	—	57,122	62,040
Net deferred tax liabilities recognized in the consolidated statement of financial position	10,642	—	—

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

35. LONG-TERM EMPLOYEE BENEFITS

Group

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Stock appreciation rights	7,039	10,468	13,163
Net defined benefit retirement obligation	67,915	67,139	91,385
	<u>74,954</u>	<u>77,607</u>	<u>104,548</u>

(a) Stock Appreciation Rights (SARs)

The board of SPL Acquisition Corp (“SPL”), a wholly-owned subsidiary of the Company, approved a long-term incentive plan in December 2015. Under this plan, SPL could issue up to 50,000 Stock Appreciation Rights (“SARs”). As at 31 December 2017, 31 December 2018 and 30 September 2019, 49,225 SARs, 49,225 SARs and 48,350 SARs had been granted.

Pursuant to the long-term incentive plan, the income obtained by the beneficiary is the incremental part between the exercise value and the initial value. The exercise value is the lesser of the common stock value and the formula value. Among which, the formula value is the specified EBITDA divided by the shares of common stocks.

The initial value of SARs granted in 2015, 2016 and 2017 were \$562.30 per share, \$562.30 per SARs and \$500.62 per SARs, respectively. The settlement or payment of SARs may be in the form of cash or equivalent SPL’s or the Company’s common stock, or both. The grant of SARs lasts for four years and the expiration date is the tenth year since the grant date. Vesting of SARs is in accordance with the terms in respective grant agreements signed with the participants. As at 31 December 2017, 31 December 2018 and 30 September 2019, 37,500 SARs, 44,600 SARs and 46,725 SARs had been vested.

Any vested SARs granted shall become exercisable in three equal instalments with the first instalment becoming exercisable on the fifth anniversary of the grant date and in the next two instalments on the seventh anniversary of the grant date and the ninth anniversary of the grant date.

(b) Net Defined Benefit Retirement Obligation

The Group makes contributions to a defined benefit retirement plan for the employees working in SPL Acquisition Corp., which covers 15%, 11% and 12% of the Group’s employees during the year ended 31 December 2017, the year ended 31 December 2018 and the period ended 30 September 2019, respectively. The plan is administered by a trustee, who is independent, with its assets held separately from those of the Group.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

35. LONG-TERM EMPLOYEE BENEFITS—continued

(b) Net Defined Benefit Retirement Obligation—continued

The plan is funded by contributions from the Group in accordance with an independent actuary’s recommendation based on an annual actuarial valuation. The independent actuarial valuation of the plan during the Relevant Periods was prepared by certified insurance actuaries of AON plc by using the projected unit cost method. The actuarial valuation indicates that the Group’s obligations under the defined benefit retirement plan were 45%, 49% and 48% covered by the plan assets held by the trustees at 31 December 2017, 31 December 2018 and 30 September 2019, respectively.

The plan exposes the Group to actuarial risks, such as longevity risk, currency risk, interest rate risk and market risk.

(i) The amounts recognized in the consolidated statement of financial position are as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Present value of wholly or partly funded by obligation	127,488	137,452	183,164
Fair value of plan assets	(57,593)	(67,698)	(88,285)
	<u>69,895</u>	<u>69,754</u>	<u>94,879</u>
Expected to be settled in the next twelve months	(1,980)	(2,615)	(3,494)
	<u>67,915</u>	<u>67,139</u>	<u>91,385</u>

(ii) Plan assets

As at 31 December 2017, 31 December 2018 and 30 September 2019, the Group’s liability under this plan was covered by deposits placed with several banks. There is no plan asset invested in the Company’s own financial instruments or any property occupied or other assets used by the Group.

(iii) Movements in the present value of the defined benefit obligation

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
At the beginning of year/period	109,584	127,488	137,452
Actuarial losses/(gain) arising from experience	13,250	(10,192)	29,546
Benefits paid by the plan	(907)	(1,153)	(1,009)
Current service cost	8,220	9,827	7,164
Interest cost	4,532	4,941	4,526
Exchange difference	(7,191)	6,541	5,485
At the end of year/period	<u>127,488</u>	<u>137,452</u>	<u>183,164</u>

The weighted average duration of the defined benefit obligation was 18.6 years, 17.4 years and 17.4 years during the years ended 31 December 2017, the year ended 31 December 2018, and the period ended 30 September 2019, respectively.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

35. LONG-TERM EMPLOYEE BENEFITS—continued

(b) Net Defined Benefit Retirement Obligation—continued

(iv) Movements in plan assets

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
At the beginning of year/period	50,200	57,593	67,698
Group’s contributions paid to the plan	8,730	9,045	12,337
Benefits paid by the plan	(877)	(1,153)	(1,009)
Interest income	2,016	2,365	2,061
Return on plan assets, excluding interest income	523	(3,300)	4,557
Exchange difference	(2,999)	3,148	2,641
At the end of year/period	<u>57,593</u>	<u>67,698</u>	<u>88,285</u>

(v) Amounts recognized in the consolidated statement of profit or loss and other comprehensive income are as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Current service cost	8,220	9,827	7,164
Net interest on the net defined benefit liability	2,516	2,576	2,465
Total amount recognized in profit or loss	<u>10,736</u>	<u>12,403</u>	<u>9,629</u>
Actuarial losses/(gains)	13,250	(10,192)	29,546
Return on plan assets, excluding interest income	(523)	3,300	4,557
Total amounts recognized in other comprehensive income	<u>12,727</u>	<u>(6,892)</u>	<u>34,103</u>
Total defined benefits costs	<u>23,463</u>	<u>5,511</u>	<u>43,732</u>

The current service cost and the net interest on the net defined benefit liability are recognized in cost of sales, selling and distribution expenses and administrative expenses in the consolidated statement of profit or loss.

(vi) Significant actuarial assumptions (expressed as weighted averages) and a sensitivity analysis are as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Discount rate	3.67%	4.30%	3.14%
Future salary increases	3.50%	3.50%	3.50%

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

35. LONG-TERM EMPLOYEE BENEFITS—continued

(b) Net Defined Benefit Retirement Obligation—continued

The analysis below shows how the defined benefit obligation would have increased/(decreased) as a result of a 1% change in the significant actuarial assumptions:

Increase 1%	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Discount rate	(21,718)	(20,153)	(26,305)
Future salary increases	11,250	9,918	12,945
Decrease 1%	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Discount rate	28,182	25,815	33,696
Future salary increases	(9,694)	(8,642)	(11,281)

36. LEASE LIABILITIES

Group

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Current			
Lease liabilities	28,968	30,809	31,900
Non-current			
Lease liabilities	127,062	106,718	94,741
	<u>156,030</u>	<u>137,527</u>	<u>126,641</u>

Movement of the lease liabilities:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
At the beginning of year/period	128,501	156,030	137,527
Additions	64,353	5,266	11,634
Interest expenses	9,246	7,193	4,568
Payments	(39,172)	(36,370)	(29,314)
Disposals	—	—	(450)
Exchange realignment	(6,898)	5,408	2,676
Ending balance	<u>156,030</u>	<u>137,527</u>	<u>126,641</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

36. LEASE LIABILITIES—continued

An aging analysis of the lease liabilities as at the end of each of the Relevant Periods is as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Less than 3 months	7,143	7,765	8,304
3 to less than 12 months	21,825	23,044	23,596
1 to 3 years	53,301	49,506	46,562
Over 3 years	73,761	57,212	48,179
	<u>156,030</u>	<u>137,527</u>	<u>126,641</u>

During the Relevant Periods, the Group entered into certain long-term lease contracts for office premises, manufacturing facilities, warehouses, vehicles and equipment.

During the Relevant Periods, the Group also leased certain office premises, vehicles, tools and equipment under short-term (i.e. within 12 months) lease arrangement. The Group has elected not to recognize right-of-use assets on these short-term lease contracts. There are no restrictions or covenants imposed and no sale and leaseback transactions.

The following future cash outflows of the Group is potentially exposed to that are not reflected in the measurement of lease liabilities:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Future cash outflows for short-term leases	<u>1,087</u>	<u>1,089</u>	<u>1,495</u>

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000
			(Unaudited)
Current			
Lease liabilities	1,401	2,086	4,591
Non-current			
Lease liabilities	<u>20,146</u>	<u>19,618</u>	<u>32,641</u>
	<u>21,547</u>	<u>21,704</u>	<u>37,232</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

36. LEASE LIABILITIES—continued

Movement of the lease liabilities:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
At the beginning of year/period	23,499	21,547	21,704
Additions	—	2,170	17,311
Interest expenses	1,059	1,025	806
Payments	(3,011)	(3,038)	(2,589)
Ending balance	<u>21,547</u>	<u>21,704</u>	<u>37,232</u>

An aging analysis of the lease liabilities as at the end of each of the Relevant Periods is as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Less than 3 months	502	513	1,218
3 to less than 12 months	899	1,573	3,373
1 to 3 years	2,041	2,607	8,807
Over 3 years	18,105	17,011	23,834
	<u>21,547</u>	<u>21,704</u>	<u>37,232</u>

During the Relevant Periods, the Company entered into certain long-term lease contracts for office premises and warehouses.

During the Relevant Periods, the Company also leased certain office premises under short-term (i.e. within 12 months) lease arrangement. The Company has elected not to recognize right-of-use assets on these short-term lease contracts. There are no restrictions or covenants imposed and no sale and leaseback transactions.

The following future cash outflows of the Company is potentially exposed to that are not reflected in the measurement of lease liabilities:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Future cash outflows for short-term leases	<u>6,034</u>	<u>4,598</u>	<u>3,449</u>

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

37. SHARE CAPITAL

Company

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
Registered, issued and fully paid 1,247,201,704 ordinary shares	1,247,202	1,247,202	1,247,202 (Unaudited)

38. RESERVES

Group

The amounts of the Group’s reserves and the movements therein are presented in the consolidated statement of changes in equity of the Historical Financial Information.

(i) Statutory surplus reserve

In accordance with the Company Law of the PRC, the company in the PRC are required to allocate 10% of the statutory after-tax profits to the statutory reserve until the cumulative total of the reserve reaches 50% of the company registered capital. Subject to approval from the relevant PRC authorities, the statutory reserve may be used to offset any accumulated losses or increase the registered capital of the company. The statutory reserve is not available for dividend distribution to shareholders of the PRC subsidiaries.

(ii) Merger reserve

The merger reserve of the Group represents the difference between the aggregate of the then net assets of the subsidiary acquired and the consideration paid by the Group for the business combination under common control.

(iii) Exchange fluctuation reserve

The exchange fluctuation reserve represents exchange differences arising from the translation of the financial statement of foreign operations whose functional currencies are different from the Group’s presentation currency.

The amounts of the Group’s reserves and the movements therein for the current and prior years are presented in the consolidated statements of changes in equity on pages I-[●] to I-[●] to the Historical Financial Information.

(iv) Share option reserve

The share option reserve of the Group represents the fair value of equity-settled share-based payment granted in 2012 and was early terminated in 2013.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

38. RESERVES—continued

(v) Fair value reserve

The fair value reserve of the Group represents the fair value movement of equity investment designated at fair value through other comprehensive income.

(vi) Defined benefit contribution reserve

The defined benefit contribution reserve of the Group represents actuarial losses/(gain) arising from net defined benefit retirement obligation.

Company

	Share premium	Share option reserve	Fair value reserve	Other reserve	Statutory surplus reserve	Retained profits	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
At 1 January 2017	4,248,203	33,937	360,106	—	482,057	1,808,423	6,932,726
Profit for the year	—	—	—	—	—	80,949	80,949
Other comprehensive income for the year:							
Change in fair value of equity investments designated at fair value through other comprehensive income, net of tax . . .	—	—	(166,464)	—	—	—	(166,464)
Total comprehensive income for the year	—	—	(166,464)	—	—	80,949	(85,515)
Transfer from retained profits	—	—	—	—	8,228	(8,228)	—
Dividend declared to shareholders	—	—	—	—	—	(311,800)	(311,800)
Others	—	—	—	(705)	—	—	(705)
At 31 December 2017	<u>4,248,203</u>	<u>33,937</u>	<u>193,642</u>	<u>(705)</u>	<u>490,285</u>	<u>1,569,344</u>	<u>6,534,706</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

38. RESERVES—continued

	Share premium	Merger reserve	Share option reserve	Fair value reserve	Other reserve	Statutory surplus reserve	Retained profits	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
At 1 January 2018	4,248,203	—	33,937	193,642	(705)	490,285	1,569,344	6,534,706
Profit for the year	—	—	—	—	—	—	284,841	284,841
Other comprehensive income for the year:								
Change in fair value of equity investments designated at fair value through other comprehensive income, net of tax . . .	—	—	—	(178,805)	—	—	—	(178,805)
Total comprehensive income for the year	—	—	—	(178,805)	—	—	284,841	106,036
Share of other reserves of associates	—	—	—	—	6,097	—	—	6,097
Acquisition of a subsidiary (note 41)	—	(1,996,731)	—	—	—	—	—	(1,996,731)
Transfer of fair value reserve of equity investments at fair value through other comprehensive income . . .	—	—	—	(14,995)	—	—	14,995	—
Transfer from retained profits	—	—	—	—	—	27,282	(27,282)	—
Dividend declared to shareholders	—	—	—	—	—	—	(56,124)	(56,124)
Others	—	—	—	—	29,759	—	—	29,759
At 31 December 2018	<u>4,248,203</u>	<u>(1,996,731)</u>	<u>33,937</u>	<u>(158)</u>	<u>35,151</u>	<u>517,567</u>	<u>1,785,774</u>	<u>4,623,743</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

38. RESERVES—continued

	Share premium	Merger reserve	Share option reserve	Fair value reserve	Other reserve	Statutory surplus reserve	Retained profits	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
(Unaudited)								
At 1 January 2019	4,248,203	(1,996,731)	33,937	(158)	35,151	517,567	1,785,774	4,623,743
Profit for the period	—	—	—	—	—	—	90,667	90,667
Other comprehensive income for the period								
Share of other comprehensive income of associates	—	—	—	—	269	—	—	269
Change in fair value of equity investments designated at fair value through other comprehensive income, net of tax	—	—	—	(19,792)	—	—	—	(19,792)
Total comprehensive income for the period	—	—	—	(19,792)	269	—	90,667	71,144
Deemed disposal of a subsidiary	—	—	—	—	34,479	(4,441)	(39,969)	(9,931)
Transfer of fair value reserve of equity investments at fair value through other comprehensive income	—	—	—	742	—	—	(742)	—
Other changes of investment in a subsidiary	—	—	—	—	248,551	—	—	248,551
Dividend declared to shareholders	—	—	—	—	—	—	(124,720)	(124,720)
Others	—	—	—	—	57,457	—	—	57,457
At 30 September 2019	<u>4,248,203</u>	<u>(1,996,731)</u>	<u>33,937</u>	<u>(19,208)</u>	<u>375,907</u>	<u>513,126</u>	<u>1,711,010</u>	<u>4,866,244</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

38. RESERVES—continued

	Share premium	Merger reserve	Share option reserve	Fair value reserve	Other reserve	Statutory surplus reserve	Retained profits	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
(Unaudited)								
At 1 January 2018	4,248,203	—	33,937	193,642	(705)	490,285	1,569,344	6,534,706
Profit for the period	—	—	—	—	—	—	212,865	212,865
Other comprehensive income for the period								
Change in fair value of equity investments designated at fair value through other comprehensive income, net of tax	—	—	—	(146,016)	—	—	—	(146,016)
Total comprehensive income for the period	—	—	—	(146,016)	—	—	212,865	66,849
Acquisition of a subsidiary (note 41)	—	(1,996,731)	—	—	—	—	—	(1,996,731)
Transfer of fair value reserve of equity investments at fair value through other comprehensive income	—	—	—	(6,867)	—	—	6,867	—
Dividend declared to shareholders	—	—	—	—	—	—	(56,124)	(56,124)
Others	—	—	—	—	18,107	—	—	18,107
At 30 September 2018	<u>4,248,203</u>	<u>(1,996,731)</u>	<u>33,937</u>	<u>40,759</u>	<u>17,402</u>	<u>490,285</u>	<u>1,732,952</u>	<u>4,566,807</u>

39. PARTLY-OWNED SUBSIDIARIES WITH MATERIAL NON-CONTROLLING INTERESTS

Details of the Group’s subsidiaries that have material non-controlling interests are set out below:

31 December 2017

	Percentage of equity interest held by non-controlling interests	Profit/(loss) for the year allocated to non-controlling interests	Accumulated balances of non-controlling interests at the reporting date
	%	RMB’000	RMB’000
Shenzhen Topknow Industrial Development Co., Ltd	26%	15,456	94,285
Shenzhen Hightide Biopharmaceutical Co., Ltd	43%	(8,415)	39,142
Shenzhen Penghe Property Management Co., Ltd	45%	(1,065)	55,844
Shenzhen OncoVent Co., Ltd.	<u>46%</u>	<u>(2,062)</u>	<u>23,530</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

39. PARTLY-OWNED SUBSIDIARIES WITH MATERIAL NON-CONTROLLING INTERESTS—continued

The following tables illustrated the summarized financial information of the above subsidiaries. The amounts disclosed are before any inter-company eliminations:

	Shenzhen Topknow Industrial Development Co., Ltd	Shenzhen Hightide Biopharmaceutical Co., Ltd	Shenzhen Penghe Property Management Co., Ltd	Shenzhen OncoVent Co., Ltd.
	RMB’000	RMB’000	RMB’000	RMB’000
Revenue	475,231	—	—	—
Total expense	(416,753)	(19,778)	(2,367)	(4,482)
Profit/(loss) for the year	58,478	(19,778)	(2,367)	(4,482)
Total comprehensive income/(loss) for the year	49,486	(20,136)	(2,367)	(4,482)
Current assets	823,771	79,704	6,037	33,834
Non-current assets	474,800	29,154	118,636	20,189
Current liabilities	(922,978)	(4,547)	(472)	(3,053)
Non-current liabilities	(18,858)	(11,994)	(103)	—
Net cash flows used in operating activities	(79,333)	(18,675)	—	(6,748)
Net cash flows used in investing activities	(10,094)	(5,237)	(433)	427
Net cash flows generated from financing activities	68,838	(15,205)	427	—
Effect of foreign exchange rate changes, net ...	1,717	(1,520)	—	—
Net (decrease)/increase in cash and cash equivalents	(18,872)	(40,637)	(6)	(6,321)

31 December 2018

	Percentage of equity interest held by non-controlling interests	Profit/(loss) for the year allocated to non-controlling interests	Accumulated balances of non-controlling interests at the reporting date
	%	RMB’000	RMB’000
Hightide Therapeutics, Inc	45%	(29,962)	48,412
Shenzhen Penghe Property Management Co., Ltd	45%	(1,426)	54,417
Shenzhen Ruidi Biomedical Co., Ltd	49%	(1,055)	43,470
Shenzhen OncoVent Co., Ltd.	46%	(1,359)	22,376

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

39. PARTLY-OWNED SUBSIDIARIES WITH MATERIAL NON-CONTROLLING INTERESTS—continued

The following tables illustrate the summarized financial information of the above subsidiaries. The amounts disclosed are before any inter-company eliminations:

	Hightide Therapeutics, Inc	Shenzhen Penghe Property Management Co., Ltd	Shenzhen Ruidi Biomedical Co., Ltd	Shenzhen OncoVent Co., Ltd.
	RMB’000	RMB’000	RMB’000	RMB’000
Revenue	—	—	—	—
Total expense	(67,985)	(3,170)	(2,153)	(2,954)
Loss for the year	(67,985)	(3,170)	(2,153)	(2,954)
Total comprehensive loss for the year	(69,738)	(3,170)	(2,153)	(2,954)
Current assets	87,638	5,523	46,197	31,091
Non-current assets	30,310	115,732	37,023	19,480
Current liabilities	(1,154)	(184)	(2,749)	(2,100)
Non-current liabilities	(8,367)	(145)	—	—
Net cash flows from operating activities	(76,344)	(690)	(1)	77
Net cash flows used in investing activities	(4,021)	632	(35,000)	6,223
Net cash flows generated from financing activities	89,876	—	44,686	22
Effect of foreign exchange rate changes, net	(710)	—	(22)	587
Net (decrease)/increase in cash and cash equivalents	8,801	(58)	9,663	6,909

30 September 2019 (Unaudited)

	Percentage of equity interest held by non-controlling interests	Profit/(loss) for the period allocated to non-controlling interests	Accumulated balances of non-controlling interests at the reporting date
	%	RMB’000	RMB’000
Shenzhen Penghe Property Management Co., Ltd	45%	(1,042)	53,375
Shenzhen Ruidi Biomedical Co., Ltd	49%	(1,778)	41,534
Shenzhen OncoVent Co., Ltd.	46%	(861)	21,624

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

39. PARTLY-OWNED SUBSIDIARIES WITH MATERIAL NON-CONTROLLING INTERESTS—continued

The following tables illustrate the summarized financial information of the above subsidiaries. The amounts disclosed are before any inter-company eliminations:

	Shenzhen Penghe Property Management Co., Ltd	Shenzhen Ruidi Biomedical Co., Ltd	Shenzhen OncoVent Co., Ltd.
	RMB’000	RMB’000	RMB’000
Revenue	—	—	—
Total expenses	(2,315)	(3,952)	(1,871)
Loss for the period	(2,315)	(3,952)	(1,871)
Total comprehensive Loss for the period	(2,315)	(3,952)	(1,871)
Current assets	5,449	59,719	32,617
Non-current assets	113,547	37,295	18,949
Current liabilities	(208)	(12,374)	(4,442)
Non-current liabilities	(176)	—	—
Net cash flows used in operating activities	(194)	(1,639)	(690)
Net cash flows from/(used in) investing activities	1,055	(8,616)	632
Net cash flows from financing activities	—	8,120	—
Effect of foreign exchange rate changes, net	—	370	—
Net increase/(decrease) in cash and cash equivalents	861	(1,765)	(58)

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

40. SHARE AWARD SCHEME

Share Option Scheme

Shenzhen OncoVent Co., Ltd (“OncoVent”), a subsidiary of the Company, approved a Share Option Scheme. (“the Scheme”) in 2018. Pursuant to the Scheme, OncoVent proposed to grant 4% share options of the diluted shares in the original equity structure to the CEO of OncoVent. Share options are granted when the participant reaches the agreed milestones. 2% share options will be granted when the first milestone is reached. 1% share options will be granted when the second stage is reached. And the remaining 1% of the share options will be granted when the third milestone is reached.

<u>Milestones</u>	<u>Condition</u>
The first milestone	The participant signs a labour contract with OncoVent
The second milestone	OncoVent’s new pharmaceutical varieties obtains permission to carry out Phase III clinical trials from Chinese pharmaceutical regulatory authorities
The Third milestone	New pharmaceutical varieties obtain permission to be sellable in the market from Chinese pharmaceutical regulatory authorities

The grant date is within one month when each milestone is reached. The share options shall be valid for a period of four years from the grant date. The first exercise period shall commence from the first day after expiry of the one-year period from the grant date. The vesting percentages of the share options for the following three years are 40%, 30% and 30%, respectively. When OncoVent is listed or sold, the participant may realise the benefit of share options based on the stock circulation rules at the listing place or the value of OncoVent at the time of sale. The participant may choose to convert the virtual option into actual investment to OncoVent. When and only when OncoVent is listed or sold, the participant can choose to exercise share options. The exercise price is based on the investment price and the latest financing authorised by the Board of OncoVent.

As of 31 December 2017, 31 December 2018 and 30 September 2019, the progress of the Scheme is as follows:

<u>Milestone</u>	<u>Granted percentage</u>	<u>Conditions are Met</u>	<u>Date of meet</u>	<u>Fair Value of Granted Share Options</u> RMB’000
The first milestone	2%	Yes	8 August 2017	1,271
The second milestone	1%	No	—	—
The third milestone	1%	No	—	—

41. BUSINESS COMBINATION

On 31 May 2018, the Group acquired 100% equity interest in Shenzhen Topknow Industrial Development Co., Ltd. from the shareholders of Shenzhen Topknow Industrial Development Co., Ltd. Since both the Company and Shenzhen Topknow Industrial Development Co., Ltd. are ultimately controlled by Mr. Li Li and Ms. Li Tan, the acquisition was a business combination under common control. Shenzhen Topknow Industrial Development Co., Ltd. is engaged in biopharmaceutical R&D. The purchase consideration for the acquisition is RMB2,400,000,000 in cash.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

41. BUSINESS COMBINATION—continued

The following is the consolidated statement of financial position of Shenzhen Topknow Industrial Development Co., Ltd. as at 31 May 2018:

	RMB’000
Property and equipment	265,563
Other intangible assets	76,429
Deferred tax assets	16,793
Other non-current assets	101,646
Cash and bank balances	65,322
Trade receivables	231,817
Prepayments, other receivables and other assets	218,801
Inventories	616,610
Interest-bearing bank borrowings	(330,950)
Trade and bills payables	(628,854)
Tax payable	(14,005)
Contract liabilities	(7,296)
Other payables and accruals	(195,177)
Deferred income	(12,212)
Deferred tax liabilities	(1,218)
	<u>403,269</u>
Merger reserve	1,996,731
Fair value of consideration which will be satisfied by Cash	<u>2,400,000</u>

During the Relevant Periods, the purchase consideration for the acquisition has been fully paid. As at 31 December 2018 and 30 September 2019, the Group had paid RMB1,224,000,000 and RMB1,176,000,000 respectively.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

42. DISPOSAL OF SUBSIDIARIES

(1) Disposal of Chengdu Hepatunn Pharmaceutical Co., Ltd.

In June 2018, the Group disposed of the 85% interests in Chengdu Hepatunn Pharmaceutical Co., Ltd. which was acquired by Pangu Chenchen (Shanghai) Enterprise Management Center (L.P.) (盤穀晨宸(上海)企業管理中心(有限合夥)) for a consideration of RMB34,000,000 in cash. The disposal of Chengdu Hepatunn Pharmaceutical Co., Ltd. was completed on 30 June 2018.

	<u>As at 30 June 2018</u> RMB'000
Net assets disposed of:	
Property and equipment	12,047
Other intangible assets	5,172
Other non-current assets	2,000
Cash and bank balances	6,828
Pledged deposits	5,560
Trade and bills receivables	12,834
Inventories	58,320
Prepayments, other receivables and other assets	3,350
Trade and bills payables	(68,540)
Contract liabilities	(4,875)
Accruals and other payables	(25,525)
Deferred income	(445)
Tax payable	(569)
	<u>6,157</u>
Proportion of the Group’s ownership interest	85%
Share of net assets of the subsidiary	5,234
Gain on disposal of the subsidiary	<u>28,766</u>
Satisfied by:	
Cash	<u>34,000</u>

An analysis of the net inflow of cash and cash equivalents in respect of the disposal of the subsidiary is as follows:

Cash consideration	34,000
Cash and bank balances disposed of	<u>(6,828)</u>
Net inflow of cash and cash equivalents in respect of the disposal of the subsidiary	<u>27,172</u>

(2) Deemed disposal of HighTide

On 25 March 2019, the Company’s share percentage on HighTide which was a former subsidiary of the Company was diluted from 53.81% to 48.74% as a result of the addition of new shareholders, as the result, the Group had lost control over HighTide. The fair value of the remaining 48.74% equity interest of HighTide held by the Group after the deemed disposal was RMB626,706,000 and a remeasurement gain of fair value of RMB573,865,000 was recorded.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

42. DISPOSAL OF SUBSIDIAR—continued

(2) Deemed disposal of HighTide—continued

	<u>As date of disposal</u> <u>RMB’000</u>
Net assets disposed of:	
Property and equipment	4,345
Other intangible assets	25,686
Cash and bank balances	75,898
Inventories	112
Prepayments, other receivables and other assets	1,914
Trade and bills payables	(54)
Accruals and other payables	(1,023)
Deferred income	<u>(8,277)</u>
Net assets	98,601
Non-controlling interests	<u>(402)</u>
Net assets attributable to the parent	98,199
Proportion of the Group’s ownership interest	53.81%
Share of net assets of the subsidiary	52,841
Gain on deemed disposal of the subsidiary and gain on fair value remeasurement of existing equity in the subsidiary	573,865
Investments in an associate (Note18)	<u>626,706</u>
Satisfied by:	
Cash	<u>—</u>

An analysis of the net outflow of cash and cash equivalents in respect of the disposal of the subsidiary is as follows:

Cash consideration	—
Cash and cash equivalents in the subsidiary deemed disposed of	<u>(75,898)</u>
Net outflow of cash and cash equivalents in respect of the deemed disposal of the subsidiary	<u>(75,898)</u>

43. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

During the Relevant Periods, SPL Distribution Holdings LLC, a subsidiary of the Group, provides active pharmaceutical ingredients to its customer, Curemark in exchange for equity interests of the customer. During the year ended 31 December 2018 and nine months ended 30 September 2019 and 2018, the transaction amounts were RMB256,564,000, RMB85,430,000 and RMB179,995,000, respectively. Further details are set out in note 20(d).

During the Relevant Periods and nine months ended 30 September 2018, the Group entered into lease arrangements with a total capital value at the inception of the leases of RMB64,353,000, RMB5,266,000, RMB11,184,000 and RMB3,981,000, respectively.

During the nine months ended 30 September 2019, the contingent consideration from the Controlling Shareholders, Mr. Shan Yu and Shuidi Shichuan amounting to RMB248,552,000 have been included in the balance of due from related parties.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

43. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS—continued

(b) Changes in liabilities arising from financing activities

	<u>Interest-bearing bank and other borrowings</u>	<u>Interest payables</u>	<u>Lease liabilities</u>
	RMB’000	RMB’000	RMB’000
At 1 January 2017	4,186,394	17,842	128,501
Received from loans and other borrowings	3,400,903	—	—
Additions to lease liabilities	—	—	64,353
Accretion of interest expenses	—	177,194	9,246
Repayment of interest expenses	—	(180,920)	—
Repayment of loans and other borrowings	(2,365,726)	—	—
Principal elements of lease payments	—	—	(39,172)
Foreign exchange movement	(137,506)	1,761	(6,898)
At 31 December 2017	<u>5,084,065</u>	<u>15,877</u>	<u>156,030</u>
At 1 January 2018	5,084,065	15,877	156,030
Received from loans and borrowings	3,916,955	—	—
Additions to lease liabilities	—	—	5,266
Accretion of interest expenses	—	224,298	7,193
Repayment of interest expenses	—	(224,628)	—
Repayment of loans and borrowings	(4,205,169)	—	—
Principal elements of lease payments	—	—	(36,370)
Foreign exchange movement	117,073	4,279	5,408
At 31 December 2018	<u>4,912,924</u>	<u>19,826</u>	<u>137,527</u>
	<u>Interest-bearing bank and other borrowings</u>	<u>Interest payables</u>	<u>Lease liabilities</u>
	RMB’000	RMB’000	RMB’000
At 1 January 2019	4,912,924	19,826	137,527
Received from loans and other borrowings	4,131,683	—	—
Additions to lease liabilities	—	—	11,184
Accretion of interest expenses	—	192,792	4,568
Repayment of interest expenses	—	(162,459)	—
Repayment of loans and other borrowings	(2,728,080)	—	—
Principal elements of lease payments	—	—	(29,314)
Foreign exchange movement	44,331	8,912	2,676
At 30 September 2019 (unaudited)	<u>6,360,858</u>	<u>59,071</u>	<u>126,641</u>
At 1 January 2018	5,084,065	15,877	156,030
Received from loans and borrowings	2,797,372	—	—
Additions to lease liabilities	—	—	3,981
Accretion of interest expenses	—	167,019	5,754
Repayment of interest expenses	—	(124,218)	—
Repayment of loans and borrowings	(2,838,712)	—	—
Principal elements of lease payments	—	—	(26,889)
Foreign exchange movement	86,426	(10,216)	5,938
At 30 September 2018 (unaudited)	<u>5,129,151</u>	<u>48,462</u>	<u>144,814</u>

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

44. COMMITMENTS

The Group had the following capital commitments at the end of each reporting period:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000 (Unaudited)
Contracted, but not provided for:			
Property, plant and equipment	369,671	397,317	321,109
Capital contributions payable to an investment included in financial assets at fair value through other comprehensive income	—	85,958	423
	<u>369,671</u>	<u>483,275</u>	<u>321,532</u>

45. PLEDGE OF ASSETS

Details of the Group’s interest-bearing bank and other borrowings, which are secured by the assets of the Group, are included in note 32 to the Historical Financial Information.

The summary of the pledged assets is as follows:

- (a) As at 31 December 2018 and 30 September 2019, 100% of the shares of Shenzhen Topknow Industrial Development Co., Ltd were pledged to secure certain bank loans.
- (b) As at 31 December 2017, 31 December 2018 and 30 September 2019, bills receivable amounting to RMB80,000,000, RMB95,000,000 and RMB445,000,000, respectively were pledged to secure certain bank loans.
- (c) As at 31 December 2017, 31 December 2018 and 30 September 2019, the assets (including property, plant and equipment, equity investments designated at fair value through other comprehensive income, inventory, trade and bills receivables, and cash and cash equivalents) of a subsidiary, totally amounting to RMB1,111,883,000, RMB1,485,333,000 and RMB1,553,668,000, respectively, were mortgaged to obtain loans from certain banks.
- (d) As at 31 December 2018 and 30 September 2019, the bank deposits secured for performance guarantees margin and bank acceptances margin were RMB3,873,000 and RMB91,946,000.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

46. RELATED PARTY TRANSACTIONS

(a) Name and relationship

<u>Name of related parties</u>	<u>Relationship with the Group</u>
Mr. Li Li and Ms. Li Tan 深圳市樂仁科技有限公司	Controlling Shareholders
Shenzhen Leren Technology Co., Ltd. 烏魯木齊金田土股權投資合夥企業（有限合夥）	Controlling Shareholders
Urumqi Jintiantu Equity Investment Partnership (Limited Partnership) 烏魯木齊飛來石股權投資有限公司	Controlling Shareholders
Urumqi Feilaishi Equity Investment Co., Ltd.	Controlling Shareholders
Mr. Shan Yu 烏魯木齊水滴石穿股權投資合夥企業（有限合夥）	Shareholder and key management and a close family member of the Controlling Shareholders
Urumqi Shuidi Shichuan Equity Investment Partnership (Limited Partnership) (“Shuidi Shichuan”)	Shareholder of the company and controlled by a close family member of the Controlling Shareholders
Aridis Pharmaceuticals Inc	Minority shareholder of a subsidiary
OncoQuest Inc.	Associate
Resverlogix Corp. 深圳市亞太健康管理有限公司	Associate
Shenzhen Asia Pacific Health Management Co., Ltd.	Associate

In addition to the transactions detailed elsewhere in the Historical Financial Information, the Group had the following material related party transactions during the Relevant Periods:

(b) Significant related party transactions

	<u>Year ended</u> <u>31 December</u>		<u>Nine months ended</u> <u>30 September</u>	
	<u>2017</u> <u>RMB’000</u>	<u>2018</u> <u>RMB’000</u>	<u>2018</u> <u>RMB’000</u> <u>(Unaudited)</u>	<u>2019</u> <u>RMB’000</u> <u>(Unaudited)</u>
Revenue from sales of products				
OncoQuest Inc.	10,100	3,569	2,852	6,990
Acquisition of a subsidiary (Note (i))				
Controlling shareholders	—	1,765,660	—	—
Mr. Shan Yu	—	55,460	—	—
Shuidi Shichuan	—	33,600	—	—
	<u>—</u>	<u>1,854,720</u>	<u>—</u>	<u>—</u>

(i) During the Relevant Periods, the Company acquired 100% shares of Shenzhen Topknow Industrial Development Co., Ltd. from the shareholders. Further details are included in note 41 to the Historical Financial Information.

(c) Other related party transactions

During the Relevant Periods, the Group’s banking facilities were guaranteed by its related parties with details set out in note 32 to the Historical Financial Information.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

46. RELATED PARTY TRANSACTIONS—continued

(d) Outstanding balances with related parties

As disclosed in the statements of financial position, the Group had outstanding balances with related parties at 31 December 2017, 2018 and 30 September 2019.

	As at 31 December		As at 30 September
	2017	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)
<i>Due from related parties</i>			
Trade receivables (trade in nature) (Note (i))			
OncoQuest Inc.	8,427	503	8,730
Other receivables (non-trade in nature)			
Controlling Shareholders (Note (iii))	—	—	236,616
Mr. Shan Yu (Note (iii))	—	—	7,433
Shuidi Shichuan (Note (iii))	—	—	4,502
Resverlogix Corp.	41,858	43,965	45,309
Total receivables from related parties	<u>50,285</u>	<u>44,468</u>	<u>302,590</u>
<i>Due to related parties</i>			
Controlling Shareholders (Note (ii))	—	1,119,530	—
Mr. Shan Yu (Note (ii))	—	35,168	—
Shuidi Shichuan (Note (ii))	—	21,302	—
Aridis Pharmaceuticals Inc.	—	2,472	3,189
Deposit received (trade in nature)			
OncoQuest Inc.	2,122	2,229	2,298
Total payables to related parties	<u>2,122</u>	<u>1,180,701</u>	<u>5,487</u>

(i) Trade receivables due from related parties are unsecured, interest-free and repayable on demand.

(ii) In 2018, the Company acquired 100% shares of Shenzhen Topknow Industrial Development Co. Ltd (“Topknow”) with cash consideration of RMB2,400,000,000 from Controlling Shareholders, Mr. Shan Yu, Shuidi Shichuan and other shareholders (Collectively “The Acquisition of Topknow”). As at 31 December 2018, the payables due to the Controlling Shareholders, Mr. Shan Yu and Shuidi Shichuan were RMB1,119,530,000, RMB35,168,000 and RMB21,302,000. Further details about The Acquisition of Topknow are included in note 41 to the Historical Financial Information.

(iii) According to certain conditions stipulated by the supplementary agreements on The Acquisition of Topknow, the Controlling Shareholders, Mr. Shan Yu and Shuidi Shichuan are required to pay a contingent consideration based on the achievement of the profit targets of Topknow. As at 30 September 2019, based on the projected profit performance of Topknow, the fair value of the contingent consideration arrangement was estimated to be RMB248,551,000.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

46. RELATED PARTY TRANSACTIONS—continued

(e) Compensation of key management personnel of the Group:

	Year ended 31 December		Nine months ended 30 September	
	2017 RMB’000	2018 RMB’000	2018 RMB’000 (Unaudited)	2019 RMB’000 (Unaudited)
Salaries, allowances and benefits in kind	6,978	8,492	3,863	3,892
Performance related bonuses	—	2,390	—	—
Pension scheme contributions	250	273	204	218
	<u>7,228</u>	<u>11,155</u>	<u>4,067</u>	<u>4,110</u>

Further details of directors’ and supervisors’ emoluments are included in note 9 to the Historical Financial Information.

47. FINANCIAL INSTRUMENTS BY CATEGORY

Group

The carrying amounts of each of the categories of financial instruments of the Group as at the end of each of the Relevant Periods are as follows:

Financial assets	As at 31 December		As at 30 September
	2017 RMB’000	2018 RMB’000	2019 RMB’000 (Unaudited)
Financial assets at fair value through profit or loss:			
Financial assets at fair value through profit or loss	1,255,048	1,197,660	1,603,835
Derivative financial instruments	43,150	77,174	6,811
	<u>1,298,198</u>	<u>1,274,834</u>	<u>1,610,646</u>
Financial assets at fair value through other comprehensive income:			
Equity investments designated at fair value through other comprehensive income	550,363	608,785	649,811
At amortized cost:			
Trade and bills receivables	703,202	1,084,489	1,054,996
Due from related parties	50,285	44,468	302,590
Financial assets included in prepayments, other receivables and other assets	259,088	126,627	67,763
Pledged deposits	6,141	3,837	52,027
Time deposits	2,860,549	591,809	127,510
Cash and cash equivalents	730,470	1,526,100	1,177,083
	<u>4,609,735</u>	<u>3,377,330</u>	<u>2,781,969</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

47. FINANCIAL INSTRUMENTS BY CATEGORY—continued

Financial liabilities	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000 (Unaudited)
At amortized cost:			
Trade and bills payables	162,474	205,273	253,569
Due to related parties	2,122	1,180,701	5,487
Financial liabilities included in other payables and accruals	133,439	235,636	221,196
Interest-bearing bank and other borrowings	5,084,065	4,912,924	6,360,858
Lease liabilities	156,030	137,527	126,641
	<u>5,538,130</u>	<u>6,672,061</u>	<u>6,967,751</u>

Company

The carrying amounts of each of the categories of financial instruments of the Company as at the end of each of the Relevant Periods are as follows:

Financial assets	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000 (Unaudited)
Financial assets at fair value through profit or loss:			
Financial assets at fair value through profit or loss	499,155	507,852	731,266
Derivative financial instruments	43,150	77,174	6,811
	<u>542,305</u>	<u>585,026</u>	<u>738,077</u>
Financial assets at fair value through other comprehensive income:			
Equity investments designated at fair value through other comprehensive income	281,583	69,423	32,143
At amortized cost:			
Trade and bills receivables	174,840	129,741	187,512
Due from related parties	1,207,755	2,281,000	3,011,142
Financial assets included in prepayments, other receivables and other assets	242,011	104,235	44,269
Time deposits	2,860,549	590,809	127,510
Cash and cash equivalents	367,389	1,033,773	666,690
	<u>4,852,544</u>	<u>4,139,558</u>	<u>4,037,123</u>

Financial liabilities	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	2019
			RMB’000 (Unaudited)
At amortized cost:			
Trade and bills payables	6,516	13,672	6,676
Due to related parties	120,285	1,509,833	145,488
Financial liabilities included in other payables and accruals	39,971	140,677	109,072
Interest-bearing bank and other borrowings	2,353,835	2,572,288	4,198,167
Lease liabilities	21,547	21,704	37,232
	<u>2,542,154</u>	<u>4,258,174</u>	<u>4,496,635</u>

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

48. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

As at 31 December 2017 and 2018 and 30 September 2019, the fair values of the Group’s financial assets or liabilities approximated to their respective carrying amounts.

Management has determined that the carrying amounts of cash and cash equivalents, the current portion of time deposits and pledged deposits, trade and bills receivables, amounts due from related parties, financial assets included in prepayments, other receivables and other assets, trade and bills payables, amounts due to related parties, financial liabilities included in other payables and accruals, the current portion of interest-bearing bank borrowings and lease liabilities reasonably approximate to their fair values because these financial instruments are mostly short term in nature.

The Group’s finance department headed by the Financial Controller is responsible for determining the policies and procedures for the fair value measurement of financial instruments. At each reporting date, the finance department analyzes the movements in the values of financial instruments and determines the major inputs applied in the valuation. The directors review the results of the fair value measurement of financial instruments periodically for annual financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

The following methods and assumptions were used to estimate the fair values:

The fair values of listed equity investments are based on quoted market prices. The fair values of unlisted equity investments designated at fair value have been estimated using a market-based valuation technique based on assumptions that are not supported by observable market prices or rates. The valuation requires the directors to determine comparable public companies (peers) based on industry, size, leverage and strategy, and calculates an appropriate price multiple, such as EV/EBITDA multiple and price to earnings (“P/E”) multiple, for each comparable company identified. The multiple is calculated by dividing the enterprise value of the comparable company by an earnings measure. The trading multiple is then discounted for considerations such as illiquidity and size differences between the comparable companies based on company-specific facts and circumstances. The discounted multiple is applied to the corresponding earnings measure of the unlisted equity investments to measure the fair value. The directors believe that the estimated fair values resulting from the valuation technique, which are recorded in the consolidated statement of financial position, and the related changes in fair values, which are recorded in other comprehensive income and profit or loss, are reasonable, and that they were the most appropriate values at the end of the reporting period.

The Group invests in unlisted investments, which represent wealth management products issued by banks in Mainland China. The Group has estimated the fair value of these unlisted investments by using a discounted cash flow valuation model based on the market interest rates of instruments with similar terms and risks.

The Group enters into derivative financial instruments with various counterparties, principally investment in association Derivative financial instruments, including warrants, forward currency contracts and foreign currency swaps, are measured using valuation techniques similar to Black-Scholes Model and forward pricing and swap models, using present value calculations. The models

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

48. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS—continued

incorporate various market observable inputs including the credit quality of counterparties, foreign exchange spot and forward rates and interest rate curves. The carrying amounts of forward currency contracts, foreign currency swaps and interest rate swaps are the same as their fair values.

As at 31 December 2017, 31 December 2018 and 30 September 2019, the marked to market value of the derivative asset position is net of a credit valuation adjustment attributable to derivative counterparty default risk. The changes in counterparty credit risk had no material effect on the hedge effectiveness assessment for derivatives designated in hedge relationship and other financial instruments recognised at fair value.

Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

Assets measured at fair value:

As at 31 December 2017

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	RMB’000	RMB’000	RMB’000	RMB’000
Equity investments designated at fair value through other comprehensive income	353,459	196,904	—	550,363
Financial assets at fair value through profit or loss	—	1,108,844	146,204	1,255,048
Derivative financial instruments	—	43,150	—	43,150
	<u>353,459</u>	<u>1,348,898</u>	<u>146,204</u>	<u>1,848,561</u>

As at 31 December 2018

	Fair value measurement using			
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
	RMB’000	RMB’000	RMB’000	RMB’000
Equity investments at fair value through other comprehensive income	104,422	504,363	—	608,785
Financial assets at fair value through profit or loss	—	1,197,660	—	1,197,660
Derivative financial instruments	—	77,174	—	77,174
	<u>104,422</u>	<u>1,779,197</u>	<u>—</u>	<u>1,883,619</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

48. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS—continued

Fair value hierarchy—continued

Assets measured at fair value:—continued

As at 30 September 2019
(Unaudited)

	Fair value measurement using			Total RMB’000
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	
Equity investments designated at fair value through other comprehensive income	42,095	607,716	—	649,811
Financial assets at fair value through profit or loss	—	1,603,835	—	1,603,835
Derivative financial instruments	—	6,811	—	6,811
	<u>42,095</u>	<u>2,218,362</u>	<u>—</u>	<u>2,260,457</u>

The movements in fair value measurements with Level 3 during the year/period are as follows:

	As at 31 December		As at
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000 (Unaudited)
Financial assets at fair value through profit or loss			
At 1 January	134,411	146,204	—
Total gains/(losses) recognized in the statement of profit or loss included in other income	11,793	(26,204)	—
Purchases	—	—	—
Disposals	—	(120,000)	—
At 31 December/At 30 September	<u>146,204</u>	<u>—</u>	<u>—</u>

Assets for which fair values are disclosed:

As at 31 December 2017

	Fair value measurement using			Total RMB’000
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	
Pledged deposits, non-current portion	—	6,141	—	6,141

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

48. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS—continued

Fair value hierarchy—continued

Assets for which fair values are disclosed:—continued

As at 31 December 2018

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
Pledged deposits, non-current portion	—	3,837	—	3,837

As at 30 September 2019

(Unaudited)

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
Pledged deposits, non-current portion	—	52,027	—	52,027

Liabilities for which fair values are disclosed:

As at 31 December 2017

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
Lease liabilities	—	156,030	—	156,030
Interest-bearing bank borrowings	—	5,084,065	—	5,084,065
	—	5,240,095	—	5,240,095

As at 31 December 2018

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
Lease liabilities	—	137,527	—	137,527
Interest-bearing bank borrowings	—	4,912,924	—	4,912,924
	—	5,050,451	—	5,050,451

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

48. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS—continued

Fair value hierarchy—continued

Liabilities for which fair values are disclosed:—continued

As at 30 September 2019

(Unaudited)

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	
Lease liabilities	—	126,641	—	126,641
Interest-bearing bank borrowings	—	6,360,858	—	6,360,858
	—	6,487,499	—	6,487,499

Below is a summary of significant unobservable inputs to the valuation of financial instruments together with a quantitative sensitivity analysis as at 31 December 2017:

31 December 2017

	Valuation technique	Significant unobservable inputs	Range	Sensitivity of fair value to the input
Financial assets at fair value through profit or loss	Discounted cash flow method	Long term growth rate	3%	1% increase/(decrease) in growth rate would result in increase/(decrease) in fair value by RMB447,000
		Long term operating margin	45%	1% increase/(decrease) in operating margin would result in increase/(decrease) in fair value by RMB732,000
		Weighted average cost of capital (WACC)	17%-18%	1% increase/(decrease) in growth rate would result in (decrease)/increase in fair value by RMB1,016,000

49. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments mainly include cash and cash equivalents, time deposits, pledged deposits, trade and bills receivables, other receivables, trade and bills payables and other payables and lease liabilities, which arise directly from its operations. The Group has other financial assets and liabilities such as financial assets at fair value through profit or loss, equity investments designated at fair value through other comprehensive income, derivative financial instruments, interest-bearing bank and other borrowings, due to related parties and due from related parties. The main purpose of these financial instruments is to raise finance for the Group’s operations.

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

49. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES—continued

The Group also enters into derivative transactions, including principally warrants. The purpose is to manage the interest rate and currency risks arising from the Group’s operations and its sources of finance.

The main risks arising from the Group’s financial instruments are interest rate risk, foreign currency risk, credit risk and liquidity risk. The board of directors review and agree policies for managing each of these risks and they are summarized below.

Interest rate risk

The Group’s exposure to the risk of changes in market interest rates relates primarily to the interest-bearing bank borrowings with floating interest rates.

The Group’s policy is to manage its interest cost using a mix of fixed and variable rate debts. At 31 December 2017 and 2018 and 30 September 2019, approximately 70%, 56% and 71% of the Group’s interest-bearing borrowings bore interest at fixed rates, respectively.

The following table demonstrates the sensitivity to a reasonably possible change in interest rate, with all other variables held constant, of the Group’s profit before tax (through the impact on floating rate borrowings) and the Group’s equity.

	Increase/ (decrease) in basis points	Increase/ (decrease) in profit before tax RMB’000	Increase/ (decrease) in equity* RMB’000
Year ended 31 December 2017	25	(5,425,624)	—
	(25)	5,425,624	—
Year ended 31 December 2018	25	(4,961,426)	—
	(25)	4,961,426	—
Nine months ended 30 September 2019	25	(4,667,548)	—
	(25)	4,667,548	—

* Excluding retained profits

Foreign currency risk

The Group has transactional currency exposures. Such exposures arise from sales or purchases by operating units in currencies other than the units’ functional currencies.

In addition, the Group has currency exposures from its interest-bearing bank borrowings.

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

49. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES—continued

Foreign currency risk—continued

The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in the foreign exchange rate due to changes in fair value of monetary assets and liabilities, with all other variables held constant, of the Group’s profit before tax.

	Year ended 31 December		Nine months ended
	2017	2018	30 September
	RMB’000	RMB’000	RMB’000
RMB/USD			
Strengthened 5%	(12,297)	(5,741)	(60,260)
Weakened 5%	12,297	5,741	60,260
RMB/EUR			
Strengthened 5%	6,693	(846)	(50,509)
Weakened 5%	(6,693)	846	50,509

Credit risk

An impairment analysis was performed at 31 December 2017 and 2018 and 30 September 2019 using a provision matrix to measure expected credit losses. The provision rates are based on days past due for groupings of various customer segments with similar loss patterns. The calculation reflects the probability-weighted outcome, the time value of money and reasonable and supportable information that is available at the reporting date about past events, current conditions and forecasts of future economic conditions.

Maximum exposure and year-end staging as at 31 December 2017 and 2018 and 30 September 2019

The table below shows the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification as at 31 December 2017 and 2018 and 30 September 2019. The amounts presented are gross carrying amounts for financial assets.

At 31 December 2017

	12-month	Lifetime ECLs			RMB’000
	ECLs	Simplified approach		Simplified approach	
	Stage 1	Stage 2	Stage 3	RMB’000	RMB’000
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Trade and bills receivables*	—	—	—	703,202	703,202
Financial assets included in prepayments, deposits and other receivables					
—Normal**	255,071	—	—	—	255,071
—Doubtful**	—	—	4,017	—	4,017
Amounts due from related parties	41,858	—	—	8,427	50,285
Pledged deposits	6,141	—	—	—	6,141
Time deposits	2,860,549	—	—	—	2,860,549
Cash and cash equivalents	730,470	—	—	—	730,470
	<u>3,894,089</u>	<u>—</u>	<u>4,017</u>	<u>711,629</u>	<u>4,609,735</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

49. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES—continued

Credit risk—continued

At 31 December 2018

	12-month	Lifetime ECLs			RMB’000
	ECLs	Stage 2	Stage 3	Simplified	
	Stage 1	Stage 2	Stage 3	approach	
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Trade and bills receivables*	—	—	—	1,084,489	1,084,489
Financial assets included in prepayments, deposits and other receivables					
—Normal**	122,502	—	—	—	122,502
—Doubtful**	—	—	4,125	—	4,125
Amounts due from related parties	43,965	—	—	503	44,468
Pledged deposits	3,837	—	—	—	3,837
Time deposits	591,809	—	—	—	591,809
Cash and cash equivalents	1,526,100	—	—	—	1,526,100
	<u>2,288,213</u>	<u>—</u>	<u>4,125</u>	<u>1,084,992</u>	<u>3,377,330</u>

At 30 September 2019

	12-month	Lifetime ECLs			Total
	ECLs	Stage 2	Stage 3	Simplified	
	Stage 1	Stage 2	Stage 3	approach	
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Trade and bills receivables*	—	—	—	1,054,996	1,054,996
Financial assets included in prepayments, deposits and other receivables					
—Normal**	63,621	—	—	—	63,621
—Doubtful**	—	—	4,142	—	4,142
Amounts due from related parties	293,860	—	—	8,730	302,590
Pledged deposits	52,027	—	—	—	52,027
Time deposits	127,510	—	—	—	127,510
Cash and cash equivalents	1,177,083	—	—	—	1,177,083
	<u>1,714,101</u>	<u>—</u>	<u>4,142</u>	<u>1,063,726</u>	<u>2,781,969</u>

* For trade and bills receivables to which the Group applies the simplified approach for impairment, information based on the provision matrix is disclosed in note 25 to the Historical Financial Information.

** The credit quality of the financial assets included in prepayments, other receivables and other assets is considered to be “normal” when they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk since initial recognition. Otherwise, the credit quality of the financial assets is considered to be “doubtful”.

A financial asset is credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of that financial asset have occurred. Evidence that a financial asset is credit-impaired includes observable data about the following events:

- significant financial difficulty of the debtor;
- a breach of contract such as a default or past due event;
- it is probable that the debtor will enter bankruptcy or other financial reorganisation;

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

49. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES—continued

Credit risk—continued

The Group has established a policy to perform an assessment, of whether a financial instrument’s credit risk has increased significantly since initial recognition, by considering the change in the risk of default occurring over the remaining life of the financial instrument.

Management makes periodic collective assessments for financial assets included in prepayments, other receivables and other assets as well as individual assessment on the recoverability of other receivables based on historical settlement records and past experience. The Group recognized allowance for financial assets included in prepayments, deposits and other receivables based on 12-month ECLs and adjusts for forward-looking macroeconomic data.

Liquidity risk

The Group’s objective is to maintain a balance between continuity of funding and flexibility through the use of internally generated cash flows from operations and bank borrowings. The Group regularly reviews its major funding positions to ensure that it has adequate financial resources in meeting its financial obligations.

The maturity profile of the Group’s financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, was as follows:

	As at 31 December 2017				
	On demand	Less than 1 year	1 to 3 years	Over 3 years	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Trade and bills payables	—	161,562	287	625	162,474
Financial liabilities included in other payables and accruals	133,439	—	—	—	133,439
Interest-bearing bank borrowings	—	3,388,522	916,448	1,029,242	5,334,212
Due to related parties	2,122	—	—	—	2,122
Lease liabilities	—	37,980	67,524	84,907	190,411
	<u>135,561</u>	<u>3,588,064</u>	<u>984,259</u>	<u>1,114,774</u>	<u>5,822,658</u>
	As at 31 December 2018				
	On demand	Less than 1 year	1 to 3 years	Over 3 years	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Trade and bills payables	—	203,668	822	783	205,273
Financial liabilities included in other payables and accruals	235,636	—	—	—	235,636
Interest-bearing bank borrowings	—	2,602,552	1,923,066	741,410	5,267,028
Due to related parties	1,180,701	—	—	—	1,180,701
Lease liabilities	—	38,467	60,739	64,563	163,769
	<u>1,416,337</u>	<u>2,844,687</u>	<u>1,984,627</u>	<u>806,756</u>	<u>7,052,407</u>

APPENDIX I

ACCOUNTANTS’ REPORT

II. NOTES TO THE HISTORICAL FINANCIAL INFORMATION—continued

49. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES—continued

Liquidity risk—continued

(Unaudited)	As at 30 September 2019				
	On demand	Less than 1 year	1 to 3 years	Over 3 years	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Trade and bills payables	—	250,609	2,742	218	253,569
Financial liabilities included in other payables and accruals	221,196	—	—	—	221,196
Interest-bearing bank borrowings	—	4,778,666	413,004	1,659,582	6,851,252
Due to related parties	5,487	—	—	—	5,487
Lease liabilities	—	39,435	54,573	54,065	148,073
	<u>226,683</u>	<u>5,068,710</u>	<u>470,319</u>	<u>1,713,865</u>	<u>7,479,577</u>

Capital management

The primary objectives of the Group’s capital management are to safeguard the Group’s ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise shareholders’ value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Relevant Periods.

The asset-liability ratios as at the end of each of the Relevant Periods are as follows:

	As at 31 December		As at 30 September
	2017	2018	2019
	RMB’000	RMB’000	RMB’000 (Unaudited)
Total assets	<u>14,208,856</u>	<u>13,844,278</u>	<u>15,192,829</u>
Total liabilities	<u>6,155,087</u>	<u>7,567,945</u>	<u>7,986,757</u>
Asset-liability ratio	<u>43%</u>	<u>55%</u>	<u>53%</u>

50. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company, the Group or any of the companies now comprising the Group in respect of any period subsequent to 30 September 2019.

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

APPENDIX II

[REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

APPENDIX II

[REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

APPENDIX II

[REDACTED]

[REDACTED]

THIS DOCUMENT IS IN DRAFT FORM, INCOMPLETE AND SUBJECT TO CHANGE AND THAT THE INFORMATION MUST BE READ IN CONJUNCTION WITH THE SECTION HEADED "WARNING" ON THE COVER OF THIS DOCUMENT.

APPENDIX II

[REDACTED]

[REDACTED]

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

TAXATION OF EQUITY HOLDERS

The following is a summary of certain PRC and Hong Kong tax consequences of the ownership of H Shares by an investor who purchases such H Shares in the [REDACTED] and holds the H Shares as capital assets. This summary does not purport to address all material tax consequences of the ownership of H Shares, and does not take into account the specific circumstances of any particular investor, some of which may be subject to special provisions. This summary is based on the tax laws of the PRC and Hong Kong as in effect as of the Latest Practicable Date, all of which are subject to change (or changes in interpretation), possibly with retroactive effect.

This section does not address any aspects of Hong Kong or PRC taxation other than income tax, capital gains tax, value-added tax, stamp duty and estate duty. Prospective investors are advised to consult their own tax advisors regarding the tax consequences of holding and disposing of H Shares in the PRC, Hong Kong and other jurisdictions.

PRINCIPAL TAXATION OF OUR COMPANY BY THE PRC

Enterprise Income Tax

According to the Enterprise Income Tax Law of PRC (《中華人民共和國企業所得稅法》) (the “EIT Law”), which was promulgated by the NPC on March 16, 2007, implemented on January 1, 2008, and subsequently revised on February 24, 2017 and December 29, 2018 respectively, and the Implementation Rules for the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) enacted on December 6, 2007 by the State Council and became effective on January 1, 2008, and amended on April 23, 2019, a resident enterprise shall pay EIT on its income originating from both inside and outside PRC at an EIT rate of 25%. Foreign invested enterprises in the PRC falls into the category of resident enterprises, which shall pay EIT for the income originated from domestic and overseas sources at an EIT rate of 25%. For a non-resident enterprise having no office or establishment inside China, or for a non-resident enterprise whose incomes have no actual connection to its office or establishment inside China, it shall pay enterprise income tax on the incomes derived from China. The enterprise income tax rate shall be 10%.

Pursuant to the Administrative Measures on Accreditation of High-tech Enterprises (《高新技術企業認定管理辦法》), which was adopted by the Ministry of Science and Technology, the MOF and SAT on January 29, 2016, and took effect from January 1, 2016, qualifications of an accredited high-tech enterprise shall be valid for three years from the date of issuance of the certificate. Upon obtaining the qualification as a high-tech enterprise, the enterprise shall complete tax reduction and exemption formalities with the tax authorities in charge pursuant to the provisions of Article 4 of these Measures.

Value-added Tax

According to the Interim Regulations of the PRC on Value-Added Tax (《中華人民共和國增值稅暫行條例》) which was promulgated by the State Council on December 13, 1993, and amended on November 5, 2008, February 6, 2016 and November 19, 2017, and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》) which was promulgated by the Ministry of Finance on December 25, 1993 and subsequently amended on December 15, 2008 and October 28, 2011 (collectively, the “VAT Law”), all enterprises and individuals that engage in the sale of goods, the provision of processing, repair and replacement services, sales of service, intangible assets and real estate and the importation of goods

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

within the territory of the PRC shall pay value-added tax at the rate of 17%, except when specified otherwise.

In accordance with Circular on Comprehensively Promoting the Pilot Program of the Collection of Value-added Tax in Lieu of Business Tax (《關於全面推開營業稅改徵增值稅試點的通知》), which was promulgated on March 23, 2016 and came into effect on May 1, 2016, upon approval of the State Council, the pilot program of the collection of VAT in lieu of business tax shall be promoted nationwide in a comprehensive manner starting from May 1, 2016.

The Notice on the Adjustment to VAT Rates (《關於調整增值稅稅率的通知》), promulgated by the MOF and the SAT on April 4, 2018 and became effective as of May 1, 2018 adjusted the applicative rate of VAT, and the deduction rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

According to the Announcement on Relevant Policies for Deepening Value-Added Tax Reform (《關於深化增值稅改革有關政策的公告》) Promulgated by MOF, SAT and General Administration of Customs on March 20, 2019 and became effective on April 1, 2019, with respect to VAT taxable sales or imported goods of a VAT general taxpayer, where the VAT rate of 16% applies currently, it shall be adjusted to 13%.

THE PRC TAXATION

Taxation on Dividends

Enterprise Investors

In accordance with the EIT Law, which was amended and came into effect on February 24, 2017, and the Implementation Provisions of the Enterprise Income Tax Law of the PRC, which came into effect on January 1, 2008, a non-resident enterprise is generally subject to a 10% corporate income tax on PRC-sourced income (including dividends received from a PRC resident enterprise that issues shares in Hong Kong), if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. The aforesaid income tax payable for non-resident enterprises is withheld at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due. Such withholding tax may be reduced pursuant to an applicable double taxation treaty upon application and approval.

The Circular on Issues Relating to the Withholding of Enterprise Income Tax by PRC Resident Enterprises on Dividends Paid to Overseas Non-Resident Enterprise Shareholders of H Shares (《關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》), which was issued by the SAT on November 6, 2008, further clarified that a PRC-resident enterprise must withhold corporate income tax at a rate of 10% on the dividends of 2008 and onwards that it distributes to overseas non-resident enterprise shareholders of H Shares. In addition, the Response to Questions on Levying Corporate Income Tax on Dividends Derived by Non-resident Enterprise from Holding Stock such as B Shares (《關於非居民企業取得B股等股票股息徵收企業所得稅問題的批覆》), which was issued by the SAT and came into effect on July 24, 2009, further provides that any PRC-resident enterprise whose shares are listed on overseas stock exchanges must withhold and remit corporate income tax at a rate of 10% on dividends that it distributes to non-resident enterprises. Such tax rates may be further modified pursuant to the tax treaty or agreement that China has entered into with a relevant country or area, where applicable.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), which was signed on August 21, 2006, the Chinese Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the Chinese company. If a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fourth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion issued by the State Administration of Taxation (《國家稅務總局關於〈內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排〉第四議定書》), which came into effect on December 29, 2015, states that such provisions shall not apply to arrangement made for the primary purpose of gaining such tax benefit. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law documents, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》).

Individual Investor

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) (the “**IIT Law**”), which was last amended on August 31, 2018 and came into effect on January 1, 2019 and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), which was last amended on December 18, 2018 and came into effect on January 1, 2019, dividends distributed by PRC enterprises are subject to individual income tax levied at a flat rate of 20%. According to the Notice on Issues concerning the Implementation of Differential Individual Income Tax Policies on Dividends and Bonuses of Listed Companies (Cai Shui [2015] No. 101) (《關於上市公司股息紅利差別化個人所得稅政策有關問題的通知》) (財稅[2015]101號) issued by the MOF on September 7, 2015, where an individual acquires the stocks of a listed company from public offering of the company or from the stock market, if the stock holding period is more than one year, the income from dividends shall be exempted from personal income tax for the time being. Where an individual acquires the stocks of a listed company in a public offering of the company or from the stock market, if the stock holding period is one month or less, the income from dividends shall be included into the taxable incomes in full amount; if the stock holding period is more than one month and up to one year, only 50% of the income from dividends shall be included into the taxable incomes of the individual. Individual income taxes on the aforesaid incomes shall be collected at the uniform rate of 20%. For a foreign individual who is not a resident of the PRC, the receipt of dividends from an enterprise in the PRC is normally subject to individual income tax of 20% unless a reduction is approved by the MOF or exempted by an international convention or agreement to which the PRC government is a party.

Pursuant to the Notice of the SAT on Matters Concerning the Levy and Administration of Individual Income Tax After the Repeal of Guo Shui Fa [1993] No. 45 (Guo Shui Han [2011] No. 348) (《國家稅務總局關於國稅發[1993]045號文件廢止後有關個人所得稅徵管問題的通知》) (國稅函[2011]348號) promulgated by the SAT on June 28, 2011, the resident individual investors outside the PRC who are the shareholders of the shares issued in public offerings by domestic non-foreign invested enterprises in Hong Kong enjoy preferential tax rate in accordance with the tax conventions between Mainland China and the country where the residents reside. The PRC individual income tax at the rate of 10% is applicable to dividends paid by a non-foreign invested PRC enterprise (the “**Relevant Non-foreign Invested PRC Enterprise**”) to foreign

resident individual investors (the “**Relevant Individual Investors**”) holding shares publicly offered by the Relevant Non-foreign PRC Enterprise in Hong Kong and no application for approval from the taxation authority in the PRC is required. In case the 10% tax rate is not applicable, the Relevant Non-foreign Invested PRC Enterprise shall: (i) apply on behalf of the investors to seek entitlement of the preferential tax treatment for lower tax rates if the countries of the Relevant Individual Investors have entered into income tax treaties with the PRC with tax rates lower than 10%, and arrange for refund of over payment upon approval by the tax authority according to the Regulations on the Administration of Tax Treaties for Non-resident Taxpayers (《非居民納稅人享受稅收協定待遇管理辦法》) (SAT Announcement No. 60 of 2015); (ii) pay the tax at such rates as agreed if the countries of the Relevant Individual Investors have entered into income tax treaties with the PRC with tax rates higher than 10% but lower than 20%, and no application is required; (iii) pay the personal income tax at the rate of 20% if the countries of the Relevant Individual Investors have not entered into any taxation treaties with the PRC or otherwise. A 10% PRC withholding tax will generally be withheld on dividends paid to Relevant Individual Investors unless the identity of the investor and the applicable tax rate are known to us.

Pursuant to the Circular on Certain Policy Questions Concerning Individual Income Tax (《關於個人所得稅若干政策問題的通知》), which was issued by MOF and SAT on May 13, 1994 and came into effect on the same date, the incomes gained by individual foreigners from dividends and bonuses of enterprise with foreign investment are exempt from individual income tax for the time being.

Tax Treaties

Non-PRC resident investors residing in countries which have entered into treaties for the avoidance of double taxation with the PRC or residing in Hong Kong or Macau are entitled to a reduction of the withholding taxes imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties/Arrangements with a number of countries and regions including Hong Kong, Macau, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant income tax agreements or arrangements are required to apply to the Chinese tax authorities for a refund of the withholding tax in excess of the agreed tax rate, and the refund payment is subject to approval by the Chinese tax authorities.

Taxation on Share Transfer

Enterprise Investors

In accordance with the EIT Law and its implementation provisions, a non-resident enterprise is generally subject to corporate income tax at the rate of a 10% on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. Such income tax payable for non-resident enterprises are deducted at source, where the payer of the income are required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due. Such tax may be reduced or exempted pursuant to relevant tax treaties or agreements on avoidance of double taxation.

Individual Investors

According to the IIT Law and its implementation provisions, gains realized on the sale of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

Pursuant to the Circular of Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) issued by the MOF and the State Administration of Taxation on March 20, 1998, from January 1, 1997, income of individuals from transfer of the shares of listed enterprises continues to be exempted from individual income tax. On December 31, 2009, the MOF, the State Administration of Taxation and CSRC jointly issued the Circular on Related Issues on Levying Individual Income Tax over the Income Received by Individuals from the Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的通知》), which states that individuals’ income from the transfer of listed shares on the Shanghai Stock Exchange and the Shenzhen Stock Exchange shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restriction (as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals’ Income from the Transfer of Restricted Stocks of Listed Companies (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知》) jointly issued by the above three departments on November 10, 2010).

As of the Latest Practicable Date, no aforesaid provisions have expressly provided that whether individual income tax shall be levied from non-Chinese resident individuals on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges, and to our knowledge, no such individual income tax was levied by PRC tax authorities in practice. However, there is no assurance that the PRC tax authorities will not change these practices which could result in levying income tax on non-PRC resident individuals on gains from the sale of H shares.

Stamp Duty

Pursuant to the Provisional Regulations of the PRC on Stamp Duty (《中華人民共和國印花稅暫行條例》), which came into effect on October 1, 1988 and amended on January 8, 2011, and the Implementation Provisions of Provisional Regulations of the PRC on Stamp Duty (《中華人民共和國印花稅暫行條例施行細則》), which came into effect on October 1, 1988, PRC stamp duty only applies to specific proof executed or received within the PRC, having legally binding force in the PRC and protected under the PRC laws, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

Estate Duty

The PRC currently does not impose any estate duty.

Shenzhen-Hong Kong Stock Connect Taxation Policy

On November 5, 2016, Ministry of Finance, State Taxation Administration and China Securities Regulatory Commission jointly promulgated the Circular on the Relevant Taxation Policy regarding the Pilot Inter-connected Mechanism for Trading on the Shenzhen Stock Market and the Hong Kong Stock Market (《關於深港股票市場交易互聯互通機制試點有關稅收政策的通知》) (“**SZHK Stock Connect Tax Policies**”), which clearly set forth tax policies applicable to transactions via SZHK Stock Connect and took effect on December 5, 2016.

According to the SZHK Stock Connect Tax Policies, revenues gained by mainland individual investors from the price difference arising from the trade of shares on the HKEx through SHHK Stock

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

Connect may be exempted from VAT during China’s pilot fiscal reform where the business tax is to be replaced by VAT. The dividends obtained by mainland individual investors from the listing of H-shares on HKEx via SZHK Stock Connect shall be subject to 20% personal income tax, provided that the H-share companies shall submit application to China Securities Depository and Clearing Corporation Limited (“CSDC”), after which CSDC will furnish them with a roster of the mainland individual investors, and the H-share companies may withdraw personal income tax at a rate of 20% in accordance therewith. If, however, dividends are generated from the listing of non-H-shares on HKEx via SZHK Stock Connect, such personal income tax at the rate of 20% will be deducted by CSDC. In case the individual investors have paid taxes in other jurisdictions by withdrawal in advance, the investors may apply for tax exemption to the tax authority in charge of CSDC using materials evidencing such withdrawal. Dividends gained by mainland securities investment funds via investing in shares listed on the HKEx via SZHK Stock Connect shall be subject to personal income tax according to the aforementioned provisions as if they are individual investors.

According to the SZHK Stock Connect Tax Policies, revenues made by mainland company investors from their transfer of shares that they have invested in on the HKEx via SZHK Stock Connect shall be factored in their total revenues and subject to company income tax, and if it is the mainland governmental bodies that earn incomes through trading shares listed on HKEx via SZHK Stock Connect, these incomes are exempted from VAT as they are now during the pilot period of replacement of business tax by VAT. If mainland company investors gain dividends through investment in shares listed on the HKEx via SZHK Stock Connect, such dividends shall be calculated in the total revenue of the companies and will be subject to income tax accordingly, in which case, a mainland domiciled company legally holding H shares for no less than 12 consecutive months will be exempted from company income tax for the amounts earned from the H shares during such 12-month period, while in case of a HK-based H-share company listed on the HKEx, the company shall apply to CSDC, who will provide to it the roster of mainland company investors, upon which the H-share company refrains from deducting income tax from the dividends, and payable income tax shall be declared and paid by the investors themselves; when declaring company income tax, if a mainland company investor has any tax imposed on the dividends deducted by a non-H-share company listed on the HKEx, the investor may apply for tax offset.

According to the SZHK Stock Connect Tax Policies, in case that any mainland investor trades, inherits or gives as gift shares listed on the HKEx, stamp tax will be imposed thereon according to the tax law currently prevalent in Hong Kong SAR, and the both CSDC and Hong Kong Securities Clearing Company Limited may collect the stamp tax on behalf of one another.

TAXATION IN HONG KONG

Tax on Dividends

Under the current practice of the Inland Revenue Department of Hong Kong, no tax is payable in Hong Kong in respect of dividends paid by us.

Capital Gains and Profit Tax

No tax is imposed in Hong Kong in respect of capital gains from the sale of H Shares. However, trading gains from the sale of the H Shares by persons carrying on a trade, profession or business in Hong Kong, where such gains are derived from or arise in Hong Kong from such trade, profession or business will be subject to Hong Kong profits tax, which is currently imposed at the

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

maximum rate of 16.5% on corporations and at the maximum rate of 15% on unincorporated businesses. Certain categories of taxpayers (for example, financial institutions, insurance companies and securities dealers) are likely to be regarded as deriving trading gains rather than capital gains unless these taxpayers can prove that the investment securities are held for long-term investment purposes. Trading gains from sales of H Shares effected on the Hong Kong Stock Exchange will be considered to be derived from or arise in Hong Kong. Liability for Hong Kong profits tax would thus arise in respect of trading gains from sales of H Shares effected on the Hong Kong Stock Exchange realized by persons carrying on a business of trading or dealing in securities in Hong Kong.

Stamp Duty

Hong Kong stamp duty, currently charged at the ad valorem rate of 0.1% on the higher of the consideration for or the market value of the H Shares, will be payable by the purchaser on every purchase and by the seller on every sale of Hong Kong securities, including H Shares (in other words, a total of 0.2% is currently payable on a typical sale and purchase transaction involving H Shares). In addition, a fixed duty of HK\$5.00 is currently payable on any instrument of transfer of H Shares. Where one of the parties is a resident outside Hong Kong and does not pay the ad valorem duty due by it, the duty not paid will be assessed on the instrument of transfer (if any) and will be payable by the transferee. If no stamp duty is paid on or before the due date, a penalty of up to ten times the duty payable may be imposed.

Estate Duty

The Revenue (Abolition of Estate Duty) Ordinance 2005 came into effect on February 11, 2006 in Hong Kong, pursuant to which no Hong Kong estate duty is payable and no estate duty clearance papers are needed for an application of a grant of representation in respect of holders of H Shares whose deaths occur on or after February 11, 2006.

FOREIGN EXCHANGE

The lawful currency of the PRC is Renminbi, which is currently subject to foreign exchange control and cannot be freely converted into foreign currency. The SAFE, with the authorization of the PBOC, is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

On January 29, 1996, the State Council promulgated the Regulations of the PRC on Foreign Exchange Control (《中華人民共和國外匯管理條例》) (the “**Foreign Exchange Control Regulations**”) and it came into effect on April 1, 1996. The Foreign Exchange Control Regulations classifies all international payments and transfers into current items and capital items. Most of the current items are not subject to the approval of foreign exchange administration agencies, while capital items are subject to such approval. The Foreign Exchange Control Regulations were subsequently amended on January 14, 1997 and August 1, 2008, and came into effect on August 5, 2008. The latest amendment to the Foreign Exchange Control Regulations clearly states that PRC will not impose any restriction on international current payments and transfers.

On June 20, 1996, PBOC promulgated the Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》) (the “**Settlement Regulations**”), which became effective on July 1, 1996. The Settlement Regulations does not impose any restrictions on convertibility of foreign exchange under current items, while imposing restrictions on foreign exchange transactions under capital account items.

APPENDIX III

TAXATION AND FOREIGN EXCHANGE

According to the relevant laws and regulations in the PRC, PRC enterprises (including foreign investment enterprises) which need foreign exchange for current item transactions may, without the approval of the foreign exchange administrative authorities, effect payment through foreign exchange accounts opened at financial institutions that carries foreign exchange business or operating institutions that carries settlement and sale business, on the strength of valid receipts and proof. Foreign investment enterprises which need foreign exchange for the distribution of profits to their shareholders and PRC enterprises which, in accordance with regulations, are required to pay dividends to their shareholders in foreign exchange (such as our Company) may, on the strength of resolutions of the board of directors or the shareholders’ meeting on the distribution of profits, effect payment from foreign exchange accounts opened at financial institutions that carries foreign exchange business or institutions that carries settlement and sale business, or effect exchange and payment at financial institutions that carries foreign exchange business or institutions that carries settlement and sale business.

On December 26, 2014, the SAFE issued the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》), pursuant to which a domestic company shall, within 15 business days of the date of the end of its overseas [REDACTED], register the overseas [REDACTED] with the Administration of Foreign Exchange at the place of its establishment; the [REDACTED] from an overseas [REDACTED] of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the [REDACTED] shall be consistent with the content of the document and other disclosure documents. A domestic company (except for bank financial institutions) shall present its certificate of overseas [REDACTED] to open a special account at a local bank for its [REDACTED] (or follow-on offering) and repurchase business to handle the exchange, remittance and transfer of funds for the business concerned.

On February 13, 2015, the SAFE issued the Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》). The notice came into effect on June 1, 2015. The notice has canceled two of the administrative examination and approval items, being the confirmation of foreign exchange registration under domestic direct investment and the confirmation of foreign exchange registration under overseas direct investment, instead, banks shall directly examine and handle foreign exchange registration under domestic direct investment and foreign exchange registration under overseas direct investment, and the SAFE and its branch offices shall indirectly regulate the foreign exchange registration of direct investment through banks.

According to the Notice of the State Administration of Foreign Exchange of the PRC on Revolutionize and Regulate Capital Account Settlement Management Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) issued by the SAFE and came into effect on June 9, 2016, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of raised capital by overseas [REDACTED]) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions. The tentative percentage of foreign exchange settlement for foreign currency earnings in capital account of domestic institutions is 100%, subject to adjustment of the SAFE in due time in accordance with international revenue and expenditure situations.

On January 26, 2017, Notice of the State Administration of Foreign Exchange on Further Promoting the Reform of Foreign Exchange Administration and Improving the Examination of Authenticity and Compliance (《國家外匯管理局關於進一步推進外匯管理改革完善真實合規性審核的通

知》) was issued by SAFE to further expand the scope of settlement for domestic foreign exchange loans, allow settlement for domestic foreign exchange loans with export background under goods trading, allow repatriation of funds under domestic guaranteed foreign loans for domestic utilization, allow settlement for domestic foreign exchange accounts of foreign institutions operating in the Free Trade Pilot Zones, and adopt the model of full-coverage RMB and foreign currency overseas lending management, where a domestic institution engages in overseas lending, the sum of its outstanding overseas lending in RMB and outstanding overseas lending in foreign currencies shall not exceed 30% of its owner’s equity in the audited financial statements of the preceding year.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

This appendix sets forth summaries of certain aspects of PRC laws and regulations which are relevant to the operations and business of the Company. Laws and regulations relating to taxation in the PRC are discussed separately in “Appendix III—Taxation and Foreign Exchange” to this document. This appendix also contains a summary of certain Hong Kong legal and regulatory provisions, including summaries of certain material differences between the PRC and Hong Kong company laws, certain requirements of the Hong Kong Listing Rules and additional provisions required by the Hong Kong Stock Exchange for inclusion in the articles of association of the PRC issuers. The principal objective of this summary is to provide potential [REDACTED] with an overview of the principal laws and regulatory provisions applicable to the Company. This summary is not intended to include all the data which may be important to the potential [REDACTED]. For discussion of the laws and regulations which are relevant to our business, please see the “Regulatory Environment” section of this document.

PRC LAWS AND REGULATIONS

The PRC Legal System

The PRC legal system is based on the PRC Constitution (《中華人民共和國憲法》, the “**Constitution**”), which was adopted on December 4, 1982 and amended five times on April 12, 1988, March 29, 1993, March 15, 1999, March 14, 2004 and March 11, 2018. The PRC legal system is made up of written laws, administrative regulations, local regulations, autonomous regulations, separate regulations, rules and regulations of State Council departments, rules and regulations of local governments, laws of special administrative regions and international treaties of which the PRC government is a signatory and other regulatory documents. Court judgments do not constitute legally binding precedents, although they are used for the purposes of judicial reference and guidance.

The National People’s Congress (the “**NPC**”) and its Standing Committee are empowered to exercise the legislative power of the State in accordance with the Constitution and the PRC Legislation Law (《中華人民共和國立法法》, the “**Legislation Law**”), which was adopted on July 1, 2000 and amended on March 15, 2015. The NPC has the power to formulate and amend basic laws governing state organs, civil, criminal and other matters. The Standing Committee of the NPC formulates and amends laws other than those required to be enacted by the NPC and to interpret, supplement and amend parts of the laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of state administration and has the power to formulate administrative regulations based on the Constitution and laws.

The people’s congresses of the provinces, autonomous regions and municipalities and their respective standing committees may formulate local regulations based on the specific circumstances and actual needs of their respective administrative areas, provided that such local regulations do not contravene any provision of the Constitution, laws or administrative regulations. The people’s congresses of cities divided into districts and their respective standing committees may formulate local regulations on aspects such as urban and rural construction and management, environmental protection and historical and cultural protection based on the specific circumstances and actual needs of such cities, provided that such local regulations do not contravene any provision of the Constitution, laws, administrative regulations and local regulations of their respective provinces or autonomous regions. If the law provides otherwise on the matters concerning formulation of local regulations by cities divided

APPENDIX IV

**SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS**

into districts, those provisions shall prevail. Such local regulations will become enforceable after being reported to and approved by the standing committees of the people's congresses of the relevant provinces or autonomous regions. The standing committees of the people's congresses of the provinces or autonomous regions examine the legality of local regulations submitted for approval, and such approval should be granted within four months if they are not in conflict with the Constitution, laws, administrative regulations and local regulations of such provinces or autonomous regions. Where, during the examination for approval of local regulations of cities divided into districts by the standing committees of the people's congresses of the provinces or autonomous regions, conflicts are identified with the rules and regulations of the people's governments of the provinces or autonomous regions concerned, a decision should be made by the standing committees of the people's congresses of provinces or autonomous regions to resolve the issue. People's congresses of national autonomous areas have the power to enact autonomous regulations and separate regulations in light of the political, economic and cultural characteristics of the ethnic groups in the areas concerned. The people's congresses or their standing committees of the provinces and cities where special economic zones are located may, upon authorization by the National People's Congress, formulate regulations and enforce them within the special economic zones.

The ministries and commissions of the State Council, People's Bank of China, National Audit Office and the subordinate institutions with administrative functions directly under the State Council may formulate departmental rules within the jurisdiction of their respective departments based on the laws and administrative regulations, and the decisions and orders of the State Council. Provisions of departmental rules should be the matters related to the enforcement of the laws and administrative regulations, and the decisions and orders of the State Council. The people's governments of the provinces, autonomous regions, municipalities and cities or autonomous prefectures divided into districts may formulate rules and regulations based on the laws, administrative regulations and local regulations of such provinces, autonomous regions and municipalities.

According to the Constitution, the power to interpret laws is vested in the Standing Committee of the NPC. Pursuant to the Resolution of the Standing Committee of the NPC Providing an Improved Interpretation of the Law (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) implemented on June 10, 1981, issues related to the application of laws in a court trial should be interpreted by the Supreme People's Court, issues related to the application of laws in a prosecution process of a procuratorate should be interpreted by the Supreme People's Procuratorate. If there is any disagreement in principle between Supreme People's Court's interpretations & Supreme People's Procuratorate's interpretations, such issues shall be reported to the Standing Committee of the NPC for interpretation or judgment. The other issues related to laws other than the abovementioned should be interpreted by the State Council and the competent authorities. The State Council and its ministries and commissions are also vested with the power to give interpretations of the administrative regulations and departmental rules which they have promulgated. At the regional level, the power to interpret regional laws and regulations as well as administrative rules is vested in the regional legislative and administrative authorities which promulgate such laws, regulations and rules.

The PRC Judicial System

Under the Constitution and the Law of Organization of the People's Courts of the PRC (《中華人民共和國人民法院組織法》), which is adopted on January 1, 1980 and amended three times on September 2, 1983, December 2, 1986 and October 31, 2006, the PRC judicial system is made up of

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS

the Supreme People’s Court, the local people’s courts, the military courts and other special people’s courts. The local people’s courts are divided into three levels, namely, the basic people’s courts, the intermediate people’s courts and the higher people’s courts. The basic people’s courts may set up civil, criminal and economic divisions, and certain people’s courts based on the facts of the region, population and cases. The intermediate people’s courts have divisions similar to those of the basic people’s courts and may set up other special divisions, such as the intellectual property division, if needed. These two levels of people’s courts are subject to supervision by people’s courts at higher levels. The Supreme People’s Court is the highest judicial authority in the PRC. It supervises the administration of justice by the people’s courts at all levels and special people’s courts. The Supreme People’s Procuratorate is authorized to supervise the judgment and ruling of the people’s courts at all levels which have been legally effective, and the people’s procuratorate at a higher level is authorized to supervise the judgment and ruling of a people’s court at lower levels which have been legally effective.

A people’s court takes the rule of the second instance as the final rule, that is, the judgments or rulings of the second instance at a people’s court are final. A party may appeal against the judgment or ruling of the first instance of a local people’s court. The people’s procuratorate may present a protest to the people’s court at the next higher level in accordance with the procedures stipulated by the laws. In the absence of any appeal by the parties and any protest by the people’s procuratorate within the stipulated period, the judgments or rulings of the people’s court are final. Judgments or rulings of the second instance of the intermediate people’s courts, the higher people’s courts and the Supreme People’s Court, and judgments or rulings of the first instance of the Supreme People’s Court are final. However, if the Supreme People’s Court finds some definite errors in a legally effective judgment, ruling or conciliation statement of the people’s court at any level, or if the people’s court at a higher level finds such errors in a legally effective judgment, ruling or conciliation statement of the people’s court at a lower level, it has the authority to review the case itself or to direct the lower-level people’s court to conduct a retrial. If the chief judge of all levels of people’s courts finds some definite errors in a legally effective judgment, ruling or conciliation statement, and considers a retrial is preferred, such case shall be submitted to the judicial committee of the people’s court at the same level for discussion and decision.

The Civil Procedure Law of the PRC (《中華人民共和國民事訴訟法》), the “**PRC Civil Procedure Law**”) adopted on April 9, 1991 and amended three times on October 28, 2007, August 31, 2012 and June 27, 2017 prescribes the conditions for instituting a civil action, the jurisdiction of the people’s courts, the procedures for conducting a civil action, and the procedures for enforcement of a civil judgment or ruling. All parties to a civil action conducted within the PRC must abide by the PRC Civil Procedure Law. A civil case is generally heard by the court located in the defendant’s place of domicile. The court of jurisdiction in respect of a civil action may also be chosen by explicit agreement among the parties to a contract, provided that the people’s court having jurisdiction should be located at places substantially connected with the disputes, such as the plaintiff’s or the defendant’s place of domicile, the place where the contract is executed or signed or the place where the object of the action is located. However, such choice shall not in any circumstances contravene the regulations of differential jurisdiction and exclusive jurisdiction.

A foreign individual, a person without nationality, a foreign enterprise or a foreign organization is given the same litigation rights and obligations as a citizen, a legal person or other organizations of the PRC when initiating actions or defending against litigations at a PRC court. Should a foreign court

APPENDIX IV

**SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS**

limit the litigation rights of PRC citizens or enterprises, the PRC court may apply the same limitations to the citizens and enterprises of such foreign country. A foreign individual, a person without nationality, a foreign enterprise or a foreign organization must engage a PRC lawyer in case he or it needs to engage a lawyer for the purpose of initiating actions or defending against litigations at a PRC court. In accordance with the international treaties to which the PRC is a signatory or participant or according to the principle of reciprocity, a people’s court and a foreign court may request each other to serve documents, conduct investigation and collect evidence and conduct other actions on its behalf. A PRC court shall not accommodate any request made by a foreign court which will result in the violation of sovereignty, security or public interests of the PRC.

All parties to a civil action shall perform the legally effective judgments and rulings. If any party to a civil action refuses to abide by a judgment or ruling made by a people’s court or an award made by an arbitration tribunal in the PRC, the other party may apply to the people’s court for the enforcement of the same within two years subject to application for postponed enforcement or revocation. If a party fails to satisfy within the stipulated period a judgment which the court has granted an enforcement approval, the court may, upon the application of the other party, mandatorily enforce the judgment on the party.

Where a party applies for enforcement of a legally effective judgment or ruling made by a people’s court, and the opposite party or his property is not within the territory of the PRC, the applicant may directly apply to a foreign court with jurisdiction for recognition and enforcement of the judgment or ruling. A foreign judgment or ruling may also be recognized and enforced by the people’s court in accordance with the PRC enforcement procedures if the PRC has entered into, or acceded to, international treaties with the relevant foreign country, which provided for such recognition and enforcement, or if the judgment or ruling satisfies the court’s examination according to the principle of reciprocity, unless the people’s court considers that the recognition or enforcement of such judgment or ruling would violate the basic legal principles of the PRC, its sovereignty or national security, or against the social and public interests.

The PRC Company Law, Special Regulations’ the Mandatory Provisions and Official Reply

The PRC Company Law (《中華人民共和國公司法》) was adopted by the 5th meeting of the Standing Committee of the 8th National People’s Congress Session on December 29, 1993 and came into effect on July 1, 1994. It was amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013, and October 26, 2018. The latest revised PRC Company Law was implemented on October 26, 2018.

The Special Regulations was passed at the 22nd Standing Committee Meeting of the State Council on July 4, 1994 and promulgated and implemented on August 4, 1994. The Special Regulations include provisions in respect of the overseas share offering and listing of joint stock limited companies.

The Mandatory Provisions jointly promulgated by the former Securities Commission of the State Council and the former State Commission for Restructuring the Economic System and implemented on August 27, 1994 and effective as of December 19, 1994 prescribe that the provisions should be incorporated in the articles of association of joint stock limited companies to be listed in overseas stock exchanges. Accordingly, the contents required by the Mandatory Provisions have been

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

incorporated in the Articles of Association. References to a “company” made in this Appendix are to a joint stock limited company established under the PRC Company Law with overseas-listed foreign invested shares to be issued.

According to the Official Reply, promulgated by the State Council on October 17, 2019, the notice period for a shareholders’ meeting, the shareholder proposal right, and the procedures for convening a shareholders’ meeting, for those joint stock companies established within the territory of China but listed outside the territory of China, should be governed by the PRC Company Law, and the Special Regulations will no longer apply to the aforesaid matters.

Set out below is a summary of the major provisions of the PRC Company Law, the Special Regulations, the Mandatory Provisions and Official Reply.

General

A “joint stock limited company” (“company”) refers to a corporate legal person incorporated in China under the PRC Company Law with independent legal person properties and entitlements to such legal person properties and with its registered capital divided into shares of equal par value. The liability of the company for its own debts is limited to all the properties it owns and the liability of its shareholders for the company is limited to the extent of the shares they subscribe for.

Incorporation

A company may be established by promotion or subscription. A company shall have a minimum of two but no more than 200 people as its promoters, and over half of the promoters must be resident within the PRC. Companies established by promotion are companies of which the registered capital is the total share capital subscribed for by all the promoters registered with the company’s registration authorities. No share offering shall be made before the shares subscribed for by the promoters are fully paid up. For companies established by subscription, the registered capital is the total paid-up share capital as registered with the company’s registration authorities. If laws, administrative regulations and State Council decisions provide otherwise on paid-in registered capital and the minimum registered capital, the company should follow such provisions.

For companies incorporated by way of promotion, the promoters shall subscribe in writing for the shares required to be subscribed for by them and pay up their capital contributions under the articles of association. Procedures relating to the transfer of titles to non-monetary assets shall be duly completed if such assets are to be contributed as capital. Promoters who fail to pay up their capital contributions in accordance with the foregoing provisions shall assume default liabilities in accordance with the covenants set out in the promoters’ agreement. After the promoters have subscribed for the capital contribution under the articles of association, a board of directors and a supervisory board shall be elected and the board of directors shall apply for registration of establishment by filing the articles of association with relevant administration for industry and commerce, and other documents as required by the law or administrative regulations.

Where companies are incorporated by subscription, not less than 35% of their total number of shares must be subscribed for by the promoters, unless otherwise provided by the laws or administrative regulations. A promoter who offers shares to the public must announce a share offering document and prepare a share subscription form to be completed, signed and sealed by subscribers,

APPENDIX IV

**SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS**

specifying the number and amount of shares to be subscribed for and the subscribers' addresses. The subscribers shall pay up monies for the shares they subscribe for. Where a promoter is offering shares to the public, such offer shall be underwritten by security companies established under PRC law, and underwriting agreements shall be entered into. A promoter offering shares to the public shall also enter into agreements with banks in relation to the receipt of subscription monies. The receiving banks shall receive and keep in custody the subscription monies, issue receipts to subscribers who have paid the subscription monies and is obliged to furnish evidence of receipt of those subscription monies to relevant authorities. After the subscription monies for the share issue have been paid in full, a capital verification institution established under PRC law must be engaged to conduct a capital verification and furnish a certificate thereof. The promoters shall preside over and convene an inauguration meeting within 30 days from the date of the full payment of subscription monies. The inauguration meeting shall be formed by the promoters and subscribers. Where the shares issued remain under subscribed by the cut-off date stipulated in the share offering document, or where the promoter fails to convene an inauguration meeting within 30 days of the subscription monies for the shares issued being fully paid up, the subscribers may demand that the promoters refund the subscription monies so paid together with the interest at bank rates of a deposit for the same period. Within 30 days of the conclusion of the inauguration meeting, the board of directors shall apply to the company registration authority for registration of the establishment of the company. A company is formally established and has the capacity of a legal person after approval of registration has been given by the relevant administration for industry and commerce and a business license has been issued.

A company's promoter shall be liable for the followings:

- the debts and expenses incurred in the establishment process jointly and severally if the company cannot be incorporated;
- the refund of subscription monies paid by the subscribers together with interest at bank rates of deposit for the same period jointly and severally if the company cannot be incorporated; and
- the compensation of any damages suffered by the company as a result of the promoters' fault in the course of its establishment.

Share Capital

The promoters may make a capital contribution in currencies, or non-monetary assets such as in kind or intellectual property rights or land use rights which can be appraised with monetary value and transferred lawfully, except for assets which are prohibited from being contributed as capital by the laws or administrative regulations. If a capital contribution is made in non-monetary assets, a valuation of the assets contributed must be carried out pursuant to the provisions of the laws or administrative regulations on valuation without any overvaluation or under-valuation.

The issuance of shares shall be conducted in a fair and equitable manner. The same class of shares must carry equal rights. For shares issued at the same time and within the same class, the conditions and price per share must be the same. The share offering price may be equal to or greater than the nominal value of the share, but may not be less than the nominal value.

A company must obtain the approval of CSRC to offer its shares to the overseas public. According to the Special Regulations and the Mandatory Provisions, the shares issued to foreign

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

investors and listed overseas by a company shall be in registered form, denominated in Renminbi and subscribed for in foreign currency. Shares issued to foreign investors and listed overseas are classified as overseas-listed foreign shares, and those shares issued to investors within the PRC, are known as domestic shares. Qualified foreign institutional investors approved by CSRC may hold domestic listed shares. Under the Special Regulations, upon approval of CSRC, a company may agree, in the underwriting agreement in respect of an issue of overseas-listed foreign shares, to retain not more than 15% of the aggregate number of such overseas-listed foreign invested shares proposed to be issued in addition to the number of underwritten shares. The issuance of the retained shares is deemed to be a part of this issuance.

Under the PRC Company Law, a company issuing registered share certificates shall maintain a shareholder registry which sets forth the following matters:

- the name and domicile of each shareholder;
- the number of shares held by each shareholder;
- the serial numbers of shares held by each shareholder; and
- the date on which each shareholder acquired the shares.

Increase in Share Capital

Under the PRC Company Law, where a company is issuing new shares, resolutions shall be passed at shareholder’s general meeting in accordance with the articles of association in respect of the class and amount of the new shares, the issue price of the new shares, the commencement and end dates for the issue of the new shares and the class and amount of the new shares proposed to be issued to existing shareholders.

When a company launches a public issue of new shares upon the approval by CSRC, a new share offering document and financial accounting report must be published and a subscription form must be prepared. After the issue of new share the company has been paid up, the change must be registered with the relevant company registration authorities and a public announcement must be made accordingly. Where an increase in registered capital of a company is made by means of an issue of new shares, the subscription of new shares by shareholders shall be made in accordance with the relevant provisions on the payment of subscription monies for the establishment of a company.

Reduction of Share Capital

A company may reduce its registered capital in accordance with the following procedures prescribed by the PRC Company Law:

- the company shall prepare a balance sheet and an inventory of assets;
- the reduction of registered capital must be approved by shareholders at general meeting;
- the company shall notify its creditors of the reduction in share capital within 10 days and publish the relevant announcement in newspapers within 30 days of the resolution approving the reduction being passed;
- the creditors of the company may require the company to repay its debts or provide guarantees for covering the debts within 30 days of receipt of the notification or within 45 days of the date of the announcement if he/she/it has not received any notification; and

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

- the company must apply to the relevant administration bureau for industry and commerce for registration of the change on the reduction of registered capital.

Repurchase of Shares

A company shall not purchase its own shares except under any of the following circumstances:

- (1) Reducing the registered capital of the company.
- (2) Merging with another company that holds its shares.
- (3) Using shares for employee stock ownership plan or equity incentives.
- (4) A shareholder requesting the company to purchase the shares held by him since he objects to a resolution of the shareholders’ meeting on the combination or division of the company.
- (5) Using shares for converting convertible corporate bonds issued by the listed company.
- (6) It is necessary for a listed company to protect the corporate value and the rights and interests of shareholders.

A company purchasing its own shares under any of the circumstances set forth in items (1) and (2) of the preceding paragraph shall be subject to a resolution of the shareholders’ meeting; and a company purchasing its own shares under any of the circumstances set forth in items (3), (5) and (6) of the preceding paragraph may, pursuant to the bylaws or the authorization of the shareholders’ meeting, be subject to a resolution of a meeting of the board of directors at which more than two-thirds of directors are present.

After purchasing its own shares pursuant to the provisions of the first paragraph of this article, a company shall, under the circumstance set forth in item (1), cancel them within 10 days after the purchase; while under the circumstance set forth in either item (2) or (4), transfer or cancel them within six months; and while under the circumstance set forth in item (3), (5) or (6), aggregately hold not more than 10% of the total shares that have been issued by the company, and transfer or cancel them within three years.

A listed company purchasing its own shares shall perform the obligation of information disclosure according to the Securities Law of the People’s Republic of China. A listed company purchasing its own shares under any of the circumstances set forth in items (3), (5) and (6) of paragraph 1 of this article shall carry out trading in a public and centralized manner.

A company shall not accept its own shares as the subject matter of pledge.

Transfer of Shares

Shares held by shareholders may be transferred legally. Under the PRC Company Law, a shareholder should effect a transfer of his shares on a stock exchange established in accordance with laws or by any other means as required by the State Council. Registered shares may be transferred after the shareholders endorse the back of the share certificates or in any other manner specified by the laws or administrative regulations. Following the transfer, the company shall enter the names and domiciles of the transferees into its share register. No changes of registration in the share register described above

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

shall be effected during a period of 20 days prior to convening a shareholders’ general meeting or 5 days prior to the record date for the purpose of determining entitlements to dividend distributions, unless otherwise stipulated by laws on the registration of changes in the share register of listed companies. The transfer of bearer share certificates shall become effective upon the delivery of the certificates to the transferee by the shareholder. The Mandatory Provision provides that changes due to share transfer should not be made to shareholder registry within 30 days before a shareholders’ general meeting or within 5 days before the record date for the purpose of determining entitlements to dividend distributions.

Under the PRC Company Law, shares held by promoters may not be transferred within one year of the establishment of the company. Shares of the company issued prior to the public issuance of shares may not be transferred within one year of the date of the company’s listing on a stock exchange. Directors, supervisors and the senior management of a company shall declare to the company their shareholdings in it and any changes in such shareholdings. During their terms of office, they may transfer no more than 25% of the total number of shares they hold in the company every year. They shall not transfer the shares they hold within one year of the date of the company’s listing on a stock exchange, nor within six months after they leave their positions in the company. The articles of association may set out other restrictive provisions in respect of the transfer of shares in the company held by its directors, supervisors and the senior management.

Shareholders

Under the PRC Company Law, the rights of holders of ordinary shares of a company include:

- to receive a return on assets, participate in significant decision-making and select management personnel;
- to petition the people’s court to revoke any resolution passed at a shareholders’ general meeting or a meeting of board of directors that has not been convened in compliance with the laws, administrative regulations or the articles of association or whose voting has been conducted in an invalid manner, or any resolution the contents of which are in violation of the articles of association, provided that such petition shall be submitted within 60 days of the passing of such resolution;
- to transfer the shares of the shareholders in accordance with laws, administrative regulations and provisions of the articles of associations;
- to attend or appoint a proxy to attend shareholders’ general meetings and vote at the meetings;
- to inspect the articles of association, share register, counterfoil of company debentures, minutes of shareholders’ general meetings, board resolutions, resolutions of the supervisory board and financial and accounting reports and to make suggestions or inquiries in respect of the company’s operations;
- to receive dividends in respect of the number of shares held;
- to participate in residual properties of the company in proportion to their shareholdings upon the liquidation of the company;
- and any other shareholders’ rights provided for in laws, administrative regulations, other regulatory documents and the articles of association.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

The obligations of shareholders include the obligation to abide by the company's articles of association, to pay the subscription monies in respect of the shares subscribed for, to be liable for the company's debts and liabilities to the extent of the amount of his or her subscribed shares and any other shareholder obligation specified in the articles of association.

Shareholders' General Meetings

The general meeting is the organ of authority of the company, which exercises its powers in accordance with the PRC Company Law. The general meeting may exercise its powers:

- to decide on the company's operational objectives and investment plans;
- to elect and dismiss the directors and supervisors (not being representative(s) of employees) and to decide on the matters relating to the remuneration of directors and supervisors;
- to review and approve the reports of the board of directors;
- to review and approve the reports of the supervisory board;
- to review and approve the company's annual financial budgets and final accounts;
- to review and approve the company's profit distribution proposals and loss recovery proposals;
- to decide on any increase or reduction of the company's registered capital;
- to decide on the issue of corporate bonds;
- to decide on merger, division, dissolution and liquidation of the company or change of its corporate form;
- to amend the company's articles of association; and
- to exercise any other authority stipulated in the articles of association.

A shareholders' general meeting is required to be held once every year. An extraordinary general meeting is required to be held within two months of the occurrence of any of the following:

- the number of directors is less than the number stipulated by the PRC Company Law or less than two-thirds of the number specified in the articles of association;
- the outstanding losses of the company amounted to one-third of the company's total paid-in share capital;
- shareholders individually or in aggregate holding 10% or more of the company's shares request the convening of an extraordinary general meeting;
- the board deems necessary;
- the supervisory board proposes to hold; or
- any other circumstances as provided for in the articles of association.

A shareholders' general meeting shall be convened by the board of directors, and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or is not performing his duties, the meeting shall be presided over by the vice chairman. In the event that

APPENDIX IV

**SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS**

the vice chairman is incapable of performing or is not performing his duties, a director nominated by half or more of the directors shall preside over the meeting. Where the board of directors is incapable of performing or is not performing its duties to convene the general meeting, the supervisory board shall convene and preside over shareholders' general meeting in a timely manner. If the supervisory board fails to convene and preside over shareholders' general meeting, shareholders individually or in aggregate holding 10% or more of the company's shares for 90 days or more consecutively may unilaterally convene and preside over shareholders' general meeting.

In accordance with the PRC Company Law, a notice of the general meeting stating the date and venue of the meeting and the matters to be considered at the meeting shall be given to all shareholders 20 days before the meeting. A notice of extraordinary general meeting shall be given to all shareholders 15 days prior to the meeting. For the issuance of bearer share certificates, the time and venue of and matters to be considered at the meeting shall be announced 30 days before the meeting. A single shareholder who holds, or several shareholders who jointly hold, three percent or more of the shares of the company may submit an interim proposal in writing to the board of directors ten days before the general meeting is held. The board of directors shall notify other shareholders within two days upon receipt of the proposal, and submit the said interim proposal to the general meeting for deliberation. The contents of the interim proposal shall fall within the scope of powers of the general meeting, and the proposal shall have a clear agenda and specific matters on which resolutions are to be made. The general meeting shall not make any resolution in respect of any matter not set out in the above-mentioned two types of notices. Holders of bearer share certificates who wish to attend a general meeting shall deposit their share certificates with the company five days before the meeting and till the conclusion of the meeting.

There is no specific provision in the PRC Company Law regarding the number of shareholders constituting a quorum in a shareholders' general meeting.

Under the PRC Company Law, shareholders present at a shareholders' general meeting have one vote for each share they hold, save that the company's shares held by the company are not entitled to any voting rights.

An accumulative voting system may be adopted for the election of directors and supervisors at the general meeting pursuant to the provisions of the articles of association or a resolution of the general meeting. Under the accumulative voting system, each share shall be entitled to the number of votes equivalent to the number of directors or supervisors to be elected at the general meeting, and shareholders may consolidate their votes for one or more directors or supervisors when casting a vote.

Under the PRC Company Law, resolutions of the general meeting must be passed by more than half of the voting rights held by shareholders present in person (including those represented by proxies) at the meeting, with the exception of matters relating to merger, division or dissolution of the company, increase or reduction of registered share capital, change of corporate form or amendments to the articles of association, which in each case must be passed by at least two-thirds of the voting rights held by the shareholders present at the meeting. Where the PRC Company Law and the articles of association provide that the transfer or acquisition of significant assets or the provision of external guarantees by the company and the other matters must be approved by way of resolution of the general meeting, the directors shall convene a shareholders' general meeting promptly to vote on such matters by shareholders' general meeting.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Minutes shall be prepared in respect of matters considered at the general meeting and the chairperson and directors attending the meeting shall endorse such minutes by signature. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

According to the Mandatory Provisions, the increase or reduction of share capital, the issuance of shares of any class, warrants or other similar securities and bonds, the division, merger, dissolution and liquidation of the company, the amendments to the articles of association and any other matters, which, as resolved by way of an ordinary resolution of the general meeting, may have a material impact on the company and require adoption by way of a special resolution, must be approved through special resolutions by no less than two-thirds of the voting rights held by shareholders (including proxies thereof) present at the meeting.

The Mandatory Provisions require a special resolution to be passed at the general meeting and a class meeting to be held in the event of a variation or derogation of the class rights of a shareholder class. For this purpose, holders of domestic shares and H shares are deemed to be shareholders of different classes.

Board

A company shall have a board, which shall consist of 5 to 19 members. Members of the board may include staff representatives, who shall be democratically elected by the company's staff at a staff representative assembly, general staff meeting or otherwise. The term of a director shall be stipulated in the articles of association, provided that no term of office shall last for more than three years. A director may serve consecutive terms if re-elected. A director shall continue to perform his/her duties as a director in accordance with the laws, administrative regulations and the articles of association until a duly reelected director takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of directors results in the number of directors being less than the quorum.

Under the PRC Company Law, the board of directors may exercise its powers:

- to convene shareholders' general meetings and report on its work to the shareholders' general meetings;
- to implement the resolutions passed by the shareholders at the shareholders' general meetings;
- to decide on the company's operational plans and investment proposals;
- to formulate proposal for the company's annual financial budgets and final accounts;
- to formulate the company's profit distribution proposals and loss recovery proposals;
- to formulate proposals for the increase or reduction of the company's registered capital and the issue of corporate bonds;
- to formulate proposals for the merger, division or dissolution of the company or change of corporate form;
- to decide on the setup of the company's internal management organs;
- to appoint or dismiss the company's manager and decide on his/her remuneration and, based on the manager's recommendation, to appoint or dismiss any deputy general manager and financial officer of the company and to decide on their remunerations;

APPENDIX IV

**SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS**

- to formulate the company's basic management system; and
- to exercise any other authority stipulated in the articles of association.

In addition, the Mandatory Provisions provide that the board of directors is also responsible for formulating the proposals for amendment of the articles of association of a company.

Meetings of the board of directors shall be convened at least twice each year. Notices of meeting shall be given to all directors and supervisors 10 days before the meeting. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of the voting rights, more than one-third of the directors or the supervisory board. The chairman shall convene the meeting within 10 days of receiving such proposal, and preside over the meeting. The board may otherwise determine the means and the period of notice for convening an interim board meeting. Meetings of the board of directors shall be held only if more than half of the directors are present. Resolutions of the board shall be passed by more than half of all directors. Each director shall have one vote for a resolution to be approved by the board. Directors shall attend board meetings in person. If a director is unable to attend for any reason, he/she may appoint another director to attend the meeting on his/her behalf by a written power of attorney specifying the scope of authorization.

If a resolution of the board of directors violates the laws, administrative regulations or the articles of association or resolutions of the general meeting, and as a result of which the company sustains serious losses, the directors participating in the resolution are liable to compensate the company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director shall be relieved from that liability.

Under the PRC Company Law, the following person may not serve as a director in a company:

- a person who is unable or has limited ability to undertake any civil liabilities;
- a person who has been convicted of an offense of corruption, bribery, embezzlement, misappropriation of property or destruction of the socialist market economic order, or who has been deprived of his political rights due to his crimes, in each case where less than five years have elapsed since the date of completion of the sentence;
- a person who has been a former director, factory manager or manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of the bankruptcy and liquidation of the company or enterprise;
- a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law or has been ordered to close down by law and the person was personally responsible, where less than three years have elapsed since the date of such revocation; and
- a person who is liable for a relatively large amount of debts that are overdue.

Where a company elects or appoints a director to which any of the above circumstances applies, such election or appointment shall be null and void. A director to which any of the above circumstances applies during his/her term of office shall be released of his/her duties by the company.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Other circumstances under which a person is disqualified from acting as a director of a company are set out in the Mandatory Provisions.

Under the PRC Company Law, the board shall appoint a chairman and may appoint a vice chairman.

The chairman and the vice chairman shall be elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and review the implementation of board resolutions. The vice chairman shall assist the chairman to perform his/her duties. Where the chairman is incapable of performing or is not performing his/her duties, the duties shall be performed by the vice chairman. Where the vice chairman is incapable of performing or is not performing his/her duties, a director nominated by more than half of the directors shall perform his/her duties.

The legal representative of a company, in accordance with the company's articles of association, may be the chairman, any executive director or the manager. The Special Regulations provide that a company's directors, supervisors, managers and other officers bear fiduciary duties and the duty to act diligently. They are required to faithfully perform their duties, protect the interests of the company and not to use their positions for their own benefit.

Supervisory Board

A company shall have a supervisory board composed of not less than three members. The supervisory board shall consist of representatives of the shareholders and an appropriate proportion of representatives of the company's staff, of which the proportion of representatives of the company's staff shall not be less than one-third, and the actual proportion shall be determined in the articles of association. Representatives of the company's staff at the supervisory board shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise. Directors and senior management shall not act concurrently as supervisors.

Each term of office of a supervisor is three years and he/she may serve consecutive terms if reelected. A supervisor shall continue to perform his/her duties as a supervisor in accordance with the laws, administrative regulations and the articles of association until a duly re-elected supervisor takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of supervisors results in the number of supervisors being less than the quorum.

The supervisory board may exercise its powers:

- to review the company's financial position;
- to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, regulations, the articles of association or resolutions of the shareholders' general meetings;
- when the acts of a director or senior management personnel are detrimental to the company's interests, to require the director and senior management to correct these acts;
- to propose the convening of extraordinary shareholders' general meetings and to convene and preside over shareholders' general meetings when the board fails to perform the duty of convening and presiding over shareholders' general meetings under the PRC Company Law;

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

- to submit proposals to the shareholders’ general meetings;
- to bring actions against directors and senior management personnel pursuant to the relevant provisions of the PRC Company Law; and
- to exercise any other authority stipulated in the articles of association.

Supervisors may be present at board meetings and make inquiries or proposals in respect of the resolutions of the board. The supervisory board may investigate any irregularities identified in the operation of the company and, when necessary, may engage an accounting firm to assist its work at the cost of the company.

The supervisory board shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the supervisory board shall be elected by more than half of the supervisors. According to the Reply of the Overseas Listing Department of CSRC and the Production System Department of the State Commission for Restructuring the Economic System on Opinions Concerning the Supplement and Amendment to Articles of Association by Companies to Be Listed in Hong Kong (《中國證監會海外上市部、國家體改委生產體制司關於到香港上市公司對公司章程作補充修改的意見的函》), which is promulgated and implemented on April 3, 1995, the chairman of the supervisory board shall be selected by more than two-thirds of the supervisors.

The chairman of the supervisory board shall convene and preside over supervisory board meetings. Where the chairman of the supervisory board is incapable of performing or is not performing his/her duties, the vice chairman of the supervisory board shall convene and preside over supervisory board meetings. Where the vice chairman of the supervisory board is incapable of performing or is not performing his/her duties, a supervisor recommended by more than half of the supervisors shall convene and preside over supervisory board meetings.

Manager and Senior Management

Under the PRC Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. The manager, who reports to the board of directors, may exercise his/her powers:

- to manage the production and operation and administration of the company and arrange for the implementation of the resolutions of the board of directors;
- to arrange for the implementation of the company’s annual operation plans and investment proposals;
- to formulate proposals for the establishment of the company’s internal management organs;
- to formulate the fundamental management system of the company;
- to formulate the company’s specific rules and regulations;
- to recommend the appointment or dismissal of any deputy manager and any financial officer of the company;
- to appoint or dismiss management personnel (other than those required to be appointed or dismissed by the board of directors); and
- to exercise any other authority granted by the board of directors.

APPENDIX IV

**SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS**

Other provisions in the articles of association on the manager's powers shall also be complied with. The manager shall be present at meetings of the board of directors. However, the manager shall have no voting rights at meetings of the board of directors unless he/she concurrently serves as a director.

According to the PRC Company Law, senior management refers to the manager, deputy manager, financial officer, secretary to the board of a listed company and other personnel as stipulated in the articles of association.

Duties of Directors, Supervisors and Senior Management

Directors, supervisors and senior management are required under the PRC Company Law to comply with the relevant laws, administrative regulations and the articles of association, and carry out their duties of loyalty and diligence.

Directors, supervisors and senior management are prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's property.

Directors and senior management are prohibited from:

- misappropriating company funds;
- depositing company funds into accounts under their own names or the names of other individuals to deposit;
- loaning company funds to others or providing guarantees in favor of others supported by company's property in violation of the articles of association or without approval of the general meeting or the board of directors;
- entering into contracts or transactions with the company in violation of the articles of association or without approval of the general meeting;
- using their position to procure business opportunities for themselves or others that should have otherwise been available to the company or operating businesses similar to that of the company for their own benefits or on behalf of others without approval of the general meeting;
- accepting commissions paid by a third party for transactions conducted with the company;
- unauthorized divulgence of confidential information of the company; and
- other acts in violation of their duty of loyalty to the company.

Income generated by directors or senior management in violation of aforementioned shall be returned to the company.

A director, supervisor or senior management who contravenes law, administrative regulation or articles of association in the performance of his/her duties resulting in any loss to the company shall be liable to the company for compensation.

Where a director, supervisor or senior management is required to attend a shareholders' general meeting, such director, supervisor or senior management shall attend the meeting and answer the

APPENDIX IV

**SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS**

inquiries from shareholders. Directors and senior management shall furnish all true information and data to the supervisory board, without impeding the discharge of duties by the supervisory board or supervisors.

Where a director or senior management contravenes law, administrative regulation or articles of association in the performance of his/her duties resulting in any loss to the company, shareholder(s) holding individually or in aggregate no less than 1% of the company's shares consecutively for at least 180 days may request in writing that the supervisory board institute litigation at a people's court on its behalf. Where the supervisory board violates the laws or administrative regulations or the articles of association in the discharge of its duties resulting in any loss to the company, such shareholder(s) may request in writing that the board of directors institute litigation at a people's court on its behalf. If the supervisory board or the board of directors refuses to institute litigation after receiving this written request from the shareholder(s), or fails to institute litigation within 30 days of the date of receiving the request, or in case of emergency where failure to institute litigation immediately will result in irrecoverable damage to the company's interests, such shareholder(s) shall have the power to institute litigation directly at a people's court in its own name for the company's benefit. For other parties who infringe the lawful interests of the company resulting in loss to the company, such shareholder(s) may institute litigation at a people's court in accordance with the procedure described above. Where a director or senior management contravenes any laws, administrative regulations or the articles of association in infringement of shareholders' interests, a shareholder may also institute litigation at a people's court.

The Special Regulations and the Mandatory Provisions provide that a company's directors, supervisors, manager and other senior management shall have duty of loyalty to the company. They are required to faithfully perform their duties, to protect the interests of the company and not to use their positions in the company for their own benefits. The Mandatory Provisions contain detailed stipulations on these duties.

Finance and Accounting

A company shall establish its own financial and accounting systems according to the laws, administrative regulations and the regulations of the competent financial departments of the State Council. At the end of each financial year, a company shall prepare a financial report which shall be audited by an accounting firm in accordance with the laws. The financial and accounting reports shall be prepared in accordance with the laws, administrative regulations and the regulations of the financial departments of the State Council.

The company's financial reports shall be made available for shareholders' inspection at the company 20 days before the convening of an annual general meeting. A joint stock limited company that makes public stock offerings shall publish its financial reports.

When distributing each year's profits after taxation, the company shall set aside 10% of its profits after taxation for the company's statutory common reserve fund until the fund has reached 50% or more of the company's registered capital. When the company's statutory common reserve fund is not sufficient to make up for the company's losses for the previous years, the current year's profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

profits after taxation, it may, upon passing a resolution at a shareholders' general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its discretionary common reserve fund, the remaining profits after taxation shall be distributed in proportion to the number of shares held by the shareholders, except for those which are not distributed in a proportionate manner as provided by the articles of association.

Profits distributed to shareholders by a resolution of a shareholders' general meeting or the board of directors before losses have been made good and allocations have been made to the statutory common reserve fund in violation of the requirements described above must be returned to the company. The company shall not be entitled to any distribution of profits in respect of shares held by it.

The premium over the nominal value of the shares of the company earned from the issue of share and other income as required by CSRC to be treated as the capital reserve fund shall be accounted for as the capital reserve fund. The common reserve fund of a company shall be applied to make good the company's losses, expand its business operations or increase its capital. The capital reserve fund, however, shall not be used to make good the company's losses. Upon the transfer of the statutory common reserve fund into capital, the balance of the fund shall not be less than 25% of the registered capital of the company before such transfer.

The company shall have no accounting books other than the statutory books. The company's assets shall not be deposited in any account opened under the name of an individual.

Appointment and Retirement of Auditors

Pursuant to the PRC Company Law, the engagement or dismissal of an accounting firm responsible for the company's auditing shall be determined by a shareholders' general meeting or the board of directors in accordance with the articles of association. The accounting firm should be allowed to make representations when the general meeting or the board of directors conduct a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidence, accounting books, financial and accounting reports and other accounting information to the engaged accounting firm without any refusal or withholding or falsification of information.

The Special Regulations require a company to engage an independent qualified accounting firm to audit the company's annual reports and to review and check other financial reports of the company. The accounting firm's term of office shall commence from the end of the shareholders' annual general meeting to the end of the next shareholders' annual general meeting.

Profit Distribution

According to the PRC Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve fund is provided. The Special Regulations require that any dividend and other distribution to shareholders of overseas-listed foreign shares shall be declared and calculated in RMB and paid in foreign currency.

Under the Mandatory Provisions, a company shall make foreign currency payments to shareholders through receiving agents.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Amendments to the Articles of Association

Pursuant to PRC Company Law, the resolution of a shareholders' general meeting regarding any amendment to a company's articles of association requires affirmative votes by at least two-thirds of the votes held by shareholders attending the meeting. Pursuant to the Mandatory Provisions, the company may amend its articles of association according to the laws, administrative regulations and the articles of association. The amendment to articles of association involving content of the Mandatory Provisions will only be effective upon approval of the department in charge of company examination and approval and the securities regulatory department of the State Council authorized by the State Council, while the amendment to articles of association involving matters of company registration must be registered with the relevant authority in accordance with applicable laws.

Dissolution and Liquidation

Under the PRC Company Law, a company shall be dissolved for any of the following reasons:

- the term of its operation set out in the articles of association has expired or other events of dissolution specified in the articles of association have occurred;
- the shareholders have resolved at a shareholders' general meeting to dissolve the company;
- the company is dissolved by reason of its merger or division;
- the business license of the company is revoked or the company is ordered to close down or to be dissolved in accordance with the laws; or
- the company is dissolved by a people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all shareholders of the company, on the grounds that the operation and management of the company has suffered serious difficulties that cannot be resolved through other means, rendering ongoing existence of the company a cause for significant losses to the shareholders.

In the event of paragraph 1 above, the company may carry on its existence by amending its articles of association. The amendments to the articles of association in accordance with the provisions described above shall require the approval of more than two-thirds of voting rights of shareholders attending a shareholders' general meeting.

Where the company is dissolved under the circumstances set forth in paragraph 1, 2, 4 or 5 above, it should establish a liquidation committee within 15 days of the date on which the dissolution matter occurs. The liquidation committee shall be composed of directors or any other person determined by a shareholders' general meeting. If a liquidation committee is not established within the prescribed period, the company's creditors may file an application with a people's court to appoint relevant personnel to form a liquidation committee to administer the liquidation. The people's court should accept such application and form a liquidation committee to conduct liquidation in a timely manner.

The liquidation committee may exercise following powers during the liquidation:

- to sort out the company's assets and to prepare a balance sheet and an inventory of assets;
- to notify the company's creditors or publish announcements;

APPENDIX IV

**SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS**

- to deal with any outstanding business related to the liquidation;
- to pay any overdue tax together with any tax arising during the liquidation process;
- to settle the company's claims and liabilities;
- to handle the company's remaining assets after its debts have been paid off; and
- to represent the company in any civil procedures.

The liquidation committee shall notify the company's creditors within 10 days of its establishment, and publish an announcement in newspapers within 60 days.

A creditor shall lodge his claim with the liquidation committee within 30 days of receipt of the notification or within 45 days of the date of the announcement if he has not received any notification. A creditor shall report all matters relevant to his claimed creditor's rights and furnish relevant evidence. The liquidation committee shall register such creditor's rights. The liquidation committee shall not make any settlement to creditors during the period of the claim.

Upon disposal of the company's property and preparation of the required balance sheet and inventory of assets, the liquidation committee shall draw up a liquidation plan and submit this plan to a shareholders' general meeting or a people's court for endorsement. The remaining part of the company's assets, after payment of liquidation expenses, employee wages, social insurance expenses and statutory compensation, outstanding taxes and the company's debts, shall be distributed to shareholders in proportion to shares held by them. The company shall continue to exist during the liquidation period, although it cannot conduct operating activities that are not related to the liquidation. The company's property shall not be distributed to shareholders before repayments are made in accordance with the requirements described above.

Upon liquidation of the company's property and preparation of the required balance sheet and inventory of assets, if the liquidation committee becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to a people's court for a declaration of bankruptcy in accordance with the laws. Following such declaration by the people's court, the liquidation committee shall hand over the administration of the liquidation to the people's court.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report and submit it to the shareholders' general meeting or a people's court for confirmation of its completion. Following such confirmation, the report shall be submitted to the company registration authority to cancel the company's registration, and an announcement of its termination shall be published. Members of the liquidation committee are required to discharge their duties in good faith and perform their obligation in compliance with laws. Members of the liquidation committee shall be prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's properties. Members of the liquidation committee are liable to indemnify the company and its creditors in respect of any loss arising from their willful or material default.

Liquidation of a company declared bankrupt according to laws shall be processed in accordance with the laws on corporate bankruptcy.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Overseas Listing

Pursuant to the Special Regulations, the shares of a company shall only be listed overseas after obtaining approval from CSRC and the listing must be arranged in accordance with the procedures specified by the State Council.

According to Rule 2(6) of the Regulatory Guidelines for the Application Documents and Examination Procedures for the Overseas Share Issuance and Listing by Joint Stock Companies (《關於股份公司境外發行股票和上市申報文件及審核程序的監管指引》) promulgated by CSRC (effective from January 1, 2013), the approval documents for overseas stock issuance and listing by the company granted by CSRC shall be valid for a period of 12 months.

Loss of Share Certificates

A shareholder may, in accordance with the public notice procedures set out in the PRC Civil Procedure Law, apply to a people’s court if his share certificate(s) in registered form is either stolen, lost or destroyed, for a declaration that such certificate(s) will no longer be valid. After the people’s court declares that such certificate(s) will no longer be valid, the shareholder may apply to the company for the issue of a replacement certificate(s).

The Mandatory Provisions provide for a separate procedure regarding the loss of share certificates of overseas-listed foreign shares or of H share certificates, details of which are set out in our Articles of Association.

Merger and Division

A merger agreement shall be signed by merging companies and the involved companies shall prepare respective balance sheets and inventory of assets. The companies shall within 10 days of the date of passing the resolution approving the merger notify their respective creditors and publicly announce the merger in newspapers within 30 days. A creditor may, within 30 days of receipt of the notification, or within 45 days of the date of the announcement if he has not received the notification, request the company to settle any outstanding debts or provide relevant guarantees. In case of a merger, the credits and debts of the merging parties shall be assumed by the surviving or the new company.

In case of a division, the company’s assets shall be divided and a balance sheet and an inventory of assets shall be prepared. When a resolution regarding the company’s division is approved, the company should notify all its creditors within 10 days of the date of passing such resolution and publicly announce the division in newspapers within 30 days. Unless an agreement in writing is reached with creditors before the company’s division in respect of the settlement of debts, the liabilities of the company which have accrued prior to the division shall be jointly borne by the divided companies.

Changes in the business registration of the companies as a result of the merger or division shall be registered with the relevant administration authority for industry and commerce.

In accordance with the laws, cancelation of a company shall be registered when a company is dissolved and incorporation of a company shall be registered when a new company is incorporated.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

The PRC Securities Laws, Regulations

The PRC has promulgated a number of regulations that relate to the issue and trading of the Shares and disclosure of information of companies. In October 1992, the State Council established the Securities Committee and CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities-related institutions in the PRC and administering CSRC. CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions governing securities markets, supervising securities companies, regulating public offerings of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities-related statistics and undertaking relevant research and analysis. In April 1998, the State Council consolidated the Securities Committee and CSRC and reformed CSRC.

On April 22, 1993, the State Council promulgated the Provisional Regulations Concerning the Issue and Trading of Shares (《股票發行與交易管理暫行條例》) governing the application and approval procedures for public offerings of shares, issuance of and trading in shares, the acquisition of listed companies, deposit, clearing and transfer of shares, the disclosure of information, investigation, penalties and dispute resolutions with respect to a listed company.

On December 25, 1995, the State Council promulgated the Regulations of the State Council Concerning Domestic Listed Foreign Shares of Joint Stock Limited Companies (《國務院關於股份有限公司境內上市外資股的規定》). These regulations principally govern the issue, subscription, trading and declaration of dividends and other distributions of domestic listed foreign shares and disclosure of information of joint stock limited companies having domestic listed foreign shares.

The Securities Law of the PRC (《中華人民共和國證券法》), the “**PRC Securities Law**” took effect on July 1, 1999 and was revised as of August 28, 2004, October 27, 2005, June 29, 2013 and August 31, 2014, respectively. It was the first national securities law in the PRC, and is divided into 12 chapters and 240 articles comprehensively regulating activities in the PRC securities market, including the issue and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of the State Council’s securities regulatory authorities. Article 238 of the PRC Securities Law provides that domestic enterprises must obtain prior approval from the State Council Securities regulatory authorities for its issuance of securities abroad or listing and trading of securities abroad. Currently, the issue and trading of foreign issued securities (including shares) are principally governed by the regulations and rules promulgated by the State Council and CSRC.

Arbitration and Enforcement of Arbitral Awards

The Arbitration Law of the PRC (《中華人民共和國仲裁法》) (the “**PRC Arbitration Law**”) was enacted by the Standing Committee of the NPC on August 31, 1994, which became effective on September 1, 1995 and was amended on August 27, 2009 and September 1, 2017, respectively. It is applicable to, among other matters, economic disputes involving foreign parties where all parties have entered into a written agreement to resolve disputes by arbitration before an arbitration committee constituted in accordance with the PRC Arbitration Law. The PRC Arbitration Law provides that an arbitration committee may, before the promulgation of arbitration regulations by the PRC Arbitration Association, formulate interim arbitration rules in accordance with the PRC Arbitration Law and the

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS

PRC Civil Procedure Law. Where the parties have agreed to settle disputes by means of arbitration, a people’s court will refuse to handle a legal proceeding initiated by one of the parties at such people’s court, unless the arbitration agreement is invalid.

The Listing Rules and the Mandatory Provisions require an arbitration clause to be included in the articles of association of a company listed in Hong Kong and, in the case of the Listing Rules, also in contracts between the company and each director or supervisor. Pursuant to such clause, whenever a dispute or claim arises from any right or obligation provided in the articles of association, the PRC Company Law or other relevant laws and administrative regulations concerning the affairs of the company between (i) a holder of overseas listed foreign shares and the company; (ii) a holder of overseas listed foreign shares and a holder of domestic shares; or (iii) a holder of overseas listed foreign shares and the company’s directors, supervisors or other management personnel, such parties shall be required to refer such dispute or claim to arbitration at either the China International Economic and Trade Arbitration Commission (“CIETAC”) or the Hong Kong International Arbitration Center (“HKIAC”). Disputes in respect of the definition of shareholder and disputes in relation to the company’s shareholder registry need not be resolved by arbitration. If the party seeking arbitration elects to arbitrate the dispute or claim at the HKIAC, then either party may apply to have such arbitration conducted in Shenzhen in accordance with the securities arbitration rules of the HKIAC.

Under the PRC Arbitration Law and PRC Civil Procedure Law, an arbitral award shall be final and binding on the parties involved in the arbitration. If any party fails to comply with the arbitral award, the other party to the award may apply to a people’s court for its enforcement. The people’s court can issue a ruling prohibiting the enforcement of an arbitral award made by an arbitration commission after verification by collegial bench formed by the people’s court if there is any procedural irregularity (including but not limited to irregularity in the composition of the arbitration tribunal or arbitration proceedings, the jurisdiction of the arbitration commission, or the making of an award on matters beyond the scope of the arbitration agreement).

Any party seeking to enforce an award of a foreign affairs arbitral body of the PRC against a party who or whose property is not located within the PRC may apply to a foreign court with jurisdiction over the case for recognition and enforcement of the award. Likewise, an arbitral award made by a foreign arbitral body may be recognized and enforced by a PRC court in accordance with the principle of reciprocity or any international treaties concluded or acceded to by the PRC.

The PRC acceded to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (《承認及執行外國仲裁裁決公約》, the “**New York Convention**”) adopted on June 10, 1958 pursuant to a resolution passed by the Standing Committee of the NPC on December 2, 1986. The New York Convention provides that all arbitral awards made in a state which is a party to the New York Convention shall be recognized and enforced by other parties thereto subject to their rights to refuse enforcement under certain circumstances, including where the enforcement of the arbitral award is against the public policy of that state. At the time of the PRC’s accession to the Convention, the Standing Committee of the NPC declared that (i) the PRC will only apply the Convention to the recognition and enforcement of arbitral awards made in the territories of other parties based on the principle of reciprocity; and (ii) the New York Convention will only be applied to disputes deemed under PRC laws to be arising from contractual or non-contractual mercantile legal relations.

An arrangement for mutual enforcement of arbitral awards between Hong Kong and the Supreme People’s Court of China was reached. The Supreme People’s Court of China adopted the

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Arrangements on the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region (《關於內地與香港特別行政區相互執行仲裁裁決的安排》) on June 18, 1999, which went into effect on February 1, 2000. The arrangements reflects the spirit of the New York Convention. Under the arrangements, the awards by the Mainland arbitral bodies recognized by Hong Kong may be enforced in Hong Kong and the awards by the Hong Kong arbitral bodies according to the Arbitration Ordinance of Hong Kong SAR may also be enforced in the Mainland China. If the Mainland court finds that the enforcement of awards made by the Hong Kong arbitral bodies in the Mainland will be against public interests of the Mainland, or the court of Hong Kong SAR decides that the enforcement of the arbitral awards in Hong Kong SAR will be against public policies of Hong Kong SAR, the awards may not be enforced.

MATERIAL DIFFERENCES BETWEEN CERTAIN ASPECTS OF CORPORATION LAW IN THE PRC AND HONG KONG

Hong Kong company law is primarily set out in the Companies Ordinance and the Companies (Winding Up and Miscellaneous Provisions) Ordinance, supplemented by common law and rules of equity that apply to Hong Kong. As a joint stock limited company incorporated in the PRC that is seeking a listing of shares on the Hong Kong Stock Exchange, we are governed by the PRC Company Law and all other rules and regulations promulgated pursuant to the PRC Company Law. Set out below is a summary of certain material differences between Hong Kong company law and the PRC Company Law. This summary is, however, not intended to be an exhaustive comparison.

Corporate Existence

Under Hong Kong company law, a company with share capital is incorporated by the Registrar of Companies in Hong Kong, which issues a certificate of incorporation to the Company upon its incorporation, and the company will acquire an independent corporate existence henceforth. A company may be incorporated as a public company or a private company. Pursuant to the Companies Ordinance, the articles of association of a private company incorporated in Hong Kong shall contain certain pre-emptive provisions. A public company’s articles of association do not contain such pre-emptive provisions.

Under the PRC Company Law, a joint stock limited company may be incorporated by promotion or public subscription.

Share Capital

Under Hong Kong law, the directors of a Hong Kong company may, with the prior approval of the shareholders if required, issue new shares of the company. The PRC Company Law does not provide for authorized share capital. The Company’s registered capital is the amount of its issued share capital. Any increase in the Company’s registered capital must be approved by our Shareholders’ general meeting and shall be approved by/filed with the relevant PRC governmental and regulatory authorities (if applicable).

Under the Securities Law, a company which is authorized by the relevant securities regulatory authority to list its shares on a stock exchange must have a total registered capital of not less than RMB30 million. The Companies Ordinance does not prescribe any minimum capital requirement for companies incorporated in Hong Kong.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Under the PRC Company Law, the shares may be subscribed for in the form of money or non-monetary assets (other than assets not entitled to be used as capital contributions under relevant laws or administrative regulations). For non-monetary assets to be used as capital contributions, appraisals must be carried out to ensure there is no overvaluation or undervaluation of the assets. There is no such restriction on a company incorporated in Hong Kong.

Restrictions on Shareholding and Transfer of Shares

Generally, A Shares of the Company, which are denominated and subscribed for in Renminbi, can be subscribed for and traded by PRC investors, qualified overseas institutional investors or qualified overseas strategic investors, while also being eligible securities under the Northbound Trading Link, A Shares of the Company can be subscribed for and traded by Hong Kong and other overseas investors in accordance with the rules and limits of Shenzhen-Hong Kong Stock Connect. Overseas listed shares, which are denominated in Renminbi and subscribed for in a currency other than Renminbi, may only be subscribed for, and traded by, investors from Hong Kong, Macau and Taiwan or any country and territory outside the PRC, or qualified domestic institutional investors, except as allowed under Tentative Regulatory Measures for Qualified Domestic Institutional Investors Investing in Overseas Securities (合格境內機構投資者境外證券投資管理試行辦法). If the H shares are eligible securities under the Southbound Trading Link, they are also subscribed for and traded by PRC investors in accordance with the rules and limits of Shanghai-Hong Kong Stock Connect or Shenzhen-Hong Kong Stock Connect.

Under the PRC Company Law, a promoter of a joint stock limited company is not allowed to transfer the shares it holds for a period of one year after the date of establishment of the company. Shares in issue prior to a public offering of the company cannot be transferred within one year from the listing date of the shares on a stock exchange. Shares in a joint stock limited liability company held by its directors, supervisors and senior management and transferred each year during their term of office shall not exceed 25% of the total shares they held in a company, and the shares they held in a company cannot be transferred within one year from the listing date of the shares, and also cannot be transferred within half a year after the said personnel has left office. The articles of association may set other restrictive requirements on the transfer of a company’s shares held by its directors, supervisors and senior management. There are no restrictions on shareholdings and transfers of shares under Hong Kong law apart from (i) the restriction on the Company to issue additional Shares within six months, and (ii) 12-month lockup on the Controlling Shareholders’ disposal of Shares, after the [REDACTED].

Financial Assistance for Acquisition of Shares

The PRC Company Law does not prohibit or restrict a joint stock limited company or its subsidiaries from providing financial assistance for the purpose of an acquisition of its own or its holding company’s shares. However, the Mandatory Provisions contain certain restrictions on a company and its subsidiaries on providing such financial assistance similar to those under Hong Kong company law.

Notice of Shareholders’ Meetings

Under the PRC Company Law, notice of a shareholder’s annual general meeting must be given not less than 20 days before the meeting. Whereas notice of an extraordinary general meeting must be

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

given not less than 15 days before the meeting. If a company issues bearer shares, notice of a shareholder’s general meeting must be given at least 30 days prior to the meeting.

For a company incorporated in Hong Kong with limited liability, the minimum period of notice of a general meeting is 14 days. Further, where a meeting involves consideration of a resolution requiring special notice, the company must also give its shareholders notice of the resolution at least 14 days before the meeting. The notice period for the annual shareholders’ general meeting is 21 days.

Quorum for Shareholders’ Meetings

The PRC Company Law does not specify any quorum requirement for a shareholders’ general meeting, but the Special Regulations and the Mandatory Provisions provide that general meetings may only be convened when replies to the notice of that meeting have been received from shareholders whose shares represent at least 50% of the voting rights at least 20 days before the proposed date of the meeting, or if that 50% level is not achieved, the company shall within five days notify its shareholders again by way of a public announcement and the shareholders’ general meeting may be held thereafter. Under Hong Kong law, the quorum for a shareholders’ meeting is two members, unless the articles of association of a company specifies otherwise or the company has only one member, in which case the quorum is one.

Voting at Shareholders’ Meetings

Under the PRC Company Law, the passing of any resolution requires more than one-half of the affirmative votes held by our shareholders present in person or by proxy at a shareholders’ meeting except in cases such as proposed amendments to our Articles of Association, increase or decrease of registered capital, merger, division, dissolution or transformation, which require two-thirds of the affirmative votes cast by shareholders present in person or by proxy at a shareholders’ general meeting.

Under Hong Kong law, an ordinary resolution is passed by a simple majority of affirmative votes cast by shareholders present in person, or by proxy, at a general meeting, and a special resolution is passed by not less than three-fourths of affirmative votes cast by shareholders present in person, or by proxy, at a general meeting.

Variation of Class Rights

The PRC Company Law makes no specific provision relating to variation of class rights. However, the PRC Company Law states that the State Council can promulgate requirements relating to other kinds of shares. The Mandatory Provisions contain detailed provisions relating to the circumstances which are deemed to be variations of class rights and the approval procedures required to be followed in respect thereof. These provisions have been incorporated in the Articles of Association, which are summarized in “Appendix V—Summary of Articles of Association” to this document.

Under the Companies Ordinance, no rights attached to any class of shares can be varied except (i) with the passing of a special resolution by the shareholders of the relevant class at a separate meeting sanctioning the variation, (ii) with the written consent of shareholders representing at least three-fourths of the total voting rights of shareholders of the relevant class, or (iii) if there are provisions in the articles of association relating to the variation of those rights, then in accordance with those provisions.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

As required by the Hong Kong Listing Rules and the Mandatory Provisions, we have adopted in the Articles of Association provisions protecting class rights in a similar manner to those found in Hong Kong law. Holders of overseas listed shares and domestic listed shares are defined in the Articles of Association as different classes. The special procedures for voting by a class of Shareholders shall not apply in the following circumstances: (i) where we issue, either separately or concurrently in any 12-month period, upon approval by special resolutions passed at a general meeting, A shares and H shares not more than 20% of each of the existing issued A shares and H shares, respectively; (ii) where the plan for the issue of A shares and H shares upon our establishment is implemented within 15 months following the date of approval or within the valid period of the approval by the securities regulatory authorities under the State Council or within the stated period as stipulated by applicable requirements.

Derivative Action by Minority Shareholders

Under Hong Kong company law, a shareholder may, with the leave of the Court, start a derivative action on behalf of a company for any misconduct committed by its directors against the company. For example, leave may be granted where the directors control a majority of votes at a general meeting, and could thereby prevent the company from suing the directors in its own name.

Pursuant to the PRC Company Law, in the event where the directors and senior management of a joint stock limited company violate laws, administrative regulations or its articles of association, resulting in losses to the company, the shareholders individually or jointly holding over 1% of the shares in the company for more than 180 consecutive days may request in writing the board of supervisors to initiate proceedings in the people’s court. In the event that the supervisors violates as such, the above said shareholders may send written request to the board of directors to initiate proceedings in the people’s court. Upon receipt of such written request from the shareholders, if the board of supervisors or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days upon receipt of the request, or if under urgent situations, failure of initiating immediate proceeding may cause irremediable damages to the company, the above said shareholders shall, for the benefit of the company’s interests, have the right to initiate proceedings directly to the court in their own name.

In addition, the Mandatory Provisions provide us with certain remedies against the Directors, Supervisors and senior management who breach their duties to the Company. In addition, as a condition to the listing of overseas listed foreign Shares on the Hong Kong Stock Exchange, each director and supervisor of a joint stock limited company is required to give an undertaking to observe the articles of association in favor of the company. This allows minority Shareholders to take action against our Directors and Supervisors in default.

Minority Shareholder Protection

Under the Companies Ordinance, a shareholder who alleges that the affairs of a company are conducted in a manner unfairly prejudicial to his interests may petition to the Court to make an appropriate order to give relief to the unfairly prejudicial conduct. Alternatively, pursuant to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, a shareholder may seek to wind up the company on the just and equitable ground. In addition, on the application of a specified number of members, the Financial Secretary may appoint inspectors who are given extensive statutory powers to

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

investigate the affairs of a company incorporated or registered in Hong Kong. The PRC Company Law provides that any shareholders holding 10% or above of voting rights of all issued shares of company may request a People’s Court to dissolve the company to the extent that the operation or management of the company experiences any serious difficulties and its continuous existence would cause serious losses to them, and no other alternatives can resolve such difficulties.

The Company, as required by the Mandatory Provisions, has adopted in its Articles of Association minority Shareholder protection provisions similar to (though not as comprehensive as) those available under the Hong Kong law. These provisions state that a controlling shareholder may not exercise its voting rights in a manner prejudicial to the interests of other shareholders, may not relieve a director or supervisor of his duty to act honestly in our best interests or may not approve the expropriation by a director or supervisor of our assets or the individual rights of other shareholders.

Directors

The PRC Company Law, unlike Hong Kong company law, does not contain any requirements relating to the declaration of directors’ interests in material contracts, restrictions on directors’ authority in making major dispositions, restrictions on companies providing certain benefits to directors and indemnification in respect of directors’ liability and prohibitions against compensation for loss of office without shareholders’ approval. The Mandatory Provisions, however, contain certain requirements and restrictions on major disposals and specify the circumstances under which a director may receive compensation for loss of office.

Board of Supervisors

Under the PRC Company Law, a joint stock limited company’s directors and senior management are subject to the supervision of a board of supervisors. There is no mandatory requirement for the establishment of a board of supervisors for a company incorporated in Hong Kong. The Mandatory Provisions provide that each supervisor owes a duty, in the exercise of his powers, to act in good faith and honestly in what he considers to be in the best interests of the Company and to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

Fiduciary Duties

In Hong Kong, directors owe fiduciary duties to the company, including the duty not to act in conflict with the company’s interests. Furthermore, the Companies Ordinance has codified the directors’ statutory duty of care. Under the Special Regulations, directors, supervisors, managers and other members of senior management of the company shall honestly and diligently perform their duties for the company.

Financial Disclosure

Under the PRC Company Law, a joint stock limited company is required to make available at the company for inspection by shareholders its financial report 20 days before its annual general meeting. In addition, a joint stock limited company of which the shares are publicly offered must publish its financial report.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

The Companies Ordinance requires a company incorporated in Hong Kong to send to every shareholder a copy of its financial statements, auditors’ report and directors’ report, which are to be presented before the company in its annual general meeting, not less than 21 days before such meeting. According to the PRC laws, a company shall prepare its financial accounting reports as at the end of each accounting year, and submit the same to accounting firms for auditing as required by law. The Mandatory Provisions require that a company must, in addition to preparing financial statements according to the Chinese accounting standards and regulations, have its financial statements prepared and audited in accordance with international or Hong Kong accounting standards and its financial statements must also contain a statement of the financial effect of the material differences (if any) from the financial statements prepared in accordance with the Chinese accounting standards.

The Special Regulations require that there should not be any inconsistency between the information disclosed within and outside the PRC and that, to the extent that there are differences in the information disclosed in accordance with the relevant PRC and overseas laws, regulations and requirements of the relevant stock exchanges, such differences should also be disclosed simultaneously.

Information on Directors and Shareholders

The PRC Company Law gives shareholders the right to inspect the company’s articles of association, minutes of the general meetings and financial and accounting reports. Under the articles of association, shareholders have the right to inspect and copy (at reasonable charges) certain information on shareholders and on directors which is similar to the rights of shareholders of Hong Kong companies under the Companies Ordinance.

Receiving Agent

Under both the PRC and Hong Kong law, dividends once declared will become debts payable to shareholders. The limitation period for debt recovery action under Hong Kong law is six years, while under the PRC law this limitation period is two years. The Mandatory Provisions require that the relevant company shall appoint a receiving agent for shareholders who hold overseas listed foreign shares, and the receiving agent shall receive on behalf of such holders of shares dividends declared and other monies owed by the company in respect of its overseas listed foreign shares.

Corporate Reorganization

Corporate reorganization involving a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to Section 237 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance or a compromise or arrangement between the company and its creditors or between the company and its members pursuant to Section 673 and Division 2 of Part 13 of the Companies Ordinance, which requires the sanction of the court. In addition, subject to the shareholders’ approval, an intra-group wholly-owned subsidiary company may also be amalgamated horizontally or vertically under the Companies Ordinance. Under PRC law, merger, division, dissolution of the company or the conversion of the corporate form has to be approved by shareholders in general meeting.

APPENDIX IV

SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Mandatory Transfers

Under the PRC Company Law, a company is required to make transfers equivalent to certain prescribed percentages of its after tax profit to the statutory common reserve fund. There are no corresponding provisions under Hong Kong law.

Arbitration of Disputes

In Hong Kong, disputes between shareholders and a company or its directors, managers and other senior management may be resolved through the courts. The Mandatory Provisions provides that disputes between a holder of H shares and the Company, a holder of H shares and directors, supervisors, managers and other members of senior management of the Company or a holder of H shares and a holder of domestic listed shares, arising from the Articles of Association, the PRC Company Law or other relevant laws and administrative regulations which concerns the affairs of the Company should, with certain exceptions, be referred to arbitration at either the HKIAC or the China International Economic and Trade Arbitration Commission, at the claimant’s choice. Such arbitration is final and conclusive.

Remedies of a Company

Under the PRC Company Law, if a director, supervisor or senior management person in carrying out his duties infringes any law, administrative regulation or the articles of association of a company, which results in damage to the company, that director, supervisor or manager should be responsible to the company for such damages. In addition, in compliance with the Hong Kong Listing Rules and the Mandatory Provisions, remedies of the company similar to those available under Hong Kong law (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management) have been set out in the Articles of Association.

Dividends

Pursuant to relevant PRC laws and regulations, the company in certain circumstances shall withhold, and pay to the relevant tax authorities, any tax payable under PRC law on any dividends or other distributions payable to a shareholder. Under Hong Kong law, the limitation period for an action to recover a debt (including the recovery of declared dividends) is six years, whereas under PRC laws, the relevant limitation period is two years. The company must not exercise its powers to forfeit any unclaimed dividend in respect of shares until after the expiry of the applicable limitation period.

Closure of Register of Shareholders

The Companies Ordinance requires that the register of shareholders of a company must not be closed for the registration of transfers of shares for more than thirty days (extendable to sixty days in certain circumstances) in a year, whereas, as required by the Mandatory Provisions, share transfers shall not be registered within thirty days before the date of convening a general meeting or within five days before the base date of distribution of dividends.

APPENDIX IV

**SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS**

**SUMMARY OF MATERIAL DIFFERENCES BETWEEN THE HONG KONG LISTING
RULES AND SHENZHEN STOCK EXCHANGE LISTING RULES**

As our A Shares are listed on the Shenzhen Stock Exchange, we are also subject to the Shenzhen Stock Exchange Listing Rules. Set out below is a summary of the material differences between the Hong Kong Listing Rules and the Shenzhen Stock Exchange Listing Rules:

- **Periodic financial reporting**

There are material differences in financial reporting standards and practices regarding, for example, industry-specific financial reporting requirements, announcement of preliminary results, form and content of periodic financial reports and post-vetting of periodic financial reports.

- **Classification and disclosure requirements for notifiable transactions**

The method of classification of notifiable transactions under the Hong Kong Listing Rules and the disclosure requirement pertaining to such transactions differ from those under the Shenzhen Stock Exchange Listing Rules.

- **Connected transactions**

The definition of a connected person under the Hong Kong Listing Rules and the definition of a related party under the Shenzhen Stock Exchange Listing Rules are different. In addition, the disclosure and shareholder approval requirements for connected transactions under the Hong Kong Listing Rules and for related party transactions under the Shenzhen Stock Exchange Listing Rules, as well as the respective exemptions are different.

- **Disclosure of inside information**

The scope, timing and method of disclosure of inside information are different between the Hong Kong Listing Rules and Shenzhen Stock Exchange Listing Rules.

SUMMARY OF ARTICLES OF ASSOCIATION

Set out below is a summary of the principal provisions of the Company’s Articles, the objective of which is to provide [REDACTED] with an overview of the Company’s Articles.

The Articles of Association and relevant amendments thereto were adopted by the Shareholders in Shareholders’ general meetings in accordance with applicable laws and regulations, including the PRC Company Law, the Securities Law of the PRC (《中華人民共和國證券法》), the Special Regulations, the Mandatory Provisions, the Guidance on Articles of Association of Listed Company (《上市公司章程指引》), the Official Reply and the Hong Kong Listing Rules, and will become effective on the date that the Company’s H Shares are [REDACTED] on the Hong Kong Stock Exchange. As the information contained below is in summary form, it may not contain all the information that may be important to potential investors.

SHARES

Issuance of Shares

The Company shall set up ordinary Shares at any time. According to its needs, the Company may create other classes of Shares upon approval from the authorized department of the State Council.

The Shares of the Company shall be issued by the Company following the principles of open, fairness and justice, and each share in the same class shall have the same rights.

For the same class of Shares issued at the same time, each share shall be issued on the same conditions and at the same price. All entities or individuals subscribing for the Shares shall pay the same price for each share.

The Company’s shares shall be in the form of share certificates. All the shares issued by the Company shall have a par value which shall be RMB1 for each share.

The Company may issue Shares to domestic and overseas investors upon approval by competent securities department of the State Council.

Increase, Reduction and Repurchase of Shares

The company may, in light of the company’s operational and developmental needs and in accordance with laws and regulations, increase its capital by any of the following methods subject to a separate resolution of the general meeting:

- (a) a public offering of shares;
- (b) a private placement of shares;
- (c) the payment of a bonus dividend to existing shareholders;
- (d) the conversion of reserve funds into shares; or
- (e) any other method stipulated in laws and regulations or approved by the CSRC.

The company may reduce its registered capital. Any reduction of its registered capital shall be subject to the procedures prescribed in the Company Law and other applicable provisions, as well as the Articles of Association.

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

When reducing its registered capital, the company must prepare a balance sheet and an inventory of property.

Within ten (10) days of the date on which the resolution on reducing registered capital is made, the creditors shall be notified by the company and a public announcement shall be made in the press three (3) times within thirty (30) days. A creditor shall, within thirty (30) days of receipt of such a notice or within ninety (90) days of the first public announcement where the creditor has not received the notice, have the right to require the company to settle its claim or provide a relevant debt repayment guarantee.

The registered capital after its reduction shall not be less than the statutory minimum amount.

The Company may repurchase its issued Shares in the following circumstance, after passing the procedures stipulated in laws, administrative regulations, regulations of ministries and commissions and the Articles of Association.

- (a) reduction of the Company's registered capital;
- (b) merging with another company holding Shares in the Company;
- (c) use of its shares for carrying out an employee stock ownership plan or equity incentive;
- (d) requests to the Company for acquiring their Shares from Shareholders who have voted against the resolutions passed at a Shareholders' general meeting on the merger or division of the Company;
- (e) use of shares for conversion of convertible corporate bonds issued by a listed company;
- (f) the share buyback is necessary for a listed company to maintain its company value and protect its shareholders' equity; and
- (g) other circumstances permitted by laws and administrative regulations.

Except for the circumstances set out above, the Company shall not be engaged in any activities of buying and selling its Shares.

Approval shall be obtained from general meeting when the Company is to repurchase its own Shares under the circumstances (a) and (b) set out above; for a company's share buyback under any of the circumstances stipulated in item (c), item (e) or item (f) above, a resolution of the company's board of directors shall be made by a two-third majority of directors attending the meeting according to the provisions of the company's articles of association or as authorized by the shareholders' meeting.

The shares acquired under the circumstance stipulated in item (a) hereof shall be deregistered within ten days from the date of acquisition of shares; the shares shall be assigned or deregistered within six months if the share buyback is made under the circumstances stipulated in either item (b) or item (d); and the shares held in total by a company after a share buyback under any of the circumstances stipulated in item (c), item (e) or item (f) shall not exceed 10% of the company's total outstanding shares, and shall be assigned or deregistered within three years.

With the approval of the relevant competent authorities of the State Council, the Company may repurchase its Shares by the following ways:

- (a) making a repurchase offer to all Shareholders in proportion to their shareholdings;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (b) repurchasing the Shares by public trading on a stock exchange;
- (c) repurchasing the Shares by agreement without involving a stock exchange;
- (d) by other means stipulated by laws or regulations or permitted by competent securities department of the State Council or other competent authorities.

A prior approval shall be obtained from a general meeting in respect of any share repurchase by the Company through an off-market agreement in accordance with the provisions of our Articles. After the general meeting has given its approval in the same way, the Company may rescind or alter any contracts entered into in the said manner or waive any rights under such contracts.

The contract to repurchase Shares as referred to in the paragraph includes, but is not limited to, an agreement to become obliged to repurchase or to acquire the right to repurchase Shares.

Company shall not assign a contract for repurchasing its Shares or any of its rights thereunder.

Where the Company has the right to repurchase redeemable Shares by means other than repurchases through the market or by tender, the repurchase price shall be limited to a maximum price; if repurchases are made by tender, an invitation for tenders shall be made to all Shareholders alike.

Unless the Company is undergoing liquidation, it shall comply with the following requirements with respect to a repurchase of its issued Shares:

- (a) for repurchases of Shares by the Company at their par value, payment shall be made from the book balance of its distributable profits or from the proceeds of issuance of new Shares for that purpose;
- (b) where the Company repurchases its Shares at a premium to its par value, payment up to the par value shall be made from the book balance of its distributable profits or from the proceeds of issuance of new Shares for that purpose. Payment of the portion which is in excess of the par value shall be made as follows:
 - (i) if the Shares being repurchased are issued at par value, payment shall be made from the book balance of its distributable profits; or
 - (ii) if the Shares being repurchased are issued at a premium to its par value, payment shall be made from the book balance of its distributable profits or from the proceeds of issuance of new Shares for that purpose. However, the amount deducted from the proceeds of issuance of new Shares shall not exceed the aggregate amount of the premium received by the Company from the issuance of the Shares so repurchased, nor shall it exceed the amount in the Company's capital reserve fund account (including premium on the new issue) at the time of such repurchase;
- (c) the Company shall make the following payments from the Company's distributable profits:
 - (i) acquisition of the rights to repurchase its own Shares;
 - (ii) variation of any contracts for the repurchase of its Shares; or
 - (iii) release from its obligations under any repurchase contracts;
- (d) after the aggregate par value of the canceled Shares is deducted from the Company's registered capital in accordance with the relevant provisions, the amount deducted from

the distributable profits used for the repurchase of the Shares at par value shall be credited to the Company's capital reserve fund account.

Transfer of Shares

Unless otherwise specified by laws, administrative regulations, regulations of ministries and commissions, regulatory documents and listing rules for stock exchanges where the Company's Shares are listed, the Shares of the Company may be transferred freely without any lien attached.

Registration shall be made in the Hong Kong share registrar authorized by the Company for the transfer of H Shares.

All fully paid H Shares may be freely transferred in accordance with the Company's Articles. However, the Board may refuse to recognize any documents for the transfer of H Shares without stating any reasons unless the conditions stipulated below are met:

- (a) all transfer documents and other documents relating to or affecting the title of any H Shares registered are required to be registered, with registration fees paid to the Company based on the standards prescribed by the Hong Kong Listing Rules and the fees shall not exceed the highest standard prescribed by the Hong Kong Listing Rules from time to time;
- (b) transfer documents are only in relation to H Shares;
- (c) stamp duty (as stipulated by Hong Kong law) in relation to transfer documents has been duly paid;
- (d) relevant share certificate(s) and any other evidence which the Board may reasonably require to show that the transferor has the right to transfer the Shares have been provided;
- (e) where the Shares are intended to be transferred to joint holders, the number of such joint Shareholders shall not be more than four;
- (f) Shares are free and clear of any lien of the Company.

If the Board refuses to register a share transfer, the Company shall send the transferor and the transferee a notice of refusal to register the said share transfer within 2 months from the date of submission of the application for transfer.

The Company does not accept Shares of the Company as the subject of pledges.

Shares held by promoters shall not be transferred within one year from the date of establishment of the Company. Shares issued prior to the Company's initial public offering are not transferable within one year from the date on which the Company's Shares are listed on the stock exchange.

The Directors, Supervisors and senior management personnel of the Company shall notify the Company of their holding of Shares in the Company and changes of their holdings. The Shares transferrable by them during each year of their tenures shall not exceed twenty-five percent of their total holdings of Shares of the Company. The Shares in the Company held by them are not transferable within one year from the date on which the Company's Shares are listed. The Shares in the Company held by them shall not be transferred within six months of their departure from the Company. In the

period of twelve months commencing on the date on which the aforesaid six months expires, the shares disposed by them through the listing on Stock Exchange shall not exceed fifty percent of their total holdings of Shares of the Company.

Financial Assistance for the Acquisition of Shares in Our Company

The Company or its branches and sub-branches and its subsidiaries shall not offer any financial assistance at any time by any means to purchasers or prospective purchasers who will or who intend to purchase the Company's Shares. The aforementioned purchasers include both persons who have directly or indirectly assumed obligations due to purchasing the Company's Shares.

The Company and its subsidiaries shall not offer any financial assistance at any time by any means in order to reduce or relieve the obligations of the aforesaid obligors.

"Financial assistance" referred to in our Articles shall include, without limitation, the following means:

- (a) financial assistance given as gifts;
- (b) financial assistance given by guarantee (including the assumption of liability by the guarantor or the provision of properties by the guarantor to secure the performance of obligations by the obligor), indemnity (other than an indemnity in respect of the Company's neglect or default) or the release or waiver of any rights;
- (c) the provision of loans or the entrance into any agreement under which the obligations of the Company are to be fulfilled prior to the obligations of another party, and a change in the parties to, and the assignment of rights arising under such loans or agreement; or
- (d) any other form of financial assistance given by the Company when the Company is insolvent, has no net assets, or under any other situations when its net assets would be reduced to a material extent.

The "obligations" referred to in the Articles shall include the obligations of an obligor which have arisen from entering into an agreement or making an arrangement (regardless of whether such agreement or arrangement is enforceable, or whether such obligations are assumed by the obligor individually or jointly with any other person) or any obligations that arise out of changes made in any other way to the obligor's financial condition.

The acts listed below are not prohibited by the preceding three paragraphs, subject to any prohibitions by laws and administrative regulations:

- (a) the financial assistance provided by the Company is either genuinely for the interests of the Company and the main purpose of the financial assistance is not to purchase Shares of the Company, or the financial assistance is an incidental part of an overall plan of the Company;
- (b) the lawful distribution of the Company's properties in the form of dividends;
- (c) the distribution of dividends in the form of Shares;
- (d) the reduction of registered capital, repurchase of Shares, and adjustment of shareholding structure, etc. in accordance with our Articles;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (e) the provision of a loan by the Company within its scope of business and in the ordinary course of business (provided that this does not lead to a reduction in the net assets of the Company or that if this causes a reduction, the financial assistance is taken from the Company's distributable profits); or
- (f) provision of funds by the Company for an employee shareholding scheme (provided that this does not lead to a reduction in the net assets of the Company or that if there causes a reduction, the financial assistance is taken from the Company's distributable profits).

Register of Shareholders

The Company shall have a Shareholders register to record the following matters:

- (a) the name, address (domicile), occupation or nature of each Shareholder;
- (b) the class and number of Shares held by each Shareholder;
- (c) the amount paid or payable for the Shares held by each Shareholder;
- (d) the serial number(s) of the share certificate(s) held by each Shareholder;
- (e) the date on which each Shareholder is registered as a Shareholder;
- (f) the date on which each Shareholder ceases to be a Shareholder.

Unless there is proof to the contrary, the register of Shareholders shall be sufficient evidence to the holding of the Shares of the Company by a Shareholder.

Subject to the Articles of Association and other applicable regulations, once the Shares of the Company are transferred, the name of the transferee shall be listed in the Shareholders' register as the holder of the said Shares.

Transfer of Shares shall be registered at domestic and overseas-listed share transfer register agencies assigned by the Company and recorded in the Shareholders' register.

SHARE HOLDERS AND SHAREHOLDERS' GENERAL MEETING

Rights and Obligations of Shareholders

The Shareholders holding ordinary Shares shall enjoy the following rights:

- (a) to receive dividends and other kinds of distributions as determined by the number of Shares held by them;
- (b) to request, convene, host, attend or appoint a proxy to general meetings according to laws, and to exercise voting rights based on the number of the Shares held by them;
- (c) to supervise the operations of the Company, and to make suggestions and enquiries accordingly;
- (d) to transfer, bestow or pledge of the Shares held by them in accordance with the laws, administrative regulations, regulations of ministries and commissions, listing rules for stock exchanges where the Company's Shares are listed and the provisions of the Company's Articles;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (e) to obtain relevant information in accordance with our Articles, including:
 - (i) to obtain the Company’s Articles after paying the production costs thereof;
 - (ii) to acquire the right to inspect and duplicate after paying a reasonable charge:
 - (1) all parts of the register of Shareholders;
 - (2) personal information of the Directors, Supervisors, General manager and other senior management personnel of our Company, including:
 - (a) present and former name or alias;
 - (b) principal address (place of domicile);
 - (c) nationality;
 - (d) primary and all other part-time occupations and duties;
 - (e) identification document and its number.
 - (3) information on the share capital of the Company;
 - (4) reports on the aggregate par value, number of Shares, and highest and lowest prices of each class of Shares in relation to any repurchase by the Company of its own Shares since the last financial year, as well as all the expenses paid by the Company in relation to such repurchases (classified as domestic Shares and foreign-invested Shares);
 - (5) bond stub of the Company;
 - (6) minutes of the Shareholders’ general meetings (only for Shareholders to inspect) and special resolutions of the Company, resolutions of the Board and resolutions of the Supervisory Committee;
 - (7) the latest audited financial statements of the Company, and the reports of the Board, auditors and the Board of Supervisors;
 - (8) financial and accounting reports; or
 - (9) the latest issue of annual report already submitted to the Administration for Industry and Commerce of PRC or other competent authorities for filing.

The Company shall keep documents and any other applicable documents related to Item (1), (3), (4), (6) (7), (8) and (9) at the Company’s Hong Kong domicile for public and Shareholders to inspect free of charge according to provisions of Hong Kong Listing Rules;

- (f) to participate in the distribution of the remaining assets of the Company based on the number of Shares held in the event of the Company’s dissolution or liquidation;
- (g) to demand the Company to acquire their Shares (for Shareholders who disagree with the resolutions adopted at a Shareholders’ general meeting in relation to the merger or division of the Company); and
- (h) with respect to shareholders individually or jointly hold 3% or above shares of the Company, the right to propose extraordinary resolutions and submit to the Board in written 10 days before the date of general meeting;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (i) to have other rights conferred in accordance with the law, administrative regulations, regulations of ministries and commissions or listing rules for stock exchanges where the Company's Shares are listed and our Articles.

Company shareholders holding ordinary Shares shall have the following obligations:

- (a) to abide by laws, administrative regulations regulations of ministries and commissions or listing rules for stock exchanges where the Company's Shares are listed and our Articles;
- (b) to provide share capital according to the shares subscribed for and share participation methods;
- (c) not to return shares unless prescribed otherwise in laws and administrative regulations;
- (d) not to abuse shareholders' rights to infringe upon the interests of the company or other shareholders; not to abuse the company's status as an independent legal entity or the limited liability of shareholders to damage the interests of the company's creditors;

Any company shareholder who abuses shareholders' rights and causes the company or other shareholders to suffer a loss shall be liable for making compensation in accordance with the law;

Any company shareholder who abuses the status of the company as an independent legal entity or the limited liability of shareholders to evade debts and seriously damages the interests of the company's creditors shall assume joint and several liability for the company's debts. And

- (e) other duties prescribed in the law, administrative regulations, regulations of ministries and commissions or listing rules for stock exchanges where the Company's Shares are listed and our Articles.

In addition to obligations as required by laws, administrative regulations or the listing rules of the stock exchange on which the company's shares are listed, a controlling shareholder when exercising its shareholding rights shall not exercise its voting rights to make decisions on the following matters which harm the interests of all or some shareholders:

- (a) To exempt a director or supervisor from his/her responsibility for acting in good faith for the best interests of the company;
- (b) To approve the expropriation of the company's property by a director or supervisor (for his/her own interests or another's interests) through any means including (but not limited to) any opportunity which is beneficial to the company; or
- (c) To approve the divestment of other shareholders' individual rights and interests by a director or supervisor (for his/her own interests or another's interests), including (but not limited to) any distribution rights and voting rights, but not including where the matter is submitted to the shareholders' meeting for adoption in accordance with the company's Articles of Association that there be reorganization of the company.

Power of the Meeting and Matters to be Determined

The Shareholders' general meeting shall be the governing organ of the Company. It may exercise the following powers in accordance with the law:

- (a) to decide on the business policies and investment plans of the Company;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (b) to elect and replace Directors and Supervisors which are not appointed as representatives of the employees and to decide on the remuneration of the relevant Directors and Supervisors;
- (c) to review and approve reports made by the Board;
- (d) to review and approve reports made by the Supervisory Committee;
- (e) to review and approve the Company's proposed annual financial budget and final accounts;
- (f) to review and approve the Company's plans for profit distribution and loss recovery plans;
- (g) to adopt resolutions concerning the increase or reduction of the Company's share capital;
- (h) to adopt resolutions on the issuance of bond;
- (i) to adopt resolutions on the merger, division, dissolution, liquidation or change in corporate form of the Company;
- (j) amendment of the Articles of Association;
- (k) to adopt resolutions on the engagement, dismissal or discontinuation of the appointment of accounting firms;
- (l) to review the proposals raised by the Shareholders severally or jointly representing above three percent of the Company's Shares with voting rights;
- (m) to review and approve the guarantees stated in the Article 68 of the Articles;
- (n) to review and approve the issues that the Company purchases or sells any major assets of which the amount exceeds 30% of its latest audited total assets;
- (o) to review and approve matters relating to the modification of raised fund purpose;
- (p) to review and approve the share incentive schemes; and
- (q) to review and approve other issues which should be decided by the Shareholders' general meeting as stipulated by laws, administrative regulations, regulations of ministries and commissions and listing rules for stock exchanges where the Company's Shares are listed or our Articles.

Resolutions at the general meeting shall be divided into ordinary resolutions and special resolutions.

Ordinary resolutions of the general meeting shall be passed by more than half of the voting rights represented by Shareholders (including proxies) present at the meeting.

Special resolutions of the general meeting shall be passed by more than two thirds of the voting rights represented by Shareholders (including proxies) present at the meeting.

The following matters shall be approved by general meeting by special resolutions:

- (a) increasing or reducing the share capital of the Company and issuing Shares of any class, equity warrants and other similar securities;
- (b) the issuance of corporate bonds;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (c) division, merger, dissolution, liquidation of the Company or change in the form of the Company;
- (d) amendment to the Articles of Association;
- (e) any purchase or disposal of substantial assets made, or guarantee provided by the Company within one year, with an amount exceeding 30% of the latest audited total assets of the Company;
- (f) share incentive schemes;
- (g) adjustment or change of the profit distribution policy;
- (h) other matters stipulated by laws, administrative regulations, listing rules for stock exchanges where the Company's Shares are listed or the Articles of Association, or matters which are determined by an ordinary resolution of the general meeting to be of material significance to the Company and are required to be approved by way of special resolutions.

Notice of the Meeting

The Shareholders' general meetings shall be divided into annual general meetings and extraordinary general meetings. The annual general meeting shall be convened once a year, and be held within six months after the end of each accounting year.

An extraordinary general meeting shall be convened within two months from the date of occurrence of any of the following events:

- (a) the number of Directors is less than the minimum number required by the PRC Company Law or less than two-thirds of the number stipulated in our Articles;
- (b) the outstanding loss of the Company is at least one-third of the Company's total paid-up share capital;
- (c) when Shareholders who individually or jointly holding more than ten percent of the Company's Shares with voting rights request in writing to convene an extraordinary general meeting; the number of Shares held by the Shareholders shall be calculated as at the date of request in writing made by him/her;
- (d) the Board deems it necessary to convene the meeting;
- (e) the Supervisory Committee proposes to convene the meeting; or
- (f) any other circumstances as stipulated by laws, administrative regulations, regulations of ministries and commissions and the listing rules for stock exchanges where the Company's Shares are listed or our Articles.

The conveners shall notify all shareholders by way of announcement prior to twenty working days from the date of annual general meetings. All shareholders shall be informed by way of announcement prior to fifteen days (and not less than 10 working days) from the date of extraordinary general meetings.

The notice of a Shareholders' general meeting shall:

- (a) be issued in writing;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (b) specify the time, venue and duration of the meeting;
- (c) state the matters and proposals to be deliberated at the meeting;
- (d) provide to Shareholders with all necessary information and explanation to enable Shareholders to make informed decisions on the matters to be discussed. This means that when (including but not limited to) any merger, share repurchase, share capital reorganization or any proposals relating to change in the structure of the Company are involved, the detailed terms of the proposed transaction, copies of the proposed agreement (if any) and detailed explanation as to the cause and effect of such a proposal transaction shall be provided;
- (e) if any of the Directors, Supervisors, General manager and other senior management personnel have material interest in the matters to be discussed, they shall disclose the nature and extent of such interest; and if the effects of the matters to be discussed have a different effect on a Director, Supervisor, General manager and other senior management personnel as Shareholders compared to other Shareholders of that same class, they shall explain this difference;
- (f) the full text of any proposed special resolution to be voted on at the meeting;
- (g) a prominent statement stating that all Shareholders entitled to attend the meeting and appoint proxy by written to attend and vote on his/her behalf, and such proxy need not be a Shareholder of the Company;
- (h) the time and venue for delivering the proxy form authorizing the proxy to vote of the relevant meeting;
- (i) specify the date of registration of shareholdings of Shareholders who are entitled to attend the Shareholders' general meeting. The interval between date of registration and the meeting shall not be more than 7 business days. The date of registration cannot be changed once determined; and
- (j) the name and phone number of the contact person of the meeting.

Unless otherwise stipulated by laws, administrative regulations, listing rules for stock exchanges where the Company's Shares are listed or the Articles, the notice of a Shareholders' general meeting shall be delivered by hand or prepaid mail to all Shareholders (regardless of whether they have voting rights at the Shareholders' general meeting). The address of the recipients shall be the address registered in the register of Shareholders. For holders of domestic Shares, the notice of a Shareholders' general meeting may be in the form of an announcement.

The aforesaid announcement shall be published in one or more newspapers, specified by competent securities department of the State Council between twenty to twenty-five working days interval prior to the date on which the annual general meetings meeting, and between fifteen to twenty working days (and not less than 10 working days) interval prior to the date on which the extraordinary general meetings is to be convened, and All holders of domestic Shares shall be deemed as having been notified of the forthcoming Shareholders' general meeting once the announcement is published.

Provided that such action is complied with relevant laws and regulations and the listing rules for stock exchanges where the Company's Shares are listed and fulfills relevant procedures, the Company may also send or dispatch the aforesaid notices of general meeting to the holders of H Shares

through the websites of the Company and website specified by the Hong Kong Stock Exchange or by other methods approved by Hong Kong Listing Rules and our Articles to replace the approach of delivery by hand or pre-paid post.

Resolutions of shareholders’ meetings shall be divided into ordinary and special resolutions.

An ordinary resolution at a shareholders’ meeting shall require the approval of more than half of the voting rights of shareholders (including their proxies) who are present at the meeting in order to be valid.

A special resolution at a shareholders’ meeting shall require the approval of a two-third majority of the voting rights of shareholders (including their proxies) who are present at the meeting in order to be valid.

The following matters shall be passed through ordinary resolutions at a shareholders’ meeting:

- (a) Work reports of the board of directors and the board of supervisors;
- (b) Profit distribution plan and loss recovery plan prepared by the board of directors;
- (c) Appointment and dismissal of members of the board of directors and the board of supervisors and forms of their remuneration and payment methods;
- (d) The company’s annual budget and financial accounting reports, balance sheet, profit and loss statements and other financial statements; and
- (e) Annual report;
- (f) Matters other than those which shall be passed through special resolutions as provided by laws, administrative regulations, the listing rules for stock exchanges where the Company’s Shares are listed or the company’s Articles of Association.

The following matters shall be passed through special resolutions at a shareholders’ meeting:

- (a) Company share capital increase and reduction, and the issue of any types of share, share certificate subscription and other similar securities;
- (b) The issue of corporate bonds;
- (c) Company division, consolidation, dissolution and liquidation;
- (d) Amendments to the company’s Articles of Association; and
- (e) Other matters which are deemed by the shareholders’ meeting to have a major impact on the company and where it is passed by ordinary resolution at the shareholders’ meeting that the matter be resolved by special resolution.

Special Procedures for Voting by Class Shareholders

Shareholders who hold different classes of Shares shall be class Shareholders.

Class Shareholders shall have rights and obligations in accordance with the laws, administrative regulations and the Articles of Association.

Apart from holders of other classes of Shares, holders of domestic Shares and H Shares are regarded as Shareholders of different classes.

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

If the Company proposes to change or nullify certain rights of a certain class of Shareholders, this proposal should be passed by a special resolution at the Shareholders’ general meeting and passed at the meeting convened according to Article 134 to 138 of the Articles by the related class of Shareholders.

The rights of a certain class of Shareholders shall be deemed to be changed or nullified in the following circumstances:

- (a) to increase or reduce in the number of the Shares of such class, or increase or reduce the number of the Shares of other class which enjoy the same or more voting rights, distribution rights or other privileges;
- (b) to convert part or whole of the Shares of such class into other class(es), convert part or whole of the Shares of other class(es) into such class, or grant such conversion rights;
- (c) to nullify or reduce the rights of such class of Shares to receive payable dividends or cumulative dividends;
- (d) to reduce or nullify the privileged rights of such class of Shares to acquire dividends or obtain distribution of assets during liquidation of the Company;
- (e) to increase, nullify or reduce the conversion, option, voting, transfer or privileged allotment rights of such class of Shares or the rights of such class of Shares to obtain securities issued by the Company;
- (f) to nullify or reduce the rights of such class of Shares to receive amounts payable by the Company in a particular currency;
- (g) to establish new class(es) of Shares with the same or more voting rights, distribution rights or other privileges as compared with those enjoyed by such class of Shares;
- (h) to impose restriction or additional restrictions on the transfer or ownership of such class of Shares;
- (i) to grant the share subscription options or share conversion options of such class or another class of Shares;
- (j) to increase the rights or privileges of other class(es) of Shares;
- (k) any restructuring scheme of the Company that may result in the assumption of disproportionate responsibilities by different classes of Shareholders during the restructuring; or
- (l) to revise or nullify the provisions under the chapter with title of “Special Procedures for Voting by Class Shareholders” in our Articles.

Where issues specified in (b) to (h), (k) to (l) of the preceding provisions are involved, the affected class Shareholders, whether or not they are entitled to vote at Shareholders’ general meetings originally, shall have the right to vote at class general meetings. However, the Shareholders with conflicts of interests shall have no voting rights at the meeting for such class of Shareholders.

A resolution of the meeting for a certain class of Shareholders shall be adopted by above two-thirds of the voting Shares represented by Shareholders of such class present at the meeting.

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

The special voting procedure at a Shareholders' general meeting for class Shareholders shall not apply for the following cases:

- (a) upon the approval by way of a special resolution passed by a Shareholders' general meeting, the Company independently or simultaneously issues domestic Shares and overseas listed foreign Shares every twelve months, provided that the amount of each class of Shares intended to be issued is not more than twenty percent of the issued and outstanding Shares of the respective class;
- (b) the Company's plan on issuing domestic Shares and overseas listed foreign Shares at the time of establishment, which is completed within fifteen months from the date of approval from competent securities department under the State Council or within validity period of the approval documents, or
- (c) where with the approval by the securities regulatory authorities of the State Council the shareholders who hold the domestic shares of the Company transfer the shares held by them to foreign investors and cause these shares to be listed and traded on an overseas stock exchange.

DIRECTORS AND SENIOR MANAGEMENT PERSONNEL

Appointment, Removal and Retirement

Directors shall be elected or removed from office by Shareholders at a Shareholders' general meeting. Each term of office of a Director shall be three years, and a Director may be re-elected and re-appointed upon expiry of his/her term of office. The Board of the Company consists of 7 Directors, including 3 independent Directors.

The Board shall have one chairman, which shall be elected or removed from office by more than half of all Directors.

Candidates for Directors, excluding the candidates for independent Directors, shall be nominated by the Board or Shareholders individually or jointly holding above three percent of the Company's total Shares with voting rights and be selected by the Shareholders' general meeting.

A person may not serve as a Director, Supervisor, General manager or other senior management of the Company if such person:

- (i) has no civil capacity or has limited civil capacity;
- (ii) was sentenced for the offense of corruption, bribery, expropriation, misappropriation of property or for disrupting the social and economic order, and less than five years has elapsed since the sentence was served, or has been deprived of political rights due to such crimes, and less than five years has elapsed since the deprivation was completed;
- (iii) has served as a director, factory manager or general manager of a company or enterprise that was bankrupted and liquidated, and was personally liable for the bankruptcy of such company or enterprise, and less than three years has elapsed since the date of completion of the bankruptcy and liquidation of the company or enterprise;
- (iv) was a former legal representative of a company or an enterprise which has had its business license revoked and been ordered to close down its business for violating the laws, and was personally liable for that revocation, and less than three years has elapsed since the date of revocation;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (v) has comparatively large amount of individual debts that have become overdue and have not been settled;
- (vi) has been currently under investigation for criminal offense and which investigation is not yet concluded;
- (vii) has been prohibited to enter the capital market by competent securities department of the State Council and the period has not expired;
- (viii) is prohibited from acting as leader of an enterprise by virtue of any laws and administrative regulations;
- (ix) is not a natural person;
- (x) has been convicted by relevant competent authorities for violation of securities related laws and regulations, where such violation involved fraudulent or dishonest acts, and less than five years has elapsed since the date of such conviction; or
- (xi) other contents stipulated by laws, administrative regulations, regulations of ministries and commissions or listing rules for stock exchanges where the Company's Shares are listed.

Power to Dispose of the Assets of Our Company or Any Subsidiary

For the disposal of fixed assets by the Board, if the aggregate of the expected value of the fixed assets proposed to be disposed of and the value of the fixed assets which had been disposed of within four months preceding such proposal for disposal exceeds thirty-three percent of the fixed assets value shown in the most recent balance sheet reviewed at a Shareholders' general meeting, the Board shall not dispose of or approve of the disposal of such fixed assets without the approval of the Shareholders' general meeting.

The disposal of fixed assets referred to in this paragraph includes the transfer of interests of certain assets, but excludes the provision of fixed assets as pledges to any guarantees.

A breach of the above paragraph shall not affect the validity of transactions entered into by the Company in disposing of fixed assets.

Borrowing Powers

The Articles of Association do not contain any special provision in respect of the manner in which borrowing powers may be exercised by the Directors, other than provisions which (a) give the Board the power to formulate proposals for the issuance of corporate bonds by the Company; and (b) require the issuance of corporate bonds to be approved by the Shareholders in general meeting by way of a special resolution.

Disclosure of Interests in Contracts with Our Company

The Directors, Supervisors, General manager and other senior management personnel of the Company having any direct or indirect material conflict of interests in any executed or proposed contracts, transactions or arrangements (except the employment contracts between the Company and its Directors, Supervisors, General manager and other senior management personnel), regardless of whether such interests are usually subject to the approval and consent of the Board, such persons shall disclose the nature and extent of the interests to the Board as soon as possible.

That, subject to such exceptions specified in the Note 1, Appendix 3 of Hong Kong Listing Rules or exceptions otherwise approved by the Hong Kong Stock Exchange, a Director shall not vote on any Board resolution approving any contract or arrangement or any other proposal in which he or any of his close associates (the definitions are stipulated in the Hong Kong Listing Rules) has a material interest nor shall he be counted in the quorum present at the meeting.

Unless the Directors, Supervisors, General manager and other senior management personnel of the Company with conflicts of interest have disclosed their interests to the Board in accordance with the requirements of the preceding paragraph, and the Board has approved the matter without counting the interested persons into the quorum and without their participation in the vote, the Company shall have the right to rescind such contracts, transactions or arrangements, except in circumstances where the counterparty is acting in good faith and unaware of that the Directors, Supervisors, General manager and other senior management personnel are in breach of their obligations.

Loans to Directors, Supervisors and Senior Management

The Company shall not, directly or indirectly, provide loans or loan guarantees to the Directors, Supervisors, General manager and other senior management personnel of the Company and its parent company, nor shall the Company provide the same to their connected persons.

The preceding provision shall not apply to the following circumstances:

- (a) loans or loan guarantees provided by the Company to its subsidiaries;
- (b) loans, loan guarantees or other funds provided by the Company to the Directors, Supervisors, General manager and other senior management personnel of the Company pursuant to their employment contracts which were adopted by the Shareholders’ general meeting, with which the foregoing persons can make payments in the interests of the Company or for the expenses incurred in performing their duties and responsibilities for the Company;
- (c) where the normal scope of business of the Company includes the provisions of loans and loan guarantees, loans and loan guarantees can be provided by the Company to the relevant Directors, Supervisors, General manager and other senior management personnel of the Company and their connected persons, provided that the loans and loan guarantees are provided on normal commercial terms and conditions.

If the Company provides a loan in breach of the provisions above, the person who has received the loan shall repay it immediately regardless of the terms of the loan.

Remunerations and Compensation for Loss of Office

The Company shall enter into written contracts with the Directors and the Supervisors regarding remuneration which are subject to the prior approval from the Shareholders’ general meeting. The aforesaid “remunerations” include:

- (a) remuneration for the Directors, Supervisors or senior management personnel of the Company;
- (b) remuneration for the Directors, Supervisors or senior management personnel of the subsidiaries of the Company;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (c) remuneration for those providing other services for managing the Company and its subsidiaries; and
- (d) compensation to Directors or Supervisors for loss of office or upon retirement.

Except for the contracts mentioned above, the Directors and Supervisors shall not initiate litigation against the Company and claim benefits due to them for the foregoing matters.

The remuneration contracts between the Company and its Directors or Supervisors shall stipulate that if the Company is to be acquired, the Directors and Supervisors of the Company shall, subject to prior approval from the Shareholders’ general meeting, be entitled to compensation or other funds for loss of their positions or upon retirement. The “acquisition of the Company” mentioned in this paragraph refers to one of the following circumstances:

- (a) a takeover offer made by any person to all Shareholders; and
- (b) a takeover offer made by any person with the intent of becoming a “Controlling Shareholder”. See the definition of “Controlling Shareholder” in Article 270 of our Articles.

If Directors and Supervisors do not comply with the preceding provisions, any funds received by them shall go to the persons who have accepted the offer mentioned above and sell their Shares. The Directors and Supervisors shall bear the expenses arising from the proportional distribution of such amounts, and such expenses shall not be deducted from the amounts.

FINANCIAL, PROFIT DISTRIBUTION AND ACCOUNTING SYSTEM

The Company shall establish its financial and accounting system in accordance with laws, administrative regulations and the provisions of competent departments.

The Company shall prepare its financial statements in accordance with PRC accounting standards and regulations, as well as in accordance with international accounting standards or the accounting standards of the overseas locality in which the Company’s Shares are listed. If there are any material differences between the financial statements prepared in accordance with the two accounting standards, such differences shall be stated in the notes to the financial statements. When distributing the after-tax profits of a given fiscal year, the Company shall take as final the smaller amount of after-tax profits out of the aforesaid two kinds of financial statements.

The interim results or financial information published or disclosed by the Company shall be prepared in accordance with the PRC accounting standards and regulations, as well as the international accounting standards or the accounting standards of the overseas locality where the Company’s Shares are listed.

Except as otherwise provided in the Company’s Articles, the Company shall send the aforesaid report or report of the Board along with the balance sheet(including all documents attached to the balance sheet required by law and regulations) and income statement or income and expenditure statement or financial report summary to each Shareholder of H Share by hand or pre-paid post or other means approved by Hong Kong Stock Exchange at least twenty-one days prior to the convening of the Shareholders’ general meeting. The address of the recipients shall be the address registered in the register of Shareholders.

Profit Distribution

The Company shall withdraw 10% of the annual profits as the statutory reserve fund the Company. Such withdrawal may be stopped when the statutory reserve fund of the Company has accumulated to at least 50% of the registered capital of the Company.

If the statutory reserve fund is insufficient to make up for the losses of the preceding year, the profits of the current year shall first be used to make up for the said losses before any statutory reserve fund is withdrawn as per the preceding paragraph.

After statutory reserve fund is withdrawn out of the after-tax profits, discretionary reserve fund may also be withdrawn out of the same as per a resolution made at a general meeting.

The after-tax profits remaining after makeup of losses and withdrawal of capital reserves shall be profits distributable to shareholders, which shall be distributed by the Company to the shareholders in proportion to their shareholding according to the resolution of the general meeting.

If the general meeting, in violation of the provision in the preceding paragraph, distributes profits to shareholders before recovering losses and withdrawing statutory reserve fund, the profits thus distributed shall be returned to the Company.

The capital reserve of the Company shall be used to make up for the losses, enhance the operating scale or increase the capital of the Company. However, the capital reserve shall not be used to recover the losses of the Company.

The capital reserve shall include:

- (a) Premium arising from issue above the par value of the stock; and
- (b) Other revenue required by the financial authority under the State Council to be stated as capital reserve.

When statutory reserve fund is converted into capital, the amount of the said fund left shall not be less than 25% of the registered capital of the Company before such conversion.

Accounting Firm

The company shall appoint an accounting firm qualified to engage in securities-related business to undertake matters including audits of accounting statements, the verification of net assets and other relevant consultancy services. The term of appointment shall be one year which commence on the date of conclusion of the current shareholders' meeting and end on the date of conclusion of the subsequent shareholders' meeting, and may be renewed.

The company's appointment of an accounting firm shall be decided by the general meeting. The board of directors shall not appoint any accounting firm prior to a decision being made by the general meeting, unless it is otherwise provided in our articles of association.

An accounting firm appointed by the company shall have the following rights:

- (a) To inspect, at any time, the company's account books, records or vouchers, and shall have the right to require the directors, managers or other senior officers to provide relevant data and explanations;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (b) To require the company to adopt all reasonable measures to obtain from its subsidiaries data and explanations which the accounting firm requires for the performance of its duties; and
- (c) To attend shareholders' meetings and to obtain information which is available to any shareholder who has the right to receive notice of a meeting or on other matters related to the meeting, and to speak at any shareholders' meeting about matters related to its functions as accounting firm to the company.

The remuneration of an accounting firm or methods for determining remuneration shall be decided at a shareholders' meeting. The remuneration of an accounting firm appointed by the board of directors shall be determined by the board of directors.

MERGER, DIVISION, DISSOLUTION AND LIQUIDATION OF THE COMPANY

In the case of the consolidation or division of the company, a consolidation or division plan shall be drafted by the board of directors and after the plan is adopted according to the procedures stipulated in the company's Articles of Association, the relevant procedures for examination and approval shall then be carried out in accordance with the law. If a shareholder objects to the consolidation or division plan, that shareholder shall have the right to require the company or those shareholders who approve the consolidation or division plan to purchase his/her shares at a fair price. The content of a resolution on the consolidation or division of the company shall be made into a special document to be available for inspection by shareholders.

For holders of foreign shares of the company listed in Hong Kong the aforesaid document shall be delivered by mail.

In a merger of companies, the companies shall execute a merger agreement and prepare their respective balance sheets and schedules of assets. The companies shall notify their creditors within ten days of adopting merger resolutions, and shall publish notices more than three times in information disclosure press within 30 days. Creditors shall be entitled to claim full repayment of all debts owed by the companies or require that appropriate assurances are provided within 30 days of receiving the notice, or within 45 days of publication of the first notice if any such creditor does not receive the notice.

If the company is to be divided, its assets shall be divided accordingly.

In a division of the company, a balance sheet and a schedule of assets shall be prepared. The company shall notify its creditors within ten days of the date on which the division resolution is made, and shall make announcements more than three times in the information disclosure press within 30 days.

The Company shall be dissolved in any of the following circumstances:

- (a) other dissolved matters stipulated in our Articles;
- (b) if the Shareholders' general meeting resolves to do so;
- (c) if a dissolution is necessary as a result of a merger or division of the Company;
- (d) the Company is declared bankrupt pursuant to the law as a result of its inability to pay due debts;

APPENDIX V**SUMMARY OF ARTICLES OF ASSOCIATION**

- (e) if the business license of the Company is revoked or if it is ordered to close down its business; or
- (f) where the operation and management of the Company falls into serious difficulties and its continued existence would cause material losses to Shareholders, the Shareholders holding above ten percent of the total voting rights of the Company may apply to the people's court to dissolve the Company if there are no other solutions.

If the Board decides that the Company shall be liquidated (except for liquidation resulting from the Company's declaration of bankruptcy), it shall state in the notice of Shareholders' general meeting convened for such purpose that the Board have conducted a comprehensive investigation into the situation of the Company and believes that the Company is able to pay off all its debts within twelve months following the commencement of the liquidation.

After the Shareholders' general meeting adopts a resolution in favour of the liquidation, the functions and powers of the Board of the Company shall be terminated immediately.

The liquidation committee shall follow the instructions of the Shareholders' general meetings and shall report to the Shareholders' general meeting at least once a year on the income and expenditure of the liquidation committee, the business of the Company and the progress of the liquidation, and shall make a final report to the Shareholders' general meeting at the end of the liquidation.

AMENDMENTS TO THE ARTICLES

In any of the following circumstances, the Company shall amend the Articles:

- (a) if upon amendments to the PRC Company Law or relevant laws and administrative regulations, any terms contained in the Articles become inconsistent with the provisions of the amended laws and administrative regulations;
- (b) a change in the Company causes inconsistency with those contained in the Articles; or
- (c) a resolution being passed by the Shareholders' general meeting to amend our Articles.

If the amendments to our Articles are subject to approval by relevant competent authorities, the amendments to our Articles adopted at the Shareholders' general meeting shall be reported to the competent authority for approval; if registration matters are involved, the Company shall apply for registration of the changes in accordance with the law.

OTHER PROVISIONS MATERIAL TO OUR COMPANY AND OUR SHAREHOLDERS**General Provisions**

The Company is a joint stock company with limited liability and permanently surviving.

From the date on which the Articles come into effect, the Articles shall constitute a legally binding document to the Company, Shareholders, Directors, Supervisors and senior management personnel, regulating the Company's organization and activities, and the rights and obligations between the Company and each Shareholder and among the Shareholders inter se.

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

The Company may, based on its operating and development needs, increase its share capital pursuant to laws, subject to the resolution on general meeting. The Company may increase its capital by the following ways:

- (a) public offering of Shares;
- (b) non-public offering of Shares;
- (c) placing Shares to existing Shareholders;
- (d) distributing bonus Shares to existing Shareholders;
- (e) transferring reserve funds to increase share capital; or
- (f) other methods permitted by laws, administrative regulations, competent securities department and other relevant competent authorities of the State Council.

Board of Directors

The Board of Directors shall exercise the following functions and powers:

- (a) convening Shareholders' general meetings and reporting its performance at the Shareholders' general meetings;
- (b) implementing resolutions of the Shareholders' general meetings;
- (c) determining or making significant amendment to the Company's business plans and investment plans;
- (d) formulating annual financial budget plans and final account plans;
- (e) formulating profit distribution plans and plans for recovery of losses of the Company;
- (f) formulating proposals for the increase or reduction of the Company's registered capital, and for the issuance of the Company's debentures or other securities and the listing;
- (g) drafting proposals for the Company's major acquisition, purchase of the Company's Shares or merger, division, dissolving and change in corporate form of the Company;
- (h) determining investments, acquisition and disposal of assets, pledge of assets, external guarantees, entrusted investments, connected transactions and other matters within the authorization scope of Shareholders' general meeting;
- (i) deciding on the Company's internal management structure;
- (j) appointing or dismissing the General manager and the secretary to the Board of the Company; appointing or dismissing Vice General manager and Chief Financial Officer of the Company based on the nominations of the General manager, and determining their emoluments, rewards and penalties;
- (k) establishing the basic management system of the Company;
- (l) drafting proposals for the amendment to the Articles;
- (m) managing the information disclosures of the Company;
- (n) proposing the engagement or change of the appointment of accounting firms to the Shareholders' general meeting;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (o) reviewing work reports of the General manager of the Company and examine his or her work;
- (p) other duties and powers stipulated by laws, administrative regulations, regulations of ministries and commissions, listing rules for stock exchanges where the Company's Shares are listed and the Company's Articles.

The Board of Directors shall hold a regular meeting at least four times a year, and the Board meeting shall be convened by the chairman of the Board. Notices of the regular Board meeting shall be sent to all Directors and Supervisors at least fourteen days prior to the date of the meeting.

A meeting of the Board of Directors shall only be held if it has a quorum of more than one half of the directors unless otherwise required in the Articles of the Company.

Resolutions adopted at the Board meeting must be approved by more than one half of all members of the Directors unless otherwise required in the Articles of the Company.

Resolutions of the Board shall be passed on a "one person one vote" basis.

General manager

The Company shall have one General manager, who shall be accountable to the Board and shall exercise the following powers:

- (i) to be in charge of the Company's operation and management and to implement there solutions of the Board, and report work to the Board;
- (ii) to formulate and implement the Company's annual business plan and investment plan;
- (iii) to formulate the Company's internal management structure;
- (iv) to draft the basic management scheme of the Company;
- (v) to formulate the Company's concrete bylaws;
- (vi) to propose the appointment or dismissal of the Company's vice general manager(s) and the chief financial officer;
- (vii) to determine the appointment or dismissal of responsible management personnel except for whom should be appointed or dismissed by the Board of Directors;
- (viii) to formulate the plans for the salary, benefits, rewards and punishments of the Company's employees, and to determine the employment and dismissal of the Company's employees; and
- (ix) to exercise other powers conferred by the Articles of Association and the Board.

The general manager may be present at a meeting of the Board. The general manager has no voting rights at the Board meetings unless he is also a director.

Secretary of the Board

There shall be a secretary of the Board. The secretary to the Board shall have necessary professional knowledge and experience. The secretary to the Board shall be responsible for the

preparations for general meetings and Board meetings, keeping of documentation and shareholders' data, matters relating to information disclosure of the Company, etc., to ensure:

- (a) complete organizational documents and records are available for the Company;
- (b) the Company prepares and submits documents and reports required by relevant authorities pursuant to the law; and
- (c) the register of Shareholders of the Company is properly established, and that persons entitled to receive relevant records and documents of the Company are given timely access to such records and documents.

Supervisory Committee

The Directors, General manager and other senior managements shall not act concurrently as Supervisors.

Each Supervisor shall serve for a term of three years, which may be re-elected upon the expiration of his/her term.

The Company shall have a Supervisory Committee. The Board of Supervisors shall consist of three supervisors, including two shareholders representative supervisors and one employee representative supervisor. The shareholders representative supervisors shall be elected by Shareholder's general meeting.

The Supervisory Committee shall have one chairman. The appointment and removal of the chairman shall be made with a resolution passed by over two-thirds of all members of the Supervisory Committee.

The Supervisory Committee shall exercise the following powers:

- (a) to review and give written comments to regular reports of the Company formulated by the Board;
- (b) to monitor financial situations of the Company;
- (c) to supervise the related acts of any of the Directors and senior management personnel and propose the removal of who violates any laws, administrative regulations, the Articles of Association or resolutions passed by the Shareholders' meeting;
- (d) to demand any Director or senior management personnel who acts in a manner which is detrimental to the Company's interest to rectify such behaviors;
- (e) to propose the convening of extraordinary general meeting and to convene and preside over extraordinary general meeting when the Board fails to perform the duty of convening and presiding Shareholders' general meetings;
- (f) to verify the financial information such as financial reports, business reports and profit distribution plans to be submitted by the Board at the general meetings and, should any queries arise, to engage, in the name of the Company, certified public accountants and practicing auditors for a re-examination of the aforesaid information;
- (g) to make proposal to the Shareholders' general meeting;

APPENDIX V

SUMMARY OF ARTICLES OF ASSOCIATION

- (h) to represent the Company to negotiate with the Directors and senior management members or bringing actions against Directors and senior management members according to Article 152 of the Company Law;
- (i) to investigate the Company should any abnormal operation situation arise; to authorize accounting firms, law firms and other professional institutions to assist the investigation and the fees shall be borne by the Company; and
- (j) other powers stipulated by our Articles.

Meetings of the Supervisory Committee shall be convened at least once each six months and be convened and presided by its chairman.

A Supervisor shall be elected by more than half of all Supervisors to convene and host the meetings of Supervisory Committee when the chairman fails or refuses to perform the duty.

Resolution of Disputes

The Company shall abide by the following rules for dispute resolution:

- (a) If any disputes or claims in relation to the Company's business, with respect to any rights or obligations under our Articles, the PRC Company Law or any other relevant laws and administrative regulations, arise between Shareholders of overseas listed foreign Shares and the Company, between Shareholders of overseas listed foreign Shares and the Company's Directors, Supervisors, President (Chief Executive Officer) or other senior management personnel of the Company, or between Shareholders of overseas listed foreign Shares and Shareholders of domestic Shares, the parties concerned shall submit such disputes or claims to arbitration.

When the aforementioned disputes or claims are submitted to arbitration, such disputes or claims shall be submitted in their entirety, and all persons (being the Company, the Company's Shareholders, Directors, Supervisors, President (Chief Executive Officer) or other senior management personnel of the Company) that have a cause of action based on the same grounds or the persons whose participation is necessary for the resolution of such disputes or claims, shall comply with the arbitration.

Disputes with respect to the definition of Shareholders and disputes concerning the register of Shareholders need not be resolved by arbitration.

- (b) An applicant may choose for the arbitration to be arbitrated either by the China International Economic and Trade Arbitration Commission in accordance with its arbitration rules or the Hong Kong International Arbitration Centre in accordance with its securities arbitration rules. Once a claimant submits a dispute or claim to arbitration, the other party must carry out the arbitration at the arbitration institution selected by the claimant.

If an applicant opts for arbitration by the Hong Kong International Arbitration Centre, either party may request for the arbitration to be conducted in Shenzhen in accordance with the securities arbitration rules of the Hong Kong International Arbitration Centre.

- (c) Unless otherwise provided by laws and administrative regulations, the laws of the PRC shall apply to the settlement of any disputes or claims that are resolved by arbitration described in item (a) above.
- (d) The award of the arbitration institution shall be final and binding upon all parties.

1. FURTHER INFORMATION ABOUT OUR COMPANY

A. Incorporation

The predecessor of our Company, Shenzhen Hepalink Industrial Development Company Limited (深圳市海普瑞實業發展有限公司) was incorporated in China on April 21, 1998. On January 19, 2001, Shenzhen Hepalink Industrial Development Company Limited was renamed as Shenzhen Hepalink Biotechnology Company Limited (深圳市海普瑞生物技術有限公司) and it was further renamed as Shenzhen Hepalink Pharmaceutical Company Limited (深圳市海普瑞藥業有限公司) on September 28, 2002. On December 27, 2007, upon approval by the Ministry of Commerce, it was restructured into a foreign invested joint-stock company and was renamed as Shenzhen Hepalink Pharmaceutical Group Co., Ltd (深圳市海普瑞藥業股份有限公司). Since May 6, 2010, our A Shares have been listed on the Shenzhen Stock Exchange with the stock code of 002399. The Company was further renamed as Shenzhen Hepalink Pharmaceutical Group Co., Ltd. (深圳市海普瑞藥業集團股份有限公司) on February 20, 2017. Our registered office is located at No.21, Langshan Road, Nanshan District, Shenzhen, People’s Republic of China.

We have established a place of business in Hong Kong at Level 54, Hopewell Centre, 183 Queen’s Road East, Hong Kong and were registered with the Registrar of Companies in Hong Kong as a non- Hong Kong company under Part 16 of the Companies Ordinance on December 30, 2019. Ms. Ella Wong Wai Yee and Ms. Chan Sze Ting have been appointed as the authorized representatives of our Company for the acceptance of service of process and notices on behalf of our Company in Hong Kong. The address for service of process on our Company in Hong Kong is the same as our principal place of business in Hong Kong as set out above.

As our Company was established in the PRC, we are subject to relevant laws and regulations of the PRC. A summary of the relevant aspects of laws and regulations of the PRC and our Articles of Association is set out in Appendices IV and V to this document respectively.

B. Changes in the Share Capital of Our Company

There has been no alteration in our share capital within two year immediately preceding the date of this document.

Upon completion of the [REDACTED], but without taking into account any exercise of the [REDACTED], our registered capital will increase to RMB[REDACTED], comprising 1,247,201,704 A Shares and [REDACTED] H Shares fully paid up, representing approximately [REDACTED]% and [REDACTED]% of our registered capital, respectively.

C. Shareholders’ Resolutions

Pursuant to the Shareholders’ meeting held on December 18, 2019, the following resolutions, among others, were duly passed:

- (a) the issue by our Company of H Shares of nominal value of RMB1.00 each and such H Shares be [REDACTED] on the Hong Kong Stock Exchange;
- (b) the number of H Shares to be issued before the exercise of the [REDACTED] shall not exceed [REDACTED]% of the enlarged share capital of the Company upon completion of the [REDACTED] and granting the [REDACTED] the [REDACTED] of no more than [REDACTED]% of the above number of H Shares to be [REDACTED];

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

- (c) subject to the completion of the [REDACTED], the conditional adoption of the Articles of Association, which shall become effective on [REDACTED]; and
- (d) authorization of the Board and its authorized persons to handle all matters relating to, among other things, the [REDACTED], the issue and [REDACTED] of the H Shares.

D. Further Information about Our Subsidiaries

The list of our subsidiaries as of September 30, 2019 is set out in the Accountants’ Report, the text of which is set out in Appendix I to this document. Save as disclosed below, there has been no alteration in the share capital of any of our subsidiaries within the two years immediately preceding the date of this document.

Shenzhen Ruidi Biomedical Co., Ltd.

On January 3, 2019, the registered capital of Shenzhen Ruidi Biomedical Co., Ltd. was increased from US\$11,760,000 to US\$14,117,647.

Techdow (Hong Kong)

On July 18, 2019, the registered capital of Techdow (Hong Kong) was increased from HK\$162,278,000 to HK\$233,960,000.

Hepalink (Hong Kong)

On August 20, 2019, the registered capital of Hepalink (Hong Kong) was increased from HK\$225,311,678 to HK\$330,221,445.

Histar (Shanghai) Co., Ltd.

On December 23, 2019, the registered capital of Histar (Shanghai) Co., Ltd. was increased from RMB1,000,000 to RMB19,960,000.

E. Restriction on Share Repurchases

For details of the restrictions on share repurchases by our Company, please refer to “Appendix V—Summary of Articles of Association” to this document.

2. FURTHER INFORMATION ABOUT OUR BUSINESS

A. Summary of Our Material Contracts

We have entered into the following contracts (not being contracts entered into in the ordinary course of business) within two years preceding the date of this document, which are or may be material and a copy of each has been delivered to the Registrar for registration:

- (a) the equity transfer agreement dated June 6, 2018 between our Company, Hepatunn and Pangu Chenchen (Shanghai) Enterprise Management Center (Limited Partnership) (盤穀晨宸 (上海) 企業管理中心 (有限合夥)) (“Pangu Chenchen”) to transfer our Company’s 85% equity interest in Hepatunn to Pangu Chenchen for a consideration of RMB 34 million;

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

- (b) the subscription agreement dated January 31, 2019 between our Company and Resverlogix to subscribe for 2,213,398 shares in Resverlogix for an aggregate subscription price of US\$5,000,000;
- (c) the subscription agreement dated March 27, 2019 between Hepalink (Hong Kong), amongst other investors, and Kymab Group Limited (“Kymab”) to subscribe for 3,500,000 convertible preferred shares in Kymab for an aggregate subscription price of US\$3,500,000;
- (d) the subscription agreement dated March 29, 2019 between our Company and Resverlogix to subscribe for 4,479,793 shares in Resverlogix for an aggregate subscription price of US\$10,000,000; and
- (e) the [REDACTED].

B. Intellectual Property Rights

As of the Latest Practicable Date, our Company has registered or applied for the following intellectual property rights, which are or may be material in relation to our Company’s business.

Trademarks

As of the Latest Practicable Date, we have registered the following trademarks, which we consider to be or may be material in relation to our business:

<u>Trademark Registered</u>	<u>Place of Registration</u>	<u>Registration No.</u>	<u>Class</u>	<u>Expiration Date</u>
麥可林	China	9822622	5	January 6, 2023
普洛希	China	9822643	5	October 13, 2022
Meclean	China	9822674	5	January 20, 2023
Proxin	China	9822699	5	October 6, 2022
	China	3681896	5	February 13, 2026
Hepalink				
	China	3681888	5	January 27, 2026
海普瑞				
	China	3681887	30	March 6, 2025
海普瑞				
	China	1773677	30	May 20, 2022
Hepalink				

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

Trademark Registered	Place of Registration	Registration No.	Class	Expiration Date
 海普瑞	China	12034965	13	June 27, 2024
 海普瑞	China	12034996	30	June 27, 2024
 海普瑞	China	12035015	31	June 27, 2024
 海普瑞	China	12035028	5	June 27, 2024
 海普瑞	China	12038331	35	July 20, 2024
海普瑞	China	14007675	2	March 13, 2025
海普瑞	China	14007691	3	March 13, 2025
海普瑞	China	14007712	4	April 20, 2025
海普瑞	China	14007746	6	May 6, 2025
海普瑞	China	14007765	7	September 6, 2025
海普瑞	China	14007780	15	April 20, 2025
海普瑞	China	14007794	18	April 20, 2025
海普瑞	China	14007815	22	April 20, 2025
海普瑞	China	14007825	24	April 20, 2025
海普瑞	China	14007836	43	April 20, 2025
海普瑞	China	14007848	44	April 20, 2025
海普瑞	China	14007868	45	April 20, 2025
海普瑞	China	14007879	42	April 20, 2025
海普瑞	China	14172796	35	April 20, 2025
海普瑞	China	14172797	33	April 20, 2025
海普瑞	China	14172798	28	April 20, 2025
海普瑞	China	14172799	27	April 20, 2025
海普瑞	China	14172800	26	April 20, 2025

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

Trademark Registered	Place of Registration	Registration No.	Class	Expiration Date
海普瑞	China	14172801	25	April 20, 2025
海普瑞	China	14172802	23	April 20, 2025
海普瑞	China	14172803	21	April 20, 2025
海普瑞	China	14172804	20	April 20, 2025
海普瑞	China	14172805	19	April 20, 2025
海普瑞	China	14172806	17	April 27, 2025
海普瑞	China	14172807	16	April 27, 2025
海普瑞	China	14172808	14	April 27, 2025
海普瑞	China	14172809	12	April 27, 2025
海普瑞	China	14172810	11	July 6, 2025
海普瑞	China	14172811	10	April 27, 2025
海普瑞	China	14172812	9	July 13, 2025
海普瑞	China	14172813	8	April 27, 2025
海普瑞	China	14172814	1	April 27, 2025
海普瑞	China	14607358	40	July 20, 2025
海普瑞	China	14607359	38	July 20, 2025
海普瑞	China	14607360	37	July 20, 2025
海普瑞	China	14607361	34	July 20, 2025
海普瑞	China	14607362	29	July 20, 2025
海普瑞	China	14607363	32	July 20, 2025
海普瑞	China	14607364	39	July 20, 2025
海普瑞	China	14607365	41	July 20, 2025
 	Hong Kong	301949400	5, 10, 30	February 14, 2022
 Hepalink	Hong Kong	301949419AA	5,	May 27, 2022
 Hepalink	Hong Kong	301949419AB	10, 30	May 27, 2022
 Hepalink	Canada	TMA830051	1, 5	August 17, 2027

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

Trademark Registered	Place of Registration	Registration No.	Class	Expiration Date
Neoparin	Poland	R.281679	5	March 9, 2025
Neoparin	European Union	EUTM 015162753	5, 35, 42	March 1, 2026
INHIXA	China	21947175	5	January 6, 2028
 Techdow	China	10585526	5	April 6, 2024
 Techdow	China	10585525	10	May 6, 2023
 Techdow 天立	China	10585524	5	June 13, 2024
PROLOSU	China	9868256	5	October 20, 2022
PRONIE	China	9868046	5	October 20, 2022
PROLTON	China	9868035	5	October 20, 2022
ROSMIN	China	9868021	5	October 20, 2022
ROSGIN	China	9868009	5	October 20, 2022
ROSUTON	China	9863263	5	October 20, 2022
PROWIKUN	China	9863247	5	October 20, 2022
PROTMING	China	9863233	5	October 20, 2022
PROCHINN	China	9863225	5	October 20, 2022
PROTWIN	China	9863204	5	October 20, 2022
PROGINN	China	9863194	5	October 20, 2022
ROSUQING	China	9863175	5	October 20, 2022
ROSUKUN	China	9863157	5	October 20, 2022
REKEPIN	China	9855728	5	October 20, 2022
ROSULEO	China	9855723	5	October 20, 2022
洛舒靜	China	9855719	5	October 20, 2022
普洛蘇	China	9855716	5	October 20, 2022
普洛泰	China	9855713	5	January 20, 2023
普洛通	China	9855707	5	January 20, 2023
洛舒明	China	9855704	5	October 20, 2022
洛舒優	China	9855702	5	October 20, 2022
洛舒通	China	9855698	5	November 27, 2022
普洛明	China	9853209	5	October 13, 2022
普洛清	China	9853194	5	October 20, 2022
普洛維寧	China	9853183	5	May 20, 2024
普洛靜	China	9853167	5	October 20, 2022

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

<u>Trademark Registered</u>	<u>Place of Registration</u>	<u>Registration No.</u>	<u>Class</u>	<u>Expiration Date</u>
洛舒清	China	9853154	5	October 13, 2022
洛舒康	China	9853143	5	January 6, 2023
TECHDOW	China	7531868	10	October 27, 2020
PROLONGIN	China	4901083	5	March 13, 2029
PROLONGIN	China	4901082	1	January 20, 2029
PROLONGIN	China	4901056	10	September 6, 2028
普洛寧	China	4802359	1	February 13, 2029
普洛寧	China	4802357	10	June 6, 2028
洛舒平	China	4802356	1	February 13, 2029
洛舒平	China	4802354	10	June 6, 2028
TECHDOW	China	4782170	5	February 13, 2029
天道;TECHDOW	China	4782169	5	May 20, 2029
天道	China	4782168	5	May 20, 2029
瑞開平	China	4619247	5	September 20, 2028

Patents

For material patents, patent applications we owned or licensed from other entities as of the Latest Practicable Date, see “Business—Intellectual Property” section of the document.

Domain Names

As of the Latest Practicable Date, we have registered the following domain names which we consider to be or may be material in relation to our business:

<u>Domain name</u>	<u>Name of Registered Proprietor</u>	<u>Expiry Date</u>
hepalink.net	Hepalink	June 23, 2020
hepalink.com	Hepalink	December 22, 2022
hepalink.hk	Hepalink	April 15, 2020
techdow.com	Shenzhen Techdow	June 15, 2022
techdow.net	Shenzhen Techdow	June 23, 2022
techdow.com.cn	Shenzhen Techdow	June 23, 2022
techdow.uk	Techdow Europe AB	July 18, 2020
techdow.es	Techdow Europe AB	July 18, 2020
techdow.it	Techdow Europe AB	July 19, 2020
techdow.fr	Techdow Europe AB	July 21, 2020
techdow.be	Techdow Europe AB	July 21, 2020

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

<u>Domain name</u>	<u>Name of Registered Proprietor</u>	<u>Expiry Date</u>
techdow.nl	Techdow Europe AB	July 21, 2020
techdow-pharma.co.uk . . .	Techdow Europe AB	August 3, 2020
techdow.co.at	Techdow Europe AB	December 11, 2020
多普樂.中國	Topknow	April 30, 2022
天道.cn	Shenzhen Techdow	April 30, 2022
多普樂.cn	Topknow	April 30, 2022
neoparin.be	Techdow Pharma Poland Sp. z o.o.	March 8, 2020
neoparin.cz	Techdow Pharma Poland Sp. z o.o.	February 28, 2020
neoparin.fr	Techdow Pharma Poland Sp. z o.o.	February 29, 2020
neoparin.es	Techdow Pharma Poland Sp. z o.o.	February 22, 2020
neoparin.nl	Techdow Pharma Poland Sp. z o.o.	February 29, 2020
neoparin.lt	Techdow Pharma Poland Sp. z o.o.	February 27, 2020
neoparin.lv	Techdow Pharma Poland Sp. z o.o.	February 27, 2020
neoparin.de	Techdow Pharma Poland Sp. z o.o.	February 29, 2020
neoparin.pl	Techdow Pharma Poland Sp. z o.o.	March 1, 2020
neoparin.ru	Techdow Pharma Poland Sp. z o.o.	March 15, 2020
neoparin.ro	Techdow Pharma Poland Sp. z o.o.	July 9, 2020
neoparin.ch	Techdow Pharma Poland Sp. z o.o.	March 30, 2020
neoparin.se	Techdow Pharma Poland Sp. z o.o.	March 1, 2020
neoparin.uk	Techdow Pharma Poland Sp. z o.o.	March 1, 2020
neoparin.it	Techdow Pharma Poland Sp. z o.o.	March 1, 2020
neoparin.eu	Techdow Pharma Poland Sp. z o.o.	March 1, 2020
neoparin.com	Techdow Pharma Poland Sp. z o.o.	March 1, 2020

C. Share Incentive Schemes II and III

Our Company adopted the Share Incentive Scheme II (“**Scheme II**”) and the Share Incentive Scheme III (“**Scheme III**,” and together with Scheme II, the “**Schemes**”) in November 2016 and December 2018, respectively. The Schemes are not subject to the provisions of Chapter 17 of the Listing Rules as the Schemes do not involve the grant of options by our Company to subscribe for new Shares upon our [REDACTED]. The following is a summary of the principal terms of the Schemes:

(a) Purpose

The purpose of Schemes is to promote the success and enhance the value of the Company by linking the personal interests of the employees to those of the Shareholders. It is intended to provide flexibility to the Company in its ability to motivate, attract and retain the services of the employees

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

upon whose judgment, interest and special effort the successful conduct of the Company’s operation is largely dependent.

(b) Scope of Participants

The participants of Scheme II are our Directors (excluding our independent Directors and external Directors), Supervisors (excluding our external supervisors), senior management and core staff members of the Company and the subsidiaries.

The participants of Scheme III are employees of our Company and our subsidiaries (excluding our Directors, Supervisors and senior management).

(c) Term of the Schemes

Scheme II was effective for an initial period of 36 months from December 12, 2016 to December 11, 2019. Scheme III is effective for a period of 24 months from December 28, 2018 to December 27, 2020. Within two months prior to the expiration of the respective term of each Scheme, with the approval of more than two-thirds of the votes of holders of the interests under relevant Scheme (the “**Holders**”), who attend the Holders’ meeting, and subject to the approval of the Board of Directors of our Company, the term of the relevant Scheme may be extended, provided that each extension shall not exceed 12 months. Each Scheme may be terminated upon expiry of the respective lock up period as detailed below when all the assets underlying such Scheme become monetary assets.

On December 6, 2019, the Company, with the Board’s approval, extended the term of Scheme II for 12 months, up to December 11, 2020.

(d) Source of Shares under the Schemes

The Shares underlying the Schemes shall be A Shares purchased from the secondary market through bidding, block trade, share transfer or other methods in compliance with the applicable laws and regulations.

(e) Maximum Number of Shares

All the Shares underlying Scheme II have been purchased as of March 9, 2017. As of the Latest Practicable Date, the total number of Shares underlying Scheme II is 15,118,035 A Shares, accounting for approximately 1.21% of the total outstanding share capital of our Company.

All the Shares underlying Scheme III have been purchased as of February 1, 2019. The total number of Shares underlying Scheme III is 3,886,264 A Shares, accounting for approximately 0.31% of the total outstanding share capital of our Company as of the Latest Practicable Date.

The maximum number of shares to be granted to an employee under each Scheme shall not exceed 1% of the total outstanding share capital of our Company.

(f) Administration of the Schemes

The Holders’ meeting is the highest management authority of the Schemes. A management committee has been set up to oversee the daily management of respective Scheme.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

For Scheme II, the management committee has appointed Guolian Securities Co., Ltd to establish a single customer assets management plan. Guolian Securities Co., Ltd is responsible for the management of the assets underlying Scheme II, including purchasing and holding the Shares and cash under Scheme II.

For Scheme III, the management committee has appointed CMS Asset Management Co., Ltd to establish a single customer assets management plan. CMS Asset Management Co., Ltd is responsible for the management of the assets underlying Scheme III, including purchasing and holding the Shares and cash under Scheme III.

(g) Source of Funds to be Used to Purchase the Shares under the Schemes

The source of funds for the Schemes consists of (i) the funds raised by the participants and (ii) loans provided by the Controlling Shareholders of our Company.

The maximum amount of the funds to be raised for Scheme II and Scheme III shall not exceed RMB400 million and RMB87 million, respectively. The Holders shall pay the subscription amount before the establishment of the relevant single customer asset management plan.

(h) Lock-up Period

The Shares underlying Scheme II are not subject to lock-up as of the Latest Practicable Date.

The lock-up period for the Shares underlying Scheme III is from February 2, 2019 to February 1, 2020, being a period of 12 months commencing from the date of publication of the announcement in respect of the transfer of the last batch of Shares to the relevant single customer asset management plan.

(i) Rights of the Holders

The Holders of each Scheme are entitled to the following rights:

- 1) to share the interests of the assets underlying the Scheme in proportion to his holding in the Scheme;
- 2) to attend the general meeting of Holders in person or by proxy, and to exercise the corresponding voting rights;
- 3) to supervise the administration of the Scheme, and to make suggestions or inquiries as applicable;
- 4) to waive the voting rights attached to the underlying Shares of the Company he holds indirectly through the Scheme; and
- 5) to exercise other rights stipulated by laws, administrative regulations, or the terms of the Scheme.

(j) Obligations of the Holders

The Holders of each Scheme have the following obligations:

- 1) to assume the risks associated with Scheme in proportion to his holding in the Scheme;

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

- 2) to comply with the provisions of the Rules Governing Employee Share Scheme;
- 3) not to request the Company to distribute the assets underlying the Scheme during the term of the Scheme; and
- 4) to assume the obligations provided by applicable laws, administrative regulations and other obligations stipulated under the terms of the Scheme.

(k) Transfer of Holders' Interests

During the term of the respective Scheme, no Holder shall in any way transfer, withdraw, charge or mortgage his holding interests in the Scheme or use such interests to guarantee or repay debts except for unusual circumstances as provided under the terms of the relevant Scheme.

(l) Distribution of interests under the Schemes

Upon the expiry of the respective lock up period of each Scheme, the liquidation of the Scheme shall be completed within fifteen business days upon the sale of all the Shares underlying the Scheme. The proceeds from the sale of all the Shares underlying the Scheme shall be distributed in the following order:

- 1) to repay the loans provided by the Shareholders for the Scheme and the associated interests;
- 2) to repay the funds contributed by the employee and the associated return based on the performance of the employee in accordance with the terms of the Scheme; and
- 3) the remaining proceeds (if any) shall be distributed among the Holders in proportion to their interest in the Scheme.

D. OncoVent Share Option Scheme

The following is a summary of the principal terms of the OncoVent Share Option Scheme, the share option scheme adopted by our subsidiary, OncoVent, in June 2018. The OncoVent Share Option Scheme is not subject to the provisions of Chapter 17 of the Listing Rules.

(a) Purpose

The purpose of the OncoVent Share Option Scheme is to promote the long-term success of OncoVent and the interests of its shareholders and employees by providing a means through which OncoVent may grant equity-based incentives to motivate, attract and retain the services of its employees upon whose judgment, interest and special effort the successful conduct of OncoVent's operation is largely dependent.

(b) Scope of Participants

Those eligible to participate in the OncoVent Share Option Scheme include the employees of OncoVent who meet the performance targets.

(c) Administration of the Schemes

The OncoVent Share Option Scheme is administered by the board of directors of OncoVent (the “**Administrator**”). Pursuant to the OncoVent Share Option Scheme, the Administrator may, from time to time, select from eligible persons to whom awards in the form of options in OncoVent shares (“**OncoVent Options**”) will be granted.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

(d) Maximum number of shares

The maximum number of shares which may be granted under the OncoVent Share Option Scheme shall not exceed 10% of the total enlarged share capital of OncoVent taking into account the shares to be issued upon the exercise of the options.

(f) Term of OncoVent Share Option Scheme

OncoVent Options granted at each stage is valid for a period of four years. Grantees are subject to a lock-up period of one year commencing from the grant date.

(g) Exercise of OncoVent Options

The grantees may exercise the OncoVent Options within ten business days upon expiry of the lock up period in accordance with the terms of grant letter. When OncoVent is listed or sold, the participants may realise the benefit of share options based on the stock circulation rules at the listing place or the value of OncoVent at the time of sale. The participant may choose to convert the option into actual investment to OncoVent.

The exercise price per OncoVent Share underlying the OncoVent Options shall be determined by the Administrator with reference to the fair value of OncoVent. If OncoVent carries out financing transactions within the preceding twelve months, the fair value shall be determined with reference to the valuation of OncoVent for the purpose of such financing transactions. If no financing transaction is carried out during such twelve months period, the fair value shall be determined by the Administrator.

Outstanding OncoVent Options granted

The proposal to grant the OncoVent Options under the OncoVent Share Option Scheme as set out above has been approved by the boards of OncoVent and our Company.

As at the Latest Practicable Date, we proposed to grant OncoVent Options representing 4% of the enlarged share capital of OncoVent to one participant, namely Mr. Shi Yuenian (“**Mr. Shi**”) of 18 Yale Street, Roslyn Heights, New York, the United States, who acts as the CEO of OncoVent, provided that the participant reaches the agreed milestones. Mr. Shi will be granted OncoVent Options representing 2%, 1% and 1% of the enlarged share capital of OncoVent when the first, second and third milestone is reached, respectively.

<u>Milestones</u>	<u>Conditions</u>
The first milestone	The participant signs employment contract with OncoVent
The second milestone	OncoVent new pharmaceutical varieties obtains permission to carry out Phase III clinical trials from Chinese pharmaceutical regulatory authorities
The third milestone	New pharmaceutical varieties obtain permission to sell in the market from Chinese pharmaceutical regulatory authorities

The grant date is within one month when each milestone is reached. 40%, 30% and 30% of the OncoVent Options granted will vest in each of the three years following the expiry of the one-year lock up period. When and only when OncoVent is listed or sold, the grantee can choose to exercise OncoVent Options. As of the Latest Practicable Date, the conditions for the first milestone has been met and the conditions for the remaining milestones have yet to be met. The exercise price, corresponding to the fair value of the OncoVent Options granted to Mr. Shi upon the fulfillment of the first milestone, was approximately RMB1,271,000.

OncoVent does not intend to make any further grants of the OncoVent Options under the OncoVent Share Option Scheme after the [REDACTED].

3. FURTHER INFORMATION ABOUT OUR DIRECTORS AND SUPERVISORS

A. Particulars of Directors’ and Supervisors’ Contracts

Pursuant to Rules 19A.54 and 19A.55 of the Hong Kong Listing Rules, we have entered into a contract with each of our Directors and Supervisors in respect of, among other things, (i) compliance of relevant laws of regulations, (ii) observance of the Articles of Association, and (iii) provisions on arbitration.

Save as disclosed above, none of the Directors or Supervisors has or is proposed to have a service contract with any member of our Group (other than contracts expiring or determinable by the relevant employer within one year without the payment of compensation other than statutory compensation).

B. Remuneration of Directors and Supervisors

Save as disclosed in “Directors, Supervisors and Senior Management” and under “Appendix I—Accountant’s Report—Notes to the Financial Information—9. Directors’ and Supervisors’ Remuneration”, no Director or Supervisor received other remuneration or benefits in kind from our Company in respect of each of the two financial years ended December 31, 2018 and the nine months ended September 30, 2019.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

4. DISCLOSURE OF INTERESTS

A. Disclosure of Interests of Directors and Supervisors

Save as disclosed below, immediately following the completion of the [REDACTED] assuming that the [REDACTED] is not exercised, none of our Directors or Supervisors has any interest and/or short position in the Shares, underlying Shares and debentures of our Company or our associated corporations (within the meaning of Part XV of the SFO) which will be required to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interest or short position which they were taken or deemed to have under such provisions of the SFO) or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required, pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules to be notified to our Company, once the Shares are [REDACTED] on the Hong Kong Stock Exchange.

Name	Title	Nature of Interest	Class of Shares	Number of Shares	Approximate percentage of shareholding in the relevant class	Approximate percentage of shareholding in the total share capital immediately after the [REDACTED] (assuming that the [REDACTED] is not exercised)
Mr. Li (李鋈) ^{(1), (3)}	Chairman of the Board and Executive Director	Interest in a controlled corporation	A Shares	514,349,899	41.24%	[REDACTED]%
Ms. Li Tan (李坦) ^{(2), (3)}	Executive Director	Interest in a controlled corporation	A Shares	408,041,280	32.72%	[REDACTED]%
Mr. Shan Yu (單宇) ⁽⁴⁾	Executive Director	Interest in a controlled corporation; beneficial owner	A Shares	52,302,892	4.19%	[REDACTED]%
Mr. Haihua Bu (步海華) ⁽⁵⁾	Executive Director, secretary to the Board and deputy general manager	Beneficial owner	A Shares	585,068	0.05%	[REDACTED]%

Notes:

- (1) Mr. Li holds 99% of the equity interests of Leren Technology and 100% of the equity interests of Feilaishi. Thus, he is deemed to be interested in 474,029,899 A Shares held by Leren Technology and 40,320,000 A Shares held by Feilaishi. Pursuant to a stock pledge repurchase agreement, Leren Technology has pledged 43,600,000 A Shares held in our Company to Guotai Junan Securities Co. Ltd. on December 19, 2019.
- (2) Ms. Li holds 99% of the equity interests of Jintiantu as a general partner. Thus, she is deemed to be interested in 408,041,280 A Shares held by Jintiantu.
- (3) Mr. Li and Ms. Li are the spouse of each other and are both Directors of the Company. Therefore, they are not required to aggregate their interest in the Company under the SFO.
- (4) Mr. Shan holds 99% of the equity interests of Shuidi Shichuan. Thus, he is deemed to be interested in 46,425,600 A Shares held by Shuidi Shichuan. In addition, Mr. Shan has also participated in the Share Incentive Scheme II and has a 38.88% interest in 15,118,035 A Shares held by the asset manager for the benefit of the participants of the scheme.
- (5) Mr. Bu participated in Share Incentive Scheme II and has a 3.87% interest in 15,118,035 A Shares held by the asset manager for the benefit of the participants of the scheme, respectively.

Save as disclosed in this document, as of the Latest Practicable Date, none of the Directors or Supervisors or their respective spouses and children under 18 years of age had been granted by the Company or had exercised any rights to subscribe for shares or debentures of the Company or any of its associated corporations.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

B. Disclosure of Interests of Substantial Shareholders

For information on the persons who will, immediately following the completion of the [REDACTED], have interests or short positions in our Shares or underlying Shares which would be required to be disclosed to us and the Hong Kong Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, see the section headed “Substantial Shareholders.”

Interests of substantial shareholders in members of our Group (excluding our Company)

<u>Our subsidiaries</u>	<u>Registered/Issued share capital</u>	<u>Parties with 10% or more equity interest</u>	<u>Approximate percentage of shareholding (%)</u>
Shenzhen Arimab Biomedical Co., Ltd. (深圳市瑞迪生物醫藥有限公司)	US\$14,117,647	Aridis Pharmaceuticals, Inc.	49.00%
OncoVent	US\$9,259,259	OncoQuest Inc. Quest PharmaTech Inc.	29.00% 11.00%
Shenzhen Fanpu Biotechnology Co., Ltd. (深圳市返璞生物技術有限公司)	RMB1,000,000	Mr. Zhou Hongwei	30.30%
Shenzhen Penghe Property Management Co., Ltd. (深圳朋和物業管理有限公司)	RMB132,000,000	Yulong Computer Communication Technology (Shenzhen) Co., Ltd. Shenzhen Xizhilang Food R&D Center Co., Ltd.	35.00% 10.00%

C. Disclaimers

Save as disclosed in this document:

- (a) none of our Directors or Supervisors has any direct or indirect interest in the promotion of our Company, or in any assets which have within the two years immediately preceding the date of this document been acquired or disposed of by or leased to any member of our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group;
- (b) none of our Directors or Supervisors is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group taken as a whole; and
- (c) without taking into account any Shares which may be taken up under the [REDACTED], none of our Directors knows of any person (not being a Director or chief executive of our Company) who will, immediately following completion of the [REDACTED], be interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at shareholders’ meetings of any member of our Group in the Shares or underlying Shares of our Company.

5. OTHER INFORMATION

A. Estate Duty

Our Directors have been advised that no material liability for estate duty under the PRC laws is likely to fall on our Company or any of our subsidiaries.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

B. Litigation

As of the Latest Practicable Date, no member of our Group was engaged in any litigation or arbitration of material importance and, so far as our Directors are aware, no litigation or claim of material importance is pending or threatened by or against any member of our Group.

C. Joint Sponsors

Both of the Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules.

The Joint Sponsors have made an [REDACTED] on our behalf to the Listing Committee of the Stock Exchange for a [REDACTED] of, and permission to deal in, all the H Shares to be issued as mentioned in this document.

Pursuant to the engagement letter entered into between our Company and each of the Joint Sponsors, we have agreed to pay each of the Joint Sponsors a fee of US\$1,000,000 to act as the sponsors of our Company in connection with the proposed [REDACTED] on the Stock Exchange.

D. Compliance Advisor

Our Company has appointed Somerley Capital Limited as the compliance advisor in compliance with Rule 3A.19 of the Listing Rules.

E. Preliminary Expenses

We have not incurred any material preliminary expense.

F. Promoters

Information of our promoters as of the time of our Company’s conversion is as follows:

<u>No.</u>	<u>Name</u>
1.	Leren Technology
2.	Jintiantu
3.	GS Pharma
4.	Shuidi Shichuan
5.	Feilaishi
6.	Yingshi Information

Save as disclosed in this document, within the two years immediately preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given nor is any proposed to be paid, allotted or given to any promoters in connection with the [REDACTED] and the related transactions described in this document.

APPENDIX VI

STATUTORY AND GENERAL INFORMATION

G. Qualification of Experts

The qualifications of the experts, as defined under the Hong Kong Listing Rules, who have given opinions in this document, are as follows:

<u>Name</u>	<u>Qualification</u>
Goldman Sachs (Asia) L.L.C. . . .	Licensed to conduct type 1 (dealing in securities), type 4 (advising on securities), type 5 (advising on futures contracts), type 6 (advising on corporate finance) and type 9 (asset management) regulated activities under the SFO
Morgan Stanley Asia Limited . . .	Licensed to conduct type 1 (dealing in securities), type 4 (advising on securities), type 5 (advising on futures contracts), type 6 (advising on corporate finance), and type 9 (asset management) regulated activities under the SFO
Ernst & Young	Certified Public Accountants
Tian Yuan Law Firm	PRC legal advisor
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Independent industry consultant
Hogan Lovells	Legal advisor as to International Sanctions

H. Consents of Experts

Each of the experts named in paragraph G of this Appendix has given and has not withdrawn its written consent to the issue of this document with the inclusion of its report and/or letter and/or opinion and/or the references to its name included herein in the form and context in which it is respectively included.

Save for (a) Goldman Sachs (Asia) L.L.C. and its affiliates’ interest in 249,403 A Shares; and (b) Morgan Stanley Asia Limited and its affiliates’ interest in 58,586 A Shares, as of the Latest Practicable Date, none of the experts named above has any shareholding interests in any member of our Group or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

I. Taxation of Holders of H Shares

The sale, purchase and transfer of H Shares are subject to Hong Kong stamp duty. The current rate charged on each of the seller and purchaser is HK\$1.00 for every HK\$1,000 (or part thereof) of the consideration or, if higher, the fair value of the H Shares being sold or transferred.

J. Binding Effect

This document shall have the effect, if an application is made in pursuant hereof, of rendering all persons concerned bound by all the provisions (other than the penal provisions) of sections 44A and 44B of the Hong Kong Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

K. Related Party Transactions

Our Group entered into the related party transactions within the two years immediately preceding the date of this document as mentioned in “Appendix I—Accountant’s Report—46. Related Party Transactions”.

L. Miscellaneous

Save as disclosed in this document:

- (a) within the two years immediately preceding the date of this document:
 - (i) no share or loan capital of our Company or any of our subsidiaries has been issued or agreed to be issued, or is proposed to be fully or partly paid either for cash or a consideration other than cash;
 - (ii) no share or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option;
 - (iii) no commissions, discounts, brokerages or other special terms have been granted or agreed to be granted in connection with the issue or sale of any share of our Company or any of our subsidiaries; and
 - (iv) no commission has been paid or is payable for subscription, agreeing to subscribe, procuring subscription or agreeing to procure subscription for any share in or debentures of our Company;
- (b) there are no founder, management or deferred shares or any debentures in our Company or any of our subsidiaries;
- (c) there has not been any interruption in the business of our Group which may have or has had a significant effect on the financial position of our Group in the 12 months preceding the date of this document;
- (d) our Company has no outstanding convertible debt securities or debentures;
- (e) there is no arrangement under which future dividends are waived or agreed to be waived;
- (f) save for our A Shares which are listed on the Shenzhen Stock Exchange and the H Shares to be issued in connection with the [REDACTED], none of our equity and debt securities is listed or dealt with in any other stock exchange nor is any listing or permission to deal being or proposed to be sought;
- (g) the Company currently does not intend to apply for the status of a sino-foreign investment joint stock limited liability company and does not expect to be subject to the Law of the PRC on Sino-foreign Equity Joint Ventures;
- (h) there are no procedures for the exercise of any right of pre-emption or transferability of subscription rights;
- (i) there are no restrictions affecting the remittance of profits or repatriation of capital by us into Hong Kong from outside Hong Kong; and
- (j) all necessary arrangements have been made to enable the H shares to be admitted into CCASS for clearing and settlement.

M. No Material Adverse Change

Except as disclosed in “Summary—Recent Developments,” our Directors have confirmed, after performing all the due diligence work which the Directors consider appropriate, that, as of the date of this document, there has been no other material adverse change in our financial position or prospects since September 30, 2019 and there has been no other event since September 30, 2019 which would have material adverse effect on the information presented in the Accountants’ Report in Appendix I to this document.

N. Bilingual Document

The English language and Chinese language versions of this document are being published separately, in reliance upon the exemption provided by section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

**APPENDIX VII DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES
IN HONG KONG AND AVAILABLE FOR INSPECTION**

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to the copy of this document delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) a copy of each of the [REDACTED], [REDACTED] and [REDACTED];
- (b) a copy of each of the material contracts referred to in the section headed “2. Further Information About Our Business—A. Summary of Our Material Contracts” in Appendix VI to this document; and
- (c) the written consents referred to in the section headed “5. Other information—H. Consents of Experts” in Appendix VI to this document.

DOCUMENTS AVAILABLE FOR INSPECTION

Copies of the following documents will be available for inspection at the offices of Davis Polk & Wardwell at 18/F, The Hong Kong Club Building, 3A Chater Road, Hong Kong, during normal business hours up to and including the date which is 14 days from the date of this document:

- (a) the Articles of Association;
- (b) the Accountants’ Report from Ernst & Young, the text of which is set out in Appendix I to this document;
- (c) the consolidated audited financial statements of our Group for the three years ended December 31, 2017, 2018 and 2019;
- (d) the report from Ernst & Young relating to the unaudited [REDACTED], the text of which is set out in Appendix II to this document;
- (e) the material contracts referred to in the section headed “2. Further Information About Our Business—A. Summary of Our Material Contracts” in Appendix VI to this document;
- (f) the written consents referred to in the section headed “5. Other Information—H. Consents of Experts” in Appendix VI to this document;
- (g) the service contracts referred to in the section headed “3. Further Information About Our Directors and Supervisors—A. Particulars of Directors’ and Supervisors’ Contracts” in Appendix VI to this document;
- (h) the legal opinions issued by Tian Yuan Law Firm, our legal advisor as to PRC law in respect of our general matters and property interests of the Group;
- (i) the legal memorandum issued by Hogan Lovells, our International Sanctions legal advisor;
- (j) the industry report issued by Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., the summary of which is set forth in the section headed “Industry Overview”;
- (k) the PRC Company Law, the Mandatory Provisions and the Special Regulations together with their unofficial English translations; and
- (l) the Shenzhen Stock Exchange Listing Rules, together with an unofficial English translation.