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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019.

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

For the transition period from to

Commission file number: 001-39173

I-MAB

(Exact Name of Registrant as Specified in Its Charter)

N/A
(Translation of Registrant's Name Into English)

Cayman Islands
(Jurisdiction of Incorporation or Organization)

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Shanghai, 201210
People's Republic of China
(Address of Principal Executive Offices)

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Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange On Which Registered
American depositary shares, each ten (10)	**IMAB**	The Nasdaq Stock Market LLC
American depositary shares representing twenty-three (23) ordinary shares		(The Nasdaq Global Market)
Ordinary shares, par value US$0.0001 per share*		The Nasdaq Stock Market LLC
		(The Nasdaq Global Market)

*Not for trading, but only in connection with the listing on the Nasdaq Global Market of American depositary shares.

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

133,006,644 ordinary shares outstanding, par value of US$0.0001 per share, as of December 31, 2019

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐ Yes ☒ No

†The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accountant firm that prepared or issued its audit report. ☐ Yes ☒ No

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒ International Financial Reporting Standards as issued by the International Accounting Standards Board ☐ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. ☐ Yes ☐ No

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INTRODUCTION

Unless otherwise indicated and except where the context otherwise requires, references in this annual report on Form 20-F to:

- "ADRs" refer to the American depositary receipts that evidence our ADSs;
- "ADSs" refer to our American depositary shares, each ten (10) ADSs represent twenty-three (23) ordinary shares;
- "China" or "the PRC" refers to the People's Republic of China, excluding, for the purposes of this annual report only, Hong Kong, Macau and Taiwan, and "Greater China" does not exclude Hong Kong, Macau and Taiwan;
- "China Portfolio" refers to our investigational drugs of which we in-license Greater China rights from reputable global biopharmaceutical companies and rely on our own research and development capabilities to advance into pivotal clinical trials and commercialize in Greater China with an aim for near-term product launch;
- "Global Portfolio" refers to our own proprietary novel or differentiated drug candidates that we are advancing towards clinical validation in the United States;
- "I-Mab," "we," "us," "our company" and "our" refer to I-Mab, a Cayman Islands exempted company, and its subsidiaries;
- "RMB" refers to the legal currency of China;
- "shares" or "ordinary shares" refer to our ordinary shares, par value US$0.0001 per share; and
- "US$," "U.S. dollars," "$," and "dollars" refer to the legal currency of the United States.

FORWARD-LOOKING STATEMENTS

This annual report on Form 20-F contains forward-looking statements that relate to our current expectations and views of future events. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. These statements are made under the "safe harbor" provisions of the U.S. Private Securities Litigations Reform Act of 1995.

You can identify some of these forward-looking statements by words or phrases such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "is/are likely to," "potential," "continue" or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include statements relating to:

- the timing of initiation and completion, and the progress of our drug discovery and research programs;
- the timing and likelihood of regulatory filings and approvals;
- our ability to advance our drug candidates into drugs, and the successful completion of clinical trials;
- the approval, pricing and reimbursement of our drug candidates;
- the commercialization of our drug candidates;
- the market opportunities and competitive landscape of our drug candidates;
- the payment, receipt and timing of any milestone payments in relation to the licensing agreements;
- estimates of our costs, expenses, future revenues, capital expenditures and our needs for additional financing;
- our ability to attract and retain senior management and key employees;
- our future business development, financial condition and results of operations;
- future developments, trends, conditions and competitive landscape in the industry and markets in which we operate;
- our strategies, plans, objectives and goals and our ability to successfully implement these strategies, plans, objectives and goals;
- our ability to continue to maintain our market position in China's biopharmaceutical and biotechnology industries;
- our ability to identify and integrate suitable acquisition targets;
- changes to regulatory and operating conditions in our industry and markets; and
- potential impact of COVID-19 outbreak on our current and future business development, financial condition and results of operations.

You should read this annual report and the documents that we refer to in this annual report and have filed as exhibits to this annual report completely and with the understanding that our actual future results may be materially different from what we expect. Other sections of this annual report discuss factors which could adversely impact our business and financial performance. Moreover, we operate in an evolving environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements.

You should not rely upon forward-looking statements as predictions of future events. The forward-looking statements made in this annual report relate only to events or information as of the date on which the statements are made in this annual report. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events.

Our reporting currency is Renminbi, or RMB. Unless otherwise noted, all translations from RMB to U.S. dollars and from U.S. dollars to RMB in this annual report are made at a rate of RMB6.9618 to US$1.00, the exchange rate in effect as of December 31, 2019 as set forth in the H.10 statistical release of The Board of Governors of the Federal Reserve System. We make no representation that any RMB or U.S. dollar amounts could have been, or could be, converted into U.S. dollars or RMB, as the case may be, at any particular rate, or at all.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3.KEY INFORMATION

A. Selected Financial Data

The following selected consolidated statements of operating data for the years ended December 31, 2017, 2018 and 2019, selected consolidated balance sheet data as of December 31, 2018 and 2019 and selected consolidated cash flow data for the years ended December 31, 2017, 2018 and 2019 have been derived from our audited consolidated financial statements included elsewhere in this annual report. The summary consolidated balance sheet data as of December 31, 2017 have been derived from our audited consolidated financial statements that are not included in this annual report. Our consolidated financial statements are prepared and presented in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP.

Our historical results do not necessarily indicate results expected for any future periods. The selected consolidated financial data should be read in conjunction with, and are qualified in their entirety by reference to, our audited consolidated financial statements and related notes and "Item 5. Operating and Financial Review and Prospects" below. Our consolidated financial statements are prepared and presented in accordance with U.S. GAAP.

	For the Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$
	(in thousands, except for per share data)			
Selected Consolidated Statements of Comprehensive Loss Data:				
Revenues				
Licensing and collaboration revenue	11,556	53,781	30,000	4,309
Expenses				
Research and development expenses (1)	(267,075)	(426,028)	(840,415)	(120,718)
Administrative expenses (1)	(25,436)	(66,391)	(654,553)	(94,021)
Loss from operations	(280,955)	(438,638)	(1,464,968)	(210,430)
Interest income	858	4,597	30,570	4,391
Interest expense	(5,643)	(11,695)	(2,991)	(430)
Other income (expenses), net	1,527	(16,780)	(20,205)	(2,902)
Fair value change of warrants	(14,027)	61,405	5,644	811
Loss before income tax expense	(298,240)	(401,111)	(1,451,950)	(208,560)
Income tax expense	—	(1,722)	—	—
Net loss attributable to I-Mab	(298,240)	(402,833)	(1,451,950)	(208,560)
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	—	—	(5,283)	(759)
Deemed dividend to Series B-1, B-2 and C preferred shareholders at modification of Series B-1, B-2 and C Preferred Shares	—	—	(27,768)	(3,989)
Net loss attributable to ordinary shareholders	(298,240)	(402,833)	(1,485,001)	(213,308)
Other comprehensive income				
Foreign currency translation adjustments, net of nil tax	5,918	53,689	10,747	1,544

Total comprehensive loss attributable to I-Mab	**(292,322)**	**(349,144)**	**(1,441,203)**	**(207,016)**
Net loss attributable to ordinary share-holders	**(298,240)**	**(402,833)**	**(1,485,001)**	**(213,308)**
Weighted-average number of ordinary shares used in calculating net loss per shares				
Basic and diluted	5,742,669	6,529,092	7,381,230	7,381,230
Net loss per share attributable to ordinary shareholders				
Basic	(51.93)	(61.70)	(201.19)	(28.90)
Diluted	(51.93)	(61.70)	(201.19)	(28.90)

Notes:

(1) Share-based compensation expenses were allocated as follows:

	For the Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$
	(in thousands)			
Research and development expenses	2,112	1,056	470	68
Administrative expenses	4,927	2,464	514,733	73,936
Total	**7,039**	**3,520**	**515,203**	**74,004**

	As of December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$
	(in thousands)			
Selected Consolidated Statements of Balance Sheet Data:				
Current assets:				
Cash and cash equivalents	307,930	1,588,278	1,137,473	163,388
Restricted cash	104,783	92,653	55,810	8,017
Contract assets	—	11,000	—	—
Short-term investments	—	—	32,000	4,597
Prepayments and other receivables	12,633	88,972	136,036	19,540
Other financial assets	266,245	255,958	—	—
Total current assets	691,591	2,036,861	1,361,319	195,542
Property, equipment and software	22,336	27,659	30,069	4,319
Operating lease right-of-use assets	—	—	16,435	2,361
Intangible assets	148,844	148,844	148,844	21,380
Goodwill	162,574	162,574	162,574	23,352
Other non-current assets	—	—	18,331	2,633
Total assets	**1,025,345**	**2,375,938**	**1,737,572**	**249,587**
Total liabilities	**309,151**	**415,684**	**668,090**	**95,964**
Total mezzanine equity	**1,015,989**	**2,915,358**	**3,104,177**	**445,887**
Shareholders' deficit				
Ordinary shares (US$0.0001 par value, 500,000,000 shares authorized as of December 31, 2018 and 2019; 8,363,719 shares issued and outstanding as of December 31, 2018 and 2019)	6	6	6	1
Treasury stock	(1)	(1)	—	—
Additional paid-in capital	52,369	—	389,379	55,931
Accumulated other comprehensive income	5,691	59,380	70,127	10,074
Accumulated deficit	(357,860)	(1,014,489)	(2,494,207)	(358,270)
Total shareholders' deficit	**(299,795)**	**(955,104)**	**(2,034,695)**	**(292,264)**
Total liabilities, mezzanine equity and shareholders' deficit	**1,025,345**	**2,375,938**	**1,737,572**	**249,587**

	Years Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$
	(in thousands)			
Selected Consolidated Statements of Cash Flow Data:				
Net cash used in operating activities	(252,157)	(280,705)	(867,982)	(124,678)
Net cash (used in) generated from investing activities	(157,665)	9,500	212,462	30,518
Net cash generated from financing activities	758,585	1,479,669	152,709	21,936
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(132)	59,754	15,163	2,178
Net increase (decrease) in cash, cash equivalents and restricted cash	348,631	1,268,218	(487,648)	(70,046)
Cash, cash equivalents and restricted cash, beginning of the year	64,082	412,713	1,680,931	241,451
Cash, cash equivalents and restricted cash, end of the year	412,713	1,680,931	1,193,283	171,405

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical stage biopharmaceutical company with a limited operating history. Our operations to date have focused on organizing and staffing our operations, business planning, raising capital, establishing our intellectual property portfolio and conducting pre-clinical and clinical trials of our drug candidates. We have not yet demonstrated an ability to successfully manufacture, obtain marketing approvals for or commercialize our drug candidates. We have no products approved for commercial sale and have not generated any revenue from product sales. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history.

We are focused on the discovery and development of innovative drugs for the treatment of various immuno-oncological and immuno-inflammatory diseases. Our limited operating history, particularly in light of the rapidly evolving drug research and development industry in which we operate and the changing regulatory and market environments we encounter, may make it difficult to evaluate our prospects for future performance. As a result, any assessment of our future performance or viability is subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. If we do not address these risks and difficulties successfully, our business will suffer.

We have incurred net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.

Investment in the development of biopharmaceutical products is highly speculative as it entails substantial upfront capital expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and/or safety to gain regulatory or marketing approvals or become commercially viable. To date, we have financed our activities primarily through private placements. While we have generated revenue from licensing and collaboration deals, we have not generated any revenue from commercial product sales to date, and we continue to incur significant research and development expenses and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred net losses in each period since our inception. In 2017, 2018 and 2019, our net losses were RMB298.2 million, RMB402.8 million and RMB1,452.0 million (US$208.6 million), respectively. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur net losses in the foreseeable future, and that these net losses will increase as we carry out certain activities relating to our development, including, but not limited to, the following:

- conducting clinical trials of our drug candidates;
- manufacturing clinical trial materials through contract manufacturing organizations, or CMOs, in and out of China;
- seeking regulatory approvals for our drug candidates;
- commercializing our drug candidates for which we have obtained marketing approval;
- completing the construction of and maintaining our manufacturing facilities;
- hiring additional clinical, operational, financial, quality control and scientific personnel;
- establishing a sales, marketing and commercialization team for any future products that have obtained regulatory approval;
- seeking to identify additional drug candidates;
- obtaining, maintaining, expanding and protecting our intellectual property portfolio;
- enforcing and defending any intellectual property-related claims; and
- acquiring or in-licensing other drug candidates, intellectual property and technologies.

Typically, it takes many years to develop one new drug from the time it is discovered to when it becomes available for treating patients. During the process, we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend partially on the rate of the future growth of our expenses, our ability to generate revenues and the timing and amount of milestone payments and other payments that we receive from or pay to third parties. If any of our drug candidates fails during clinical trials or does not gain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and shareholders' equity.

We recorded net cash outflow from operating activities since our inception. We may need to obtain additional financing to fund our operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our major drug candidates.

Since our inception, our operations have consumed substantial amounts of cash. We had raised over US$400 million in pre-IPO financing in the past three years and received total net proceeds of approximately US$105.3 million from our initial public offering. We spent RMB252.2 million, RMB280.7 million and RMB868.0 million (US$124.7 million) in net cash to finance our operations in 2017, 2018 and 2019, respectively.

We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical-stage drug candidates, continue the research and development of our pre-clinical stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates.

In addition, if we obtain regulatory approvals for any of our drug candidates, we expect to incur significant commercialization expenses relating to product manufacturing, marketing, sales and distribution and post-approval commitments to continue monitoring the efficacy and safety data of our future products on the market. In particular, costs that may be required for the manufacture of any drug candidate that has received regulatory approval may be substantial as we may need to modify or increase our production capacity in the future at manufacturing facilities. We may also incur expenses as we create additional infrastructure to support our operations as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts.

The recent COVID-19 outbreak has brought uncertainties and interruptions to global economy and caused significant volatility across the financial markets, which had a cooling effect on the financing and investing activities in general. We believe that our current cash and cash equivalents, together with our cash generated from operating activities, financing activities and our initial public offering, will be sufficient to meet our present anticipated working capital requirements and capital expenditures. However, if the impact of the COVID-19 and volatility in the financial markets continue, our financing activities in future to raise additional capital may be materially and adversely affected, which may in turn have an adverse effect on our ability to meet our working capital requirement and our liquidity. For other risks related to the COVID-19, see "—Our business and results of operations could be adversely affected by public health crisis (including the COVID-19 global pandemic) and natural catastrophes or other disasters outside of our control in the locations in which we, our suppliers, CROs, CMOs and other contractors operate."

Raising additional capital may cause dilution to the interests to the holders of our ADSs and our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations, licensing arrangements, strategic alliances or partnerships and government grants or subsidies. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our ADSs. The incurrence of additional indebtedness or the issuance of certain equity securities could give rise to increased fixed payment obligations and also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our ADSs to decline.

In the event we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party our rights to technologies or drug candidates on unfavorable terms, which we would have otherwise sought to develop or commercialize on our own or reserve for future potential arrangements when we are more likely to achieve more favorable terms.

Risks Related to Clinical Development of Our Drug Candidates

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. While our exclusive focus is to develop drug candidates with potential to become novel or highly differentiated drugs in China and globally, we cannot guarantee that we are able to achieve this for any of our drug candidates. Failure can occur at any time during the clinical development process. The results of pre-clinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates during later stages of clinical trials may fail to show the desired results in safety and efficacy despite having progressed through pre-clinical studies and initial clinical trials and despite the level of scientific rigor in the study, design and adequacy of execution. In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, differences in individual patient conditions, including genetic differences, and other compounding factors, such as other medications or pre-existing medical conditions.

In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. We cannot guarantee that our future clinical trial results will be favorable based on currently available clinical and pre-clinical data.

We depend substantially on the success of our drug candidates, all of which are in pre-clinical or clinical development, and our ability to identify additional drug candidates. If we are unable to successfully identify new drug candidates, complete clinical development, obtain regulatory approval and commercialize our drug candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business will depend on the successful development, regulatory approval and commercialization of our drug candidates for the treatment of patients with our targeted indications, all of which are still in pre-clinical or clinical development, and other new drug candidates that we may identify and develop. As of the date of this annual report, we have obtained IND approvals from the NMPA for six of our drug candidates, TJ202, TJ301, TJ107, TJC4, TJD5 and TJM2. In addition, we have obtained IND approvals from the FDA for three of our drug candidates, TJC4, TJD5 and TJM2; from the Taiwan Food and Drug Administration (the "TFDA") for two of our drug candidates, TJ202 and TJ301; and from the Korea Ministry of Food and Drug Safety (the "MFDS") for TJ301. However, we cannot guarantee that we are able to obtain regulatory approvals for our other existing drug candidates in a timely manner, or at all. In addition, none of our drug candidates has been approved for marketing in China or any other jurisdiction. Each of our drug candidates will require additional pre-clinical and/or clinical development, regulatory approvals in multiple jurisdictions, development of manufacturing supply and capacity, substantial investment and significant marketing efforts before we generate any revenue from product sales.

The success of our drug candidates will depend on several factors, including but not limited to the successful completion of pre-clinical and/or clinical trials or studies, receipt of regulatory approvals from applicable regulatory authorities for planned clinical trials, future clinical trials or drug registrations, establishing adequate manufacturing capabilities and capacities, commercialization of our existing drug candidates, hiring sufficient technical experts to oversee all development and regulatory activities and license renewal and meeting of the safety requirements.

If we do not achieve one or more of these in a timely manner or at all, we could experience significant delays in our ability to obtain approval for our drug candidates, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations. As a result, our financial condition, results of operations and prospects will be materially and adversely harmed.

We may not be able to identify, discover or in-license new drug candidates, and 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.

Although a substantial amount of our effort will focus on the continued clinical testing, potential approval, and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to identify, license, discover, develop, or commercialize additional drug candidates. Research programs to identify new drug candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or drug candidates that ultimately prove to be unsuccessful. Our research programs or licensing efforts may fail to identify, discover or in-license new drug candidates for clinical development and commercialization for a number of reasons, including, without limitation, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential drug candidates;
- our potential drug candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; and
- it may take greater human and financial resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs than we possess, thereby limiting our ability to diversify and expand our drug portfolio.

Because we have limited financial and managerial resources, we focus on research programs and drug candidates for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that later may prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects.

If we encounter delays or difficulties enrolling patients in our clinical trials, our clinical development progress could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the NMPA, the FDA, or similar regulatory authorities, or if there are delays in the enrollment of eligible patients as a result of the competitive clinical enrollment environment. The inability to enroll a sufficient number of patients who meet the applicable criteria for our clinical trials would result in significant delays. As of the date of this annual report, we have initiated clinical trials for TJ301 in South Korea and Greater China, for TJ107 in China, for TJ202 in Greater China, for TJC4 in China and the United States, and for TJM2 and TJD5 in the United States. In addition, we expect to initiate clinical trials for TJM2 and TJD5 in 2020 in China.

In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in the clinical trials of our competitors' drug candidates, which may further delay our clinical trial enrollments.

Patient enrollment for our clinical trials may be affected by other factors, including but not limited to the following:

- severity of the disease under investigation;
- total size and nature of the relevant patient population;
- design and eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the drug candidate under study;
- our resources to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- availability of competing therapies also undergoing clinical trials;
- our investigators' or clinical trial sites' efforts to screen and recruit eligible patients; and
- proximity and availability of clinical trial sites for prospective patients.

Even if we are able to enroll a sufficient number of patients in our clinical trials, 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 our ability to advance the development of our drug candidates.

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, without limitation:

- 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, including problems with manufacturing, supply quality, compliance with good manufacturing practice, or GMP, or obtaining sufficient quantities of a drug candidate from third parties for use in a clinical trial;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide to conduct additional clinical trials or abandon drug development programs, or regulators may require us to do so;
- 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;
- our 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;
- we might have to suspend or terminate clinical trials of our drug candidates 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;
- regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements;
- 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.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently plan, if we are unable to successfully complete clinical trials of our drug candidates or other testing, 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) obtain approval for indications that are not as broad as intended; (iii) not obtain regulatory approval at all; (iv) have the drug removed from the market after obtaining regulatory approval; (v) be subject to additional post-marketing testing requirements; (vi) be subject to restrictions on how the drug is distributed or used; or (vii) 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.

Risks Related to Obtaining Regulatory Approval for Our Drug Candidates

All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated.

All jurisdictions in which we intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We intend to focus our activities in the major markets of China and the United States. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include: refusal to approve pending applications; withdrawal of an approval; license revocation; clinical hold; voluntary or mandatory product recalls; product seizures; total or partial suspension of production or distribution; injunctions; fines; refusals of government contracts; providing restitution; undergoing disgorgement; or other civil or criminal penalties. Failure to comply with these regulations could have a material adverse effect on our business.

The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and may evolve over time, and if we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain the approval of the NMPA, the FDA and other comparable regulatory authorities is inherently uncertain and depends on numerous factors, including the substantial discretion of the regulatory authorities. Generally, such approvals take many years to obtain following the commencement of pre-clinical studies and clinical trials, although they are typically provided within 12 to 18 months after clinical trials are completed. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions. As of the date of annual report, we have obtained IND approvals from the NMPA for TJ202, TJ301, TJ107, TJC4, TJD5 and TJM2. In addition, we have obtained IND approvals from the FDA for TJC4, TJD5 and TJM2, from the TFDA for TJ202 and TJ301 and from the MFDS for TJ301. However, we cannot guarantee that we are able to obtain regulatory approvals for our other existing drug candidates or any drug candidates we may discover, in-license or acquire and seek to develop in the future.

Our drug candidates could fail to receive the regulatory approval of the NMPA, the FDA or a comparable regulatory authority for many reasons, including, without limitation:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective and potent for its proposed indication;
- failure of our clinical trial results to meet the level of statistical significance required for approval;
- failure of our clinical trial process to pass relevant good clinical practice ("GCP") inspections;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from pre-clinical studies or clinical trials;
- insufficient data collected from the clinical trials of our drug candidates to support the submission and filing of a new drug application, or NDA, or other submissions or to obtain regulatory approval;
- failure of our drug candidates to pass current Good Manufacturing Practice ("cGMP"), inspections during the regulatory review process or across the production cycle of our drug;
- failure of our clinical sites to pass audits carried out by the NMPA, the FDA or comparable regulatory authorities, resulting in a potential invalidation of our research data;
- findings by the NMPA, the FDA or comparable regulatory authorities of deficiencies related to our manufacturing processes or the facilities of third-party manufacturers with whom we contract for clinical and commercial supplies;
- changes in approval policies or regulations that render our pre-clinical and clinical data insufficient for approval; and

- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

The NMPA, the FDA or a comparable regulatory authority may require more information, including additional pre-clinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a drug candidate with an indication that is not desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

The absence of patent linkage, patent term extension and data and market exclusivity for NMPA-approved pharmaceutical products could increase the risk of early generic competition with our products in China.

In the United States, the Federal Food, Drug and Cosmetic Act, as amended by the law generally referred to as "Hatch-Waxman," provides the opportunity for patent-term restoration, meaning a patent term extension of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Finally, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the United States to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the United States Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where the FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

Depending upon the timing, duration and specifics of any FDA marketing approval process for any drug candidates we may develop, one or more of our U.S. patents, if issued, may be eligible for limited patent term extension under Hatch-Waxman. Hatch-Waxman permits a patent extension term of up to five years as compensation for patent term lost during clinical trials and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Furthermore, the applicable time period or the scope of patent protection afforded could be less than we request.

In China, however, there is no currently effective law or regulation providing for patent term extension, patent linkage, or data exclusivity (referred to as regulatory data protection). Therefore, a lower-cost generic drug can emerge onto the market much more quickly. Chinese regulators have set forth a framework for integrating patent linkage and data exclusivity into the Chinese regulatory regime, as well as for establishing a pilot program for patent term extension. To be implemented, this framework will require adoption of regulations. To date, no regulations have been issued. These factors result in weaker protection for us against generic competition in China than could be available to us in the United States. For instance, the patents we have in China are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

Our drug candidates may cause undesirable adverse events or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval.

Undesirable adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a more restrictive label, a delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or a significant change in our clinical protocol or even our development plan. In particular, as is the case with drugs treating cancers and auto-immune diseases, it is likely that there may be side effects, such as nausea, fatigue and infusion-related reactions, associated with the use of certain of our drug candidates. Results of our trials could reveal a high and unacceptable severity or prevalence of certain adverse events. In such an event, our trials could be suspended or terminated and the NMPA, the FDA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Adverse events related to our drug candidates may affect patient recruitment or the ability of enrolled subjects to complete the trial, and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

Additionally, if we or others identify undesirable side effects caused by those of our existing drug candidates that have received regulatory approval, or our other drug candidates after having received regulatory approval, this may lead to potentially significant negative consequences which include, but are not limited to, the following:

- we may suspend marketing of the drug candidate;
- regulatory authorities may withdraw their approvals of or revoke the licenses for the drug candidate;
- regulatory authorities may require additional warnings on the label;
- the FDA may require the establishment of a Risk Evaluation and Mitigation Strategy, or REMS, or the NMPA or a comparable regulatory authority may require the establishment of a similar strategy that may, for instance, restrict distribution of our drugs and impose burdensome implementation requirements on us;
- we may be required to conduct specific post-marketing studies;
- we could be subjected to litigation proceedings and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any particular drug candidate that is approved and could significantly harm our business, results of operations and prospects.

Further, combination therapy, such as using our wholly-owned drug candidates as well as third-party agents, may involve unique adverse events that could be exacerbated compared with adverse events from monotherapies. Results of our trials could reveal a high and unacceptable severity or prevalence of adverse events. These types of adverse events could be caused by our drug candidates and could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a more restrictive indication or the delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authority.

If we are unable to obtain the NMPA approval for our drug candidates to be eligible for an expedited registration pathway as innovative drug candidates, the time and cost we incur to obtain regulatory approvals may increase.

The NMPA has mechanisms in place for expedited review and approval for drug candidates that are innovative drug applications, provided such drug or drug candidate has a new and clearly defined structure, pharmacological property and apparent clinical value and has not been marketed anywhere in the world. However, there is no assurance that an innovative drug designation will be granted by the NMPA for any of our drug candidates. Moreover, an innovative drug designation, which is typically granted only towards the end of a drug's developmental stage, does not increase the likelihood that our drug candidates will receive regulatory approval on a fast-track basis, or at all.

Further, there have been recent regulatory initiatives in China in relation to clinical trial approvals, the evaluation and approval of certain drugs and medical devices and the simplification and acceleration of the clinical trial process.

As a result, the regulatory process in China is evolving and subject to change. Any future policies, or changes to current polices might require us to change our planned clinical study design or otherwise spend additional resources and effort to obtain approval of our drug candidates. In addition, policy changes may contain significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our drug candidates in the PRC, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of our drug candidates or any other drug candidate that we may in-license, acquire or develop in the future.

Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

If the NMPA, the FDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any chemistry, manufacturing, and controls ("CMC"), variations, continued compliance with current cGMPs, and GCPs and potential post-approval studies for the purposes of license renewal.

Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase 4 studies for the surveillance and monitoring of the safety and efficacy of the drug.

In addition, once a drug is approved by the NMPA, the FDA or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on our clinical trials;
- refusal by the NMPA, the FDA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- refusal by the NMPA, the FDA or comparable regulatory authorities to accept any of our other IND approvals, NDAs or BLAs;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could significantly harm our business, financial condition and prospects.

Illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The illegal importation of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in China and other countries where we commercialize our products. Unapproved foreign imports of prescription drugs are illegal under the current laws of China. However, illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (which are known as parallel imports) into higher-priced markets could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. In addition, competent government authorities may expand consumers' ability to import lower priced versions of our future approved products or competing products from outside China or other countries where we operate. Any future legislation or regulations that increase consumer access to lower priced medicines from outside China or other countries where we operate could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be 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 China, 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 could quickly erode the demand for our future approved drug candidates.

In addition, counterfeit pharmaceutical products are not expected to meet our or our collaborators' rigorous manufacturing and testing standards. A patient who receives a counterfeit pharmaceutical product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaborators' brand name(s). In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

Risks Related to Commercialization of Our Drug Candidates

Our drug candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if our drug candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians and patients and others in the medical community. Physicians and patients may prefer other drugs or drug candidates to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drugs or drug candidates and may not become profitable.

The degree of market acceptance of our drug candidates, if and only when they are approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals and patients considering our drug candidates as a safe and effective treatment;
- whether our drug candidates have achieved the perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;

- product labeling or package insert requirements of the NMPA, the FDA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the NMPA, the FDA or other comparable regulatory authorities;
- timing of market introduction of our drug candidates as well as competitive drugs;
- cost of treatment in relation to alternative treatments;
- availability of adequate coverage and reimbursement under the national and provincial reimbursement drug lists in the PRC, or from third-party payors and government authorities in the United States or any other jurisdictions;
- willingness of patients to pay any out-of-pocket expenses in the absence of coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared with alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our drug candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue or become profitable. Even if our drugs achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced which are more favorably received than our drugs, are more cost effective or render our drugs obsolete.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. While our exclusive focus is to develop drug candidates with potential to become novel or highly differentiated drugs, we continue to face competition with respect to our current drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future. Our competitors include major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. We are developing our drug candidates for the treatment of cancer in competition with a number of large biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs also for the treatment of cancer. Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. For details, see “Item 4. Information on the Company—B. Business Overview—Our Drug Pipeline.” Potential competitors further include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of our competitors have substantially greater financial, technical, and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval from the NMPA, the FDA or other comparable regulatory authorities more rapidly than we are able to and may be more effective in selling and marketing their products as well. For example, the NMPA has recently accelerated market approval of drugs for diseases with high unmet medical need. In particular, the NMPA may review and approve drugs that have gained regulatory market approval in the United States, the European Union or Japan in the recent ten years without requiring further clinical trials in China. This may lead to potential increased competition from drugs which have already obtained approval in other jurisdictions.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective or less costly than any drug candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do. Additionally, technologies developed by our competitors may render our potential drug candidates uneconomical or obsolete, and we may not be successful in marketing our drug candidates against competitors.

The manufacture of biopharmaceutical products is a complex process which requires significant expertise and capital investment, and if we encounter problems in establishing our manufacturing capabilities or manufacturing our future products, our business could suffer.

We have limited experience in managing the manufacturing process. The manufacture of biopharmaceutical products is a complex process, in part due to strict regulatory requirements. As of the date of annual report, we have no existing manufacturing infrastructure or capabilities. If we are unable to identify an appropriate production site or a suitable partner to develop our manufacturing infrastructure, or fail to do so in a timely manner, this may lead to significant delays in the manufacturing of our drug candidates once regulatory and marketing approvals have been obtained. The investment for building a new biologics manufacturing facility that is compliant with cGMP regulations may also be a significant upfront cost for us. In turn, this could materially harm our commercialization plans.

In addition, problems may arise during the manufacturing process 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 facilities or expansion of any future manufacturing facilities, including changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, increases in the prices of raw materials, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. If problems arise during the production of a batch of future products, that batch of future products may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before such product is released to the market, recall and product liability costs may also be incurred.

We have no experience in launching and marketing drug candidates. We may not be able to effectively build and manage our sales network, or benefit from third-party collaborators' sales network.

We currently have no sales, marketing or commercial product distribution capabilities and have no experience in marketing drugs. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and commercial distribution capabilities for any or all of the drugs we develop, we will likely pursue collaborative arrangements regarding the sales and marketing of our drugs. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend on the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts of our drug candidates.

There can be no assurance that we will be able to develop in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or unavailable in certain market segments for our drug candidates, and we may be subject to unfavorable pricing regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval. For example, according to a statement, Opinions on Reforming the Review and Approval Process for Pharmaceutical Products and Medical Devices, issued by the PRC State Council in August 2015, the enterprises applying for new drug approval will be required to undertake that the selling price of new drug on PRC mainland market shall not be higher than the comparable market prices of the product in its country of origin or PRC's neighboring markets, as applicable.

Our ability to commercialize any drugs successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. 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 global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. Obtaining reimbursement for our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the NMPA, the FDA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and certain other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict post-approval activities and affect our ability to sell profitably any drug candidates for which we obtain marketing approval.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the ACA of importance to our drug candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act's pharmaceutical pricing program;
- new requirements to report to CMS financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report to the FDA drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our drug candidates may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

As we out-license some of our commercialization rights and engage in other forms of collaboration worldwide, including conducting clinical trials abroad, we may be exposed to specific risks of conducting our business and operations in international markets.

Markets outside of China form an important component of our growth strategy, as we out-license some of our commercialization rights to third parties outside the PRC and conduct certain of our clinical trials abroad. If we fail to obtain applicable licenses or fail to enter into strategic collaboration arrangements with third parties in these markets, or if these collaboration arrangements turn out unsuccessful, our revenue-generating growth potential will be adversely affected.

Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- changes in a specific country's or region's political and cultural climate or economic condition;
- differing regulatory requirements for drug approvals and marketing internationally;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation or political instability;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable non-PRC tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incidental to doing business in another country;
- workforce uncertainty and labor unrest;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from an international market with low or lower prices rather than buying them locally;
- failure of our employees and contracted third parties to comply with Office of Foreign Assets Control rules and regulations and the Foreign Corrupt Practices Act of the United States, and other applicable rules and regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets.

If safety, efficacy, or other issues arise with any medical product that is used in combination with our drug candidates, we may be unable to market such drug candidate or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We plan to develop certain of our drug candidates for use as a combination therapy. If the NMPA, the FDA or another comparable regulatory agency revokes its approval of another therapeutic we use in combination with our drug candidates, we will not be able to market our drug candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with these or other therapeutics that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination drug candidates or if we cannot secure supply of any component of our drug candidates at commercially reasonable or acceptable prices, we may not be able to complete clinical development of our drug candidates on our current timeline or within our current budget, or at all.

Lack of third-party combination drugs may materially and adversely affect demand for our drugs.

Our drug candidates may be administered in combination with drugs of other pharmaceutical companies as one regimen. In addition, we often use such third-party drugs in our development and clinical trials as controls for our studies. As a result, both the results of our clinical trials and the sales of our drugs may be affected by the availability of these third-party drugs. If other pharmaceutical companies discontinue these combination drugs, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs at all or in a timely manner and on a cost-effective basis. As a result, demand for our drugs may be lowered, which would in turn materially and adversely affect our business and results of operations.

Risks Related to Our Reliance on Third Parties

As we rely on third parties to conduct our pre-clinical studies and clinical trials, if we lose our relationships with these third parties or if they do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We have relied on and plan to continue to rely on third-party contract research organization ("CROs") to monitor and manage data for some of our ongoing pre-clinical and clinical programs. We rely on these parties for the execution of our pre-clinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We also rely on third parties to assist in conducting our pre-clinical studies in accordance with Good Laboratory Practices ("GLP"). We and our CROs are required to comply with GCP, GLP and other regulatory regulations and guidelines enforced by the NMPA, the FDA and comparable foreign regulatory authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these GCP, GLP or other regulatory requirements through periodic inspections of trial sponsors, investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, GLP or other regulatory requirements, the relevant data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA or other comparable regulatory authorities may require us to perform additional clinical studies before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP requirements. In addition, our clinical trials must be conducted with drug candidates or products produced under cGMP requirements. Failure to comply with these regulations may require us to repeat pre-clinical and clinical trials, which would delay the regulatory approval process.

Our CROs have the right to terminate their agreements with us in the event of an unrectified material breach. If any of our relationships with our third-party CROs is terminated, we may not be able to (i) enter into arrangements with alternative CROs or do so on commercially reasonable terms or (ii) meet our desired clinical development timelines. In addition, there is a natural transition period when a new CRO commences work, and the new CRO may not provide the same type or level of services as the original provider and data from our clinical trials may be compromised as a result. There is also a need for relevant technology to be transferred to the new CRO, which may take time and further delay our development timelines.

Except for remedies available to us under our agreements with our CROs, we cannot control whether or not our CROs devote sufficient time and resources to our ongoing clinical, nonclinical and pre-clinical programs. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed and our costs could increase. In turn, our ability to generate revenues could be delayed or compromised.

Because we rely on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves certain risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these third parties, which could increase the risk that such information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party service providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We expect to rely on third parties to manufacture at least a portion of our drug candidate supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our drug candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

Although we plan to either construct or acquire a facility that will be used as our clinical-scale manufacturing and processing facility, we intend to also partially rely on third-party vendors to manufacture supplies and process our drug candidates. We have not yet manufactured or processed our drug candidates on a commercial scale and may not be able to do so for any of our drug candidates. We have limited experience in managing the manufacturing process, and our process may be more difficult or expensive than the approaches currently in use.

Our anticipated reliance on third-party manufacturers exposes us to certain risks, including, but not limited to, the following:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA, the FDA or other comparable regulatory authorities must approve any manufacturers as part of their regulatory oversight of our drug candidates. This approval would require new testing and cGMP-compliance inspections by the NMPA, the FDA or other comparable regulatory authorities. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drugs;
- our contract manufacturers may have little or no experience with manufacturing our drug candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our drug candidates;
- our contract manufacturers may have limited capacity or limited manufacturing slots, which may affect the timeline for the production of our drugs;
- our contract manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our drugs, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our drugs;
- our contract manufacturers are subject to ongoing periodic unannounced inspections by the NMPA and the FDA to ensure strict compliance with cGMP and other government regulations in the PRC and the United States, respectively, and by other comparable regulatory authorities for corresponding regulatory requirements. We do not have control over third-party manufacturers' compliance with these regulations and requirements;

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drugs;
- our contract manufacturers could breach or terminate their agreements with us;
- our contract manufacturers may be unable to sustain their business and become bankrupt as a result;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- products and components from our third-party manufacturers may be subject to additional customs and import charges, which may cause us to incur delays or additional costs as a result;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates by the NMPA, the FDA or other comparable regulatory authorities, result in higher costs or adversely impact the commercialization of our drug candidates. In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data is not reliable, patients could be put at risk of serious harm and the NMPA, the FDA or other comparable regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

The manufacture of biopharmaceutical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Currently, our drug raw materials for our manufacturing activities are supplied by multiple source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, our business would be materially harmed.

Manufacturers of biopharmaceutical products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process, including the absence of contamination. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error and availability of qualified personnel, as well as compliance with strictly enforced regulations in the PRC, the United States and other applicable jurisdictions. Further, if contaminants are discovered in the supply of our drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time for us to investigate and remedy the contamination. There can be no assurance that any stability failures or other issues relating to the manufacture of our drug candidates will not occur in the future. Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environment. If our contract manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our drug candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of our clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur recurring or non-recurring expenses and other charges, increase our near and long-term expenditures, issue securities that dilute the value of our ADSs, or disrupt our management and business. For example, we have entered into a license and collaboration agreement with MorphoSys AG ("MorphoSys"), pursuant to which we in-licensed from MorphoSys the development and commercialization rights of TJ202 in Greater China. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for the development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party.

Further, collaborations involving our drug candidates are subject to specific risks, which include, but are not limited to, the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue the development and commercialization of our drug candidates or may elect not to continue or renew the development or commercialization programs based on clinical trial results, change in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, discontinue a clinical trial, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates or future drugs;
- collaborators with marketing and distribution rights to one or more of our drug candidates or future drugs may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may not always be cooperative or responsive in providing their services in a clinical trial;
- disputes may arise between us and a collaborator that cause a delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates; and
- collaborators may own or co-own intellectual property covering our drug candidates or future drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into collaboration agreements and strategic partnerships or license our drugs, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate these agreements or partnerships with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business.

Neither can we be certain that, following a strategic transaction or license, we will be able to achieve the revenue or specific net income that justifies such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for our drug candidates, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected.

Our success depends in large part on our ability to protect our proprietary technology and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. As of December 31, 2019, our owned patent portfolio consist of five patents and 166 patent applications primarily in connection with the drug candidates in our Global Portfolio, including 17 Patent Cooperation Treaty ("PCT") patent applications, 12 U.S. patent applications, 15 PRC patent applications and 122 patent applications in other jurisdictions. In addition, as of December 31, 2019, we in-licensed the Greater China and Korea rights relating to 20 issued patents and 27 pending patent applications primarily in connection with TJ202, TJ101, TJ301, enoblituzumab and TJ107. We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in China, the United States and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications in all jurisdictions at a reasonable cost or in a timely manner. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. The patent examination process may require us or our licensors to narrow the scope of the claims of our or our licensors' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent.

Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates. We may become involved in interference, *inter partes* review, post grant review, ex parte reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or drug candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and other countries. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such assets might expire before or shortly after such assets are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Under the America Invents Act ("AIA") enacted in 2011, the United States moved to this first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. 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.

We enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world, including in the PRC.

Filing and prosecuting patent applications and defending patents covering our drug candidates in all countries throughout the world could be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own drug candidates and, further, may export otherwise infringing drug candidates to territories, including the PRC, where we and our licensors have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These drug candidates may compete with our drug candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions, including the PRC, do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing drug candidates in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. 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 or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our drug candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our drug candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

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 and annuity fees on any issued patent are due to be paid to the United States Patent and Trademark Office ("USPTO") and foreign patent agencies over the lifetime of a patent. In addition, the USPTO and other foreign patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which such non-compliance will result in the abandonment or lapse of the patent or patent application, and the 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, and non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our licensors fail to maintain the patents and patent applications covering our drug candidates or if we or our licensors otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our drug candidates in any indication for which they are approved.

Our owned and 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 modify or 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 as an inventor or co-inventor. 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 modify or 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.

Claims that our drug candidates or the sale or use of our future products infringe, misappropriate or otherwise violate the patents or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

We cannot guarantee that our drug candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, or with respect to the use or manufacture of the compounds we have developed or are developing. Litigation relating to patents and other intellectual property rights in the biopharmaceutical and pharmaceutical industries is common, including patent infringement lawsuits. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Some claimants may have substantially greater resources than we have and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. Third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future. For example, we are aware of a third-party U.S. patent and its counterpart European patents that relate to the use of antibodies having specificity to PD-L1 to treat cancer.

It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or for their uses, or that our drug candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our drug candidates or a similar invention, our patent application may be regarded as a competing application and may not be approved in the end. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

If a third party were to assert claims of patent infringement against us, even if we believe such third-party claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention, or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and could cause us to pay substantial damages, if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a drug candidate, or be forced, by court order or otherwise, to modify or cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights could be costly and time-consuming, regardless of the outcome. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

Issued patents covering one or more of our drug candidates could be found invalid or unenforceable if challenged in court.

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, SIPO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. Although we believe that we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. 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 a drug candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. In addition, if the breadth or strength of protection provided by our patents is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future drug candidates. Any loss of patent protection could have a material adverse impact on one or more of our drug candidates and our business.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages, cease the sale of certain drugs or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all).

Intellectual property litigation may lead to unfavorable publicity which may harm our reputation and cause the market price of our ADSs to decline, and any unfavorable outcome from such litigation could limit our research and development activities and/or our ability to commercialize our drug candidates.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our drug candidates, future drugs, programs or intellectual property could be diminished. Accordingly, the market price of our ADSs may decline. Such announcements could also harm our reputation or the market for our drug candidates, which could have a material adverse effect on our business.

In the event of intellectual property litigation, there can be no assurance that we would prevail, even if the case against us is weak or flawed. If third parties successfully assert their intellectual property rights against us, prohibitions against using certain technologies, or prohibitions against commercializing our drug candidates, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated the patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. Additionally, we may be required to obtain a license from the intellectual property owner in order to continue our research and development programs or to commercialize any resulting product. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. This may not be technically or commercially feasible, may render our products less competitive, or may delay or prevent the launch of our products to the market. Any of the foregoing could limit our research and development activities, our ability to commercialize one or more drug candidates, or both.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research programs, in-license needed technology, or enter into strategic partnerships that would help us bring our drug candidates to market.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could 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.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patent rights. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. In addition, the United States has recently enacted and is 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. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, 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. For example, in a recent case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.* , the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. Although we do not believe that our currently issued patents and any patents that may issue from our pending patent applications directed to our drug candidates if issued in their currently pending forms, as well as patent rights licensed by us, will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We also may be subject to claims that our employees, consultants, or advisers have wrongfully used or disclosed alleged trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.

In addition to our issued patents and pending patent applications, we rely on trade secret and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect this trade secret and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. 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 to be lawfully obtained or independently developed by a competitor or other third party, 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, many of our employees, consultants, and advisers, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisers, including members of our senior management, executed 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 individual’s former employer. We are not aware of any 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 who may be 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, and furthermore, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of 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, be a distraction to our management and scientific personnel and have a material adverse effect on our business, financial condition, results of operations and prospects.

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 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.

Our rights to develop and commercialize our drug candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development of our drug candidates. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use and in all territories in which we may wish to develop or commercialize our drug products. As a result, we may not be able to prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses.

We may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the drug candidates that we license from third parties. Moreover, we have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights that we jointly own with certain of our licensors and sub-licensors. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our drugs that are subject of such licensed rights could be adversely affected.

Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. Even if we are permitted to pursue the enforcement or defense of our licensed patents, we will require the cooperation of our licensors and any applicable patent owners and such cooperation may not be provided to us. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If we lose any of our licensed intellectual property, our right to develop and commercialize any of our drug candidates that are subject of such licensed rights could be adversely affected.

In addition, our licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize drug products covered by these license agreements. If such licenses are terminated, we may be required seek alternative in-license arrangements, which may not be available on commercially reasonable terms or at all, or may be non-exclusive. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, we may need to modify or cease the development, manufacture, and commercialization of one or more of our drug candidates and competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

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.

Our business relies, in large part, on our ability to develop and commercialize drug candidates we have licensed from third parties, and 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. Our licenses may not encumber all intellectual property rights owned or controlled by the affiliates of our licensors and relevant to our drug candidates, and 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. In such case, we may need to obtain additional licenses which may not be available on an exclusive basis, on commercially reasonable terms or at a reasonable cost, 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.

In addition, if our licensors breach the license agreements, we may not be able to enforce such agreements against our licensors' parent entity or affiliates. Under each of our license and intellectual property-related agreements, in exchange for licensing or sublicensing us the right to develop and commercialize the applicable drug candidates, our licensors will be eligible to receive from us milestone payments, tiered royalties from commercial sales of such drug candidates, assuming relevant approvals from government authorities are obtained, or other payments. Our license and intellectual property-related agreements also require us to comply with other obligations including development and diligence obligations, providing certain information regarding our activities with respect to such drug candidates and/or maintaining the confidentiality of information we receive from our licensors.

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 and, upon the effective date of such termination, have the right to re-obtain the licensed and sub-licensed technology and intellectual property. If any of our licensors terminate any of our licenses, 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 and other third parties may be able to market drug candidates similar or identical to ours. In such case, we may have to negotiate new or reinstated agreements with less favorable terms, and may be required to provide a grant back license to the licensors under our own intellectual property with respect to the terminated products. We may also face claims for monetary damages or other penalties under these agreements. While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the intellectual property rights licensed and sublicensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. In particular, some of the milestone payments are payable upon our drug candidates reaching development milestones before we have commercialized, or received any revenue from, sales of such drug candidate, and we cannot guarantee that we will have sufficient resources to make such milestone payments. Any uncured, material breach under the license agreements could result in our loss of exclusive rights and may lead to a complete termination of our rights to the applicable drug candidate. Any of the foregoing could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. 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 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 condition, results of operations and prospects.

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or may in the future exclusively license, which could result in the patents applied for not being issued or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our inventions, which could result in the patents applied for not being issued or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;

- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- we may obtain patents for certain compounds many years before we receive regulatory approval for drugs containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sale of the related drugs, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for commercialization in our major markets;
- we may fail to develop additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate;
- third parties may gain unauthorized access to our intellectual property due to potential lapses in our information systems; and
- the patents of others may have an adverse effect on our business, for example by preventing us from commercializing one or more of our drug candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could have a material adverse effect on our business and future prospects.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be adversely affected.

We own registered trademarks. We may not be able to obtain trademark protection in territories that we consider of significant importance to us. In addition, any of our trademarks or trade names, whether registered or unregistered, may be challenged, opposed, infringed, cancelled, circumvented or declared generic, or determined to be infringing on other marks, as applicable. We may not be able to protect our rights to these trademarks and trade names, which we will need to build name recognition by potential collaborators or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Terms of our future patents may not be sufficient to effectively protect our drug candidates and business.

In many countries where we file applications for patents, the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Although various extensions may be available, the life of a patent and the protection it affords are limited. Even if we obtain patents covering our drug candidates, we may still be open to competition from other companies, as well as generic medications once the patent life has expired for a drug. While there are patent regulations in the PRC in respect of regulatory data protection of new drugs containing new chemical components, there are currently no other clear mechanisms providing patent term extension or patent linkages for other drugs in the PRC. Therefore, it is possible that a lower-cost generic drug can emerge onto the market much more quickly. PRC regulators have set out a framework for integrating patent linkage and data exclusivity into the PRC regulatory regime, as well as for establishing a pilot program for patent term extension. This framework will require adoption of regulations to be implemented, although no such regulations have been issued to date. These factors may result in weaker protection for us against generic competition in the PRC than could be available to us in other jurisdictions, such as the United States. In addition, patents which we expect to obtain in the PRC may not be eligible to be extended for patent terms lost during clinical trials and the regulatory review process.

If we are unable to obtain patent term extensions or if such extensions are less than requested for, our competitors may obtain approval of competing products following our patent expirations and our business, financial condition, results of operations and prospects could be materially harmed as a result.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar legislation in other countries extending the terms of our patents, if issued, relating to our drug candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our U.S. patents, if issued, may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. Patent term extensions, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval by the FDA, and only one patent can be extended for a particular drug.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension for a given patent or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug will be shortened and our competitors may obtain earlier approval of competing drugs, and our ability to generate revenues could be materially adversely affected.

Risks Related to Our Industry, Business and Operations

Our future success depends on our ability to attract, retain and motivate senior management and qualified scientific employees.

We are highly dependent on the expertise of the members of our research and development team, as well as the principal members of our management. We have entered into employment agreements with our executive officers, but each of them may terminate their employment with us at any time with prior written notice. In addition, we currently do not have "key-man" insurance for any of our executive officers or other key personnel.

Recruiting, retaining and motivating qualified management, scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Further, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous biopharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, our management will be required to devote significant time to new compliance initiatives from our status as a public company, which may require us to recruit more management personnel.

We will need to increase the size and capabilities of our organization, and we may experience difficulties in managing our growth.

We expect to experience significant growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of clinical development, regulatory affairs and business development. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, and have a material adverse effect on our business.

The data and information that we gather in our research and development process could be inaccurate or incomplete, which could harm our business, reputation, financial condition and results of operations.

We collect, aggregate, process, and analyze data and information from our pre-clinical studies, manufacturing technology development programs and clinical programs. We also engage in substantial information gathering following the identification of a promising drug candidate. Because data in the healthcare industry is fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we often discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input, or analysis of these data, our ability to advance the development of our drug candidates may be materially harmed and our business, prospects and reputation may suffer.

We also engage in the procurement of regulatory approvals necessary for the development and commercialization of our products under development, for which we manage and submit data to governmental entities. These processes and submissions are governed by complex data processing and validation policies and regulations. Notwithstanding such policies and regulations, interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a customer, court or government agency that concludes that our storage, handling, submission, delivery, or display of health information or other data was wrongful or erroneous. Although we maintain insurance coverage for clinical trials, this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention, and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on CROs, our partners and other third parties to monitor and manage data for some of our ongoing pre-clinical and clinical programs and control only certain aspects of their activities. If any of our CROs, our partners or other third parties does not perform to our standards in terms of data accuracy or completeness, data from those pre-clinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For a detailed discussion, see “—Risks Related to Our Reliance on Third Parties—As we rely on third parties to conduct our pre-clinical studies and clinical trials, if we lose our relationships with these third parties or if they do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed” above.

We may be subject to liability lawsuits arising from our clinical trials.

We currently carry liability insurance covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or which is in excess of the limits of our insurance coverage. Our insurance policies also contain various exclusions, and we may be subject to particular liability claims for which we have no coverage. We will have to pay any amount awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. In addition, if we cannot successfully defend ourselves against such claims, we may incur substantial liabilities and be required to suspend or delay our ongoing clinical trials. Even a successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, liability claims may result in significant negative consequences to our business and prospects, including, but not limited to:

- decreased demand for our drug candidates or any resulting products;
- injury to our reputation;

- withdrawal of other clinical trial participants;
- costs to defend the related litigation;
- a diversion of our management's time and resources;
- substantial monetary awards to trial participants or patients;
- inability to commercialize our drug candidates; and
- a decline in the market price of our ADSs.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We maintain insurance policies that are required under PRC laws and regulations as well as insurance based on our assessment of our operational needs and industry practice. We also maintain liability insurance covering our clinical trials. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or key-man insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

Global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors including, extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. In the past, governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

In addition, there is considerable uncertainty over the long-term effects of the expansionary monetary and fiscal policies adopted by the central banks and financial authorities of some of the world's leading economies, including the United States and China. There have been concerns over unrest and terrorist threats in the Middle East, Europe and Africa and over the conflicts involving Ukraine, Syria and North Korea. There have also been concerns on the relationship among China and other Asian countries, which may result in or intensify potential conflicts in relation to territorial disputes or the trade related disputes between the United States and China. In addition, the impact of the decision by the United Kingdom to withdraw from the European Union, commonly referred to as "Brexit", and the resulting effect on the political and economic future of the U.K. and the European Union is uncertain. Brexit could adversely affect European and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions in the long term. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions in the long term.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activities by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to:

- comply with the laws of the NMPA, the FDA and other comparable regulatory authorities;

- provide true, complete and accurate information to the NMPA, the FDA and other comparable regulatory authorities;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse laws in the PRC, the United States and similar fraudulent misconduct laws in other applicable jurisdictions; or
- report financial information or data accurately or to disclose unauthorized activities to us.

For example, our founder, Dr. Jingwu Zhang Zang, was the corresponding author of a research paper prepared by scientists at GSK China's research center and published in Nature Medicine in 2010. The paper was retracted in 2013 as a result of misrepresentation of certain data for which Dr. Zang admitted his management oversight, accepted the responsibility as the corresponding author and coordinated the retraction of the paper. In addition, Dr. Zang received a warning letter from the FDA in March 1999 relating to the lack of IND approval before the initiation of a clinical research study in human subjects. For details, please see "Item 6. Directors, Senior Management and Employees—A. Directors and Senior Management—Certain Past Incidents." We cannot assure you that there will not be any inquiries, investigations or other actions against Dr. Zang by any regulatory or government authorities or any negative publicity against Dr. Zang or us regarding these incidents, any of which could distract Dr. Zang and our management's attention and negatively affect our business and results of operations.

If we obtain approval of any of our drug candidates and begin commercializing those drugs in the PRC, the United States or other applicable jurisdictions, our potential exposure under the laws of such jurisdictions will increase significantly and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation.

It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute the value of your investment in our ADSs, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including, but not limited to:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the assimilation of operations, corporate culture and personnel of the acquired business;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and its existing drugs or drug candidates and regulatory approvals;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- changes in accounting principles relating to recognition and measurement of our investments that may have a significant impact on our financial results.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

If we fail to comply with applicable anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In addition, although currently our primary operating business is in China, we are subject to the Foreign Corrupt Practices Act (the "FCPA"). The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

Any failure to comply with applicable regulations and industry standards or obtain various licenses and permits could harm our reputation and our business, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the PRC, the United States and other applicable jurisdictions impose strict rules, regulations and industry standards governing biopharmaceutical research and development activities, which apply to us. Our or our CROs' failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations. For example, if we or our CROs were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation and the accuracy of our animal research data could be questioned.

If we or our CROs or other contractors or consultants fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and third parties, such as our CROs or other contractors or consultants, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and radioactive and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological, hazardous or radioactive materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If we face allegations of non-compliance with laws and encounter sanctions, our reputation, revenues and liquidity may suffer, and our drug candidates and future drugs could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of laws could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our drugs. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from our product sales, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we partially rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our drug candidates could be delayed.

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, China's Cyber Security Law, which became effective in June 2017, created China's first national-level data protection for "network operators," which may include all organizations in China that provide services over the internet or another information network. Numerous regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. Drafts of some of these measures have now been published, including the draft rules on cross-border transfers published by the China Cyberspace Administration in 2017, which may, upon enactment, require security review before transferring human health-related data out of China. In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China. For example, the PRC State Council promulgated Regulations on the Administration of Human Genetic Resources (effective in July 2019), which require approval from the Science and Technology Administration Department of the State Council where human genetic resources, or HGR, are involved in any international collaborative project and additional approval for any export or cross-border transfer of the HGR samples or associated data. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of HGR samples and associated data and administrative fines. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

In the United States, we are subject to laws and regulations that address privacy, personal information protection and data security at both the federal and state levels. Numerous laws and regulations, including security breach notification laws, health information privacy laws, and consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information. Given the variability and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by regulators or courts in their interpretation.

Regulatory authorities in Europe have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the General Data Protection Regulation (EU) 2016/679, or GDPR, which became effective in May 2018, imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including, but not limited to, requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area (including to the United States), providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, and recordkeeping. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the new law, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. National laws of member states of the European Union are in the process of being adapted to the requirements under the GDPR. Because the GDPR specifically gives member states flexibility with respect to certain matters, national laws may partially deviate from the GDPR and impose different obligations from country to country, leading to additional complexity and uncertainty.

We expect that we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under global data protection, privacy and security laws will be sufficient. Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant civil or criminal penalties and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information, require us to change our business practices, increase our costs and materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical partners and other third parties could be negatively affected by any proceedings or actions against us or current or future data protection obligations imposed on them under applicable law, including the GDPR. In addition, a data breach affecting personal information, including health information, could result in significant legal and financial exposure and reputational damage that could potentially have an adverse effect on our business.

Our operating results for fiscal 2020, our China operations and our worldwide operations could be adversely affected by the outbreak of and response to the coronavirus or other health crises.

In December 2019 and early 2020, health officials in China began reporting on efforts related to an outbreak of and response to a novel strain of coronavirus, which is believed to have originated in Wuhan, China. In late January 2020, in response to intensifying efforts to contain the spread of the coronavirus, the Chinese government took a number of actions, which included extending the Chinese New Year holiday, quarantining and otherwise treating individuals in China who had the coronavirus, asking China residents to remain at home and to avoid gathering in public, and other actions. Following these actions in China, as well as confirmed cases of the coronavirus throughout the world, airlines and other service providers began suspending service in China. In connection with these actions, we extended the Chinese New Year holiday for our China employees to help mitigate the spread of the coronavirus. While the events related to the outbreak of and response to the coronavirus are expected to be temporary, they have disrupted our operations in China during the first few months of 2020 and could continue to disrupt our operations in China, and other juridictions. Because of the uncertainty surrounding these events, the financial impact related to the outbreak of and response to the coronavirus cannot be reasonably estimated at this time but could meaningfully affect our consolidated results for the first quarter and full year fiscal 2020. As of the date of this annual report, the outbreak has been largely concentrated in China, although additional cases continue to be confirmed in many other countries. The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Our results of operations could also be negatively impacted if the reality or fear of another communicable and rapidly spreading disease, health crisis, or natural disaster results in business interruption, travel restrictions or avoidance of public gatherings in one or more of our markets. It is difficult to predict the impact on our business, if any, of the emergence of new epidemics or other crises.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Natural disasters, acts of war or terrorism, health epidemics, or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or may be susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

Our business and results of operations could be adversely affected by public health crisis (including the COVID-19 global pandemic) and natural catastrophes or other disasters outside of our control in the locations in which we, our suppliers, CROs, CMOs and other contractors operate.

Our business could be adversely affected by the effects of epidemics, including COVID-19, avian influenza, severe acute respiratory syndrome, (SARS), influenza A (H1N1), Ebola or another epidemic. Any such occurrences could cause severe disruption to our daily operations and may even require a temporary closure of our offices and laboratories. For example, in early 2020, in response to intensifying efforts to contain the spread of COVID-19, the Chinese government took a number of actions, which included extending the Chinese New Year holiday, quarantining individuals infected with or suspected of having COVID-19, prohibiting residents from free travel, encouraging employees of enterprises to work remotely from home and cancelling public activities, among others. The COVID-19 has also resulted in temporary closure of many corporate offices, retail stores, manufacturing facilities and factories across China. As research hospitals and government agencies focus clinical resources on the pandemic, we believe that there could be some delay in regulatory interactions and inspections and patient recruitment and participation, particularly in the first quarter of 2020. Meanwhile, the outbreak of COVID-19 continues in the United States and other countries, and related government and private sector responsive actions may cause some delay in our ongoing clinical trials in the United States. We have taken a series of measures in response to the outbreak, including, among others, remote working arrangement for our employees. These measures could reduce the capacity and efficiency of our operations, which in turn could negatively affect our results of operations. The extent to which COVID-19 impacts our results of operations will depend on the future developments of the outbreak, including new information concerning the global severity of and actions taken to contain the outbreak, which are highly uncertain and unpredictable. These uncertain and unpredictable factors include, but are not limited to, potential adverse effects of the pandemic on the economy, our suppliers, CROs, CMOs and other contractors. In addition, our results of operations could be adversely affected to the extent that the outbreak harms the Chinese economy in general. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this annual report, including those relating to our ability to initiate or continue clinical trials for our drug candidates.

We have identified two material weaknesses in our internal controls, and if we fail to implement and maintain an effective system of internal controls to remediate our material weaknesses over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud.

Prior to the initial public offering of our ADSs on NASDAQ in January 2020, we were a private company with limited accounting personnel and other resources with which to address our internal controls and procedures. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. In the course of auditing our consolidated financial statements as of and for the year ended December 31, 2019, we and our independent registered public accounting firm identified two material weaknesses and control deficiencies in our internal control over financial reporting. As defined in the standards established by the U.S. Public Company Accounting Oversight Board, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses that have been identified relate to (i) our lack of sufficient and competent financial reporting and accounting personnel with appropriate knowledge of U.S. GAAP and the reporting and compliance requirements of the United States Securities and Exchange Commission, or the SEC, to formalize key controls over financial reporting and to prepare consolidated financial statements and related disclosures; and (ii) our lack of sufficient documented financial closing policies and procedures, specifically those related to (a) accounting for licensing and collaboration agreements and (b) period end expenses cut-off and accruals. These material weaknesses, if not timely remedied, may lead to significant misstatements in our consolidated financial statements in the future. Following the identification of the material weaknesses and other control deficiencies, we have taken measures and plan to continue to take measures to remediate these deficiencies. See "Item 15. Controls and Procedures—Management's Report on Internal Control over Financial Reporting—Internal Control over Financial Reporting." However, the implementation of those measures may not fully remediate the material weaknesses in a timely manner. Our failure to correct these deficiencies or our failure to discover and address any other deficiencies could result in inaccuracies in our financial statements and impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. Moreover, ineffective internal control over financial reporting could significantly hinder our ability to prevent fraud.

As required by Section 404 of the Sarbanes-Oxley Act, or Section 404, we include a report from management on the effectiveness of our internal control over financial reporting in our annual report on Form 20-F beginning with our annual report for the fiscal year ending December 31, 2020. In addition, once we cease to be an "emerging growth company" as defined in the JOBS Act, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Our management may conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue an adverse report if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, once we have become a public company, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation testing and any required remediation.

During the course of documenting and testing our internal control procedures, in order to satisfy the requirements of Section 404, we may identify other weaknesses and deficiencies in our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404. If we fail to establish and maintain adequate internal controls, we could suffer material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could limit our access to capital markets, adversely affect our results of operations and lead to a decline in the trading price of the ADSs. Additionally, ineffective internal controls could expose us to an increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list or to other regulatory investigations and civil or criminal sanctions. We could also be required to restate our historical financial statements.

Our auditor, like other independent registered public accounting firms operating in China, is not permitted to be subject to inspection by Public Company Accounting Oversight Board, and consequently investors may be deprived of the benefits of such inspection.

Our auditor, the independent registered public accounting firm that issued the audit report included elsewhere in this registration statement, as an auditor of companies that are traded publicly in the United States and a firm registered with the Public Company Accounting Oversight Board (United States), or PCAOB, is subject to laws in the United States pursuant to which the PCAOB conducts regular inspections to assess its compliance with applicable professional standards. Our auditor is located in, and organized under the laws of, the PRC, which is a jurisdiction where the PCAOB, has been unable to conduct inspections without the approval of the Chinese authorities. In May 2013, PCAOB announced that it had entered into a Memorandum of Understanding on Enforcement Cooperation with the CSRC and the PRC Ministry of Finance, which establishes a cooperative framework between the parties for the production and exchange of audit documents relevant to investigations undertaken by PCAOB, the CSRC or the PRC Ministry of Finance in the United States and the PRC, respectively. PCAOB continues to be in discussions with the China Securities Regulatory Commission, or CSRC, and the PRC Ministry of Finance to permit joint inspections in China of audit firms that are registered with PCAOB and audit Chinese companies that trade on U.S. exchanges.

On December 7, 2018, the SEC and the PCAOB issued a joint statement highlighting continued challenges faced by the U.S. regulators in their oversight of financial statement audits of U.S.-listed companies with significant operations in China. However, it remains unclear what further actions, if any, the SEC and PCAOB will take to address the problem.

On April 21, 2020, the SEC and the PCAOB issued another joint statement reiterating the greater risk that disclosures will be insufficient in many emerging markets, including China, compared to those made by U.S. domestic companies. In discussing the specific issues related to the greater risk, the statement again highlights the PCAOB's inability to inspect audit work paper and practices of accounting firms in China, with respect to their audit work of U.S. reporting companies.

This lack of PCAOB inspections in China prevents the PCAOB from fully evaluating audits and quality control procedures of our independent registered public accounting firm. As a result, we and investors in our ordinary shares are deprived of the benefits of such PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China makes it more difficult to evaluate the effectiveness of our independent registered public accounting firm's audit procedures or quality control procedures as compared to auditors outside of China that are subject to PCAOB inspections, which could cause investors and potential investors in our stock to lose confidence in our audit procedures and reported financial information and the quality of our financial statements.

Proceedings instituted by the SEC against "big four" PRC-based accounting firms, including our independent registered public accounting firm, could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act.

Starting in 2011 "big four" PRC-based accounting firms, including our independent registered public accounting firm, were affected by a conflict between U.S. and Chinese law. Specifically, for certain U.S.-listed companies operating and audited in mainland China, the SEC and the PCAOB sought to obtain from the Chinese firms access to their audit work papers and related documents. The firms were, however, advised and directed that under Chinese law, they could not respond directly to the U.S. regulators on those requests, and that requests by foreign regulators for access to such papers in China had to be channeled through the CSRC.

In late 2012, this impasse led the SEC to commence administrative proceedings under Rule 102(e) of its Rules of Practice and also under the Sarbanes-Oxley Act of 2002 against the Chinese accounting firms, including our independent registered public accounting firm. A first instance trial of the proceedings in July 2013 in the SEC's internal administrative court resulted in an adverse judgment against the firms. The administrative law judge proposed penalties on the firms including a temporary suspension of their right to practice before the SEC, although that proposed penalty did not take effect pending review by the Commissioners of the SEC. On February 6, 2015, before a review by the Commissioner had taken place, the firms reached a settlement with the SEC. Under the settlement, the SEC accepted that future requests by the SEC for the production of documents will normally be made to the CSRC. The firms were to receive matching Section 106 requests, and were required to abide by a detailed set of procedures with respect to such requests, which in substance require them to facilitate production via the CSRC. If they failed to meet specified criteria, the SEC retained authority to impose a variety of additional remedial measures on the firms depending on the nature of the failure.

Under the terms of the settlement, the underlying proceeding against the four China-based accounting firms was deemed dismissed with prejudice four years after entry of the settlement. The four-year mark occurred on February 6, 2019. While we cannot predict if the SEC will further challenge the four China-based accounting firms' compliance with U.S. law in connection with U.S. regulatory requests for audit work papers or if the results of such a challenge would result in the SEC imposing penalties such as suspensions. If additional remedial measures are imposed on the "big four" PRC-based accounting firms, including our independent registered public accounting firm, we could be unable to timely file future financial statements in compliance with the requirements of the Exchange Act.

In the event the "big four" PRC-based accounting firms become subject to additional legal challenges by the SEC or PCAOB, depending upon the final outcome, listed companies in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in China, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about any such future proceedings against these audit firms may cause investor uncertainty regarding China-based, U.S.-listed companies and the market price of our common stock may be adversely affected.

If our independent registered public accounting firm was denied, even temporarily, the ability to practice before the SEC and we were unable to timely find another registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined not to be in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to the delisting of the ADSs from the Nasdaq Global Market or deregistration from the SEC, or both, which would substantially reduce or effectively terminate the trading of the ADSs in the United States.

Our reputation is important to our business success. Negative publicity may adversely affect our reputation and business prospects.

Any negative publicity concerning us, our affiliates or any entity that shares the "I-Mab" name, even if untrue, could adversely affect our reputation and business prospects. There can be no assurance that negative publicity about us or any of our affiliates or any entity that shares the "I-Mab" name would not damage our brand image or have a material adverse effect on our business, results of operations and financial condition.

We may be subject to material litigation and regulatory proceedings.

We may be subject to litigation in China and outside China relating to securities law class actions, third-party and principal intellectual property infringement claims, claims relating to data and privacy protection, employment related cases and other matters in the ordinary course of our business. Laws, rules and regulations may vary in their scope and overseas laws and regulations may impose requirements that are more stringent than, or which conflict with, those in China. We have acquired and may acquire companies that may become subject to litigation, as well as regulatory proceedings. In addition, in connection with litigation or regulatory proceedings we may be subject to in various jurisdictions, we may be prohibited by laws, regulations or government authorities in one jurisdiction from complying with subpoenas, orders or other requests from courts or regulators of other jurisdictions, including those relating to data held in or with respect to persons in these jurisdictions. Our failure or inability to comply with the subpoenas, orders or requests could subject us to fines, penalties or other legal liability, which could have a material adverse effect on our reputation, business, results of operations and the trading price of our ADSs.

As publicly-listed companies, we and certain of our subsidiaries face additional exposure to claims and lawsuits inside and outside China. We will need to defend against these lawsuits, including any appeals should our initial defense be successful. The litigation process may utilize a material portion of our cash resources and divert management's attention away from the day-to-day operations of our company, all of which could harm our business. There can be no assurance that we will prevail in any of these cases, and any adverse outcome of these cases could have a material adverse effect on our reputation, business and results of operations. In addition, although we have obtained directors' and officers' liability insurance, the insurance coverage may not be adequate to cover our obligations to indemnify our directors and officers, fund a settlement of litigation in excess of insurance coverage or pay an adverse judgment in litigation.

The existence of litigation, claims, investigations and proceedings may harm our reputation, limit our ability to conduct our business in the affected areas and adversely affect the trading price of our ADSs. The outcome of any claims, investigations and proceedings is inherently uncertain, and in any event defending against these claims could be both costly and time-consuming, and could significantly divert the efforts and resources of our management and other personnel. An adverse determination in any litigation, investigation or proceeding could cause us to pay damages, incur legal and other costs, limit our ability to conduct business or require us to change the manner in which we operate.

Negative publicity with respect to us, our management, employees, business partners, affiliates, or our industry, may materially and adversely affect our reputation, business, results of operations and prospect.

Our reputation is vulnerable to many threats that can be difficult or impossible to control, and costly or impossible to remediate. Negative publicity about us, such as alleged misconduct or improper activities, or negative rumors relating to us, our management, employees, business partners or affiliates, can harm our business and results of operations, even if they are unsubstantiated or are satisfactorily addressed. For example, a number of media reported that our founder, Dr. Jingwu Zhang Zang, was involved in misrepresentation of certain data in a research paper prepared by scientists at GSK China's research center and published in Nature Medicine in 2010, for which Dr. Zang was the corresponding author, and consequently Dr. Zang was dismissed by GSK in 2013. In addition, Dr. Zang received a warning letter from the FDA in March 1999 relating to the lack of IND approval before the initiation of a clinical research study in human subjects. For details, please see "Item 6. Directors, Senior Management and Employees—A. Directors and Senior Management—Certain Past Incidents." To the best of our knowledge, Dr. Zang was not and is not subject to any legal or regulatory charges, proceedings or disciplinary actions in connection with these incidents or by relevant parties involved in the incidents. However, we cannot assure you that there will not be any inquiries, investigations or other actions against Dr. Zang by any regulatory or government authorities in the future. Any regulatory inquiries or investigations or other actions against Dr. Zang or our other management, any perceived unethical, fraudulent, or inappropriate business conduct by us or perceived wrong doing by any key member of our management team or other employees, our business partners or our affiliates, could harm our reputation and materially adversely affect our business. Regardless of the merits or final outcome of any such regulatory inquiries or investigations or other actions, our reputation may be substantially damaged, which may impede our ability to attract and retain talents and business partners and grow our business.

Moreover, any negative media publicity about the biopharmaceutical industry in general or product or service quality problems of other companies in the industry, including our peers, may also negatively impact our reputation. If we are unable to maintain a good reputation, our ability to attract and retain key employees and business partners could be harmed which in turn may materially and adversely affect our business, results of operations and prospect.

Change in business prospects of acquisitions may result in impairment to our goodwill, which could negatively affect our reported results of operations.

We acquired a controlling interest in I-Mab Tianjin in July 2017 and the remaining interest in I-Mab Tianjin in May 2018. In connection with our acquisition of I-Mab Tianjin, we identified RMB148.8 million of intangible assets and RMB162.6 million of goodwill of I-Mab Tianjin attributable to core technology and synergy effects expected from combining the operations of the discovery and development of innovative biologics and the development of clinical stage biologics. We are required to test our goodwill annually, or more frequently if events or changes in circumstances indicate that it might be impaired. Goodwill is allocated to cash-generating units or groups of cash-generating units for the purpose of impairment testing. An impairment loss of goodwill is recognized for the amount by which the relevant cash-generating unit's or group of cash-generating unit's carrying amount exceeds its recoverable amount, and we would be required to write down the carrying value of our goodwill during the period in which it is determined to be impaired, which would materially and adversely affect our results of operations.

We are subject to changing law and regulations regarding regulatory matters, corporate governance and public disclosure that have increased both our costs and the risk of non-compliance.

We are or will be subject to rules and regulations by various governing bodies, including, for example, once we have become a public company, the SEC, which is charged with the protection of investors and the oversight of companies whose securities are publicly traded, and the various regulatory authorities in China and the Cayman Islands, and to new and evolving regulatory measures under applicable law. Our efforts to comply with new and changing laws and regulations have resulted in and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

Risks Related to Doing Business in China

The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drugs.

Our research and development operations and manufacturing facilities are in China, which we believe confers clinical, commercial and regulatory advantages. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. See “Item 4. Information on the Company—B. Business Overview—Regulation” for a discussion of the regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. PRC authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach are aligned with the PRC government’s regulatory policies, but we cannot ensure that our strategy and approach will continue to be aligned.

Changes in the political and economic policies of the PRC government may materially and adversely affect our business, financial condition and results of operations and may result in our inability to sustain our growth and expansion strategies.

A significant portion of our operations are in China. Our financial condition and results of operations are affected to a large extent by economic, political and legal developments in China.

The PRC economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the PRC government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the PRC government continues to play a significant role in regulating industrial development by imposing industrial policies. The PRC government also exercises significant control over China’s economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions and providing preferential treatment to particular industries or companies.

While the PRC economy has experienced significant growth in the past four decades, growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may also have a negative effect on us. Our business, financial condition and results of operations could be materially and adversely affected by government control over capital investments or changes in tax regulations that are applicable to us.

In addition, the PRC government had, in the past, implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

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

Our primary business is governed by PRC laws and regulations. Our primary business operation is supervised by relevant regulatory authorities in China. The PRC legal system is a civil law system based on written statutes and, unlike the common law system, prior court decisions can only be cited as reference and have limited precedential value. Additionally, written statutes in the PRC are often principle-oriented and require detailed interpretations by the enforcement bodies to further apply and enforce such laws. Since 1979, the PRC government has developed a comprehensive system of laws, rules and regulations in relation to economic matters, such as foreign investment, corporate organization and governance, commerce, taxation and trade. However, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and may not be as consistent or predictable as in other more developed jurisdictions. As these laws and regulations are continually evolving in response to changing economic and other conditions, and because of the limited volume of published cases and their non-binding nature, any particular interpretation of PRC laws and regulations may not be definitive. Moreover, we cannot predict the effect of future developments in the PRC legal system and regulatory structure. Such unpredictability towards our contractual, property and procedural rights as well as our rights licensed, approved or granted by the competent regulatory authority could adversely affect our business and impede our ability to continue our operations. 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, if at all, and which may have a retroactive effect. Hence, we may not be aware of violation of these policies and rules until after such violation has occurred. Further, the legal protections available to us and our investors under these laws, rules and regulations may be limited.

In addition, any administrative or 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 various 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, enforcing foreign judgments or bringing actions in China against us or our management named in this annual report based on foreign laws.

We are a company incorporated under the laws of the Cayman Islands, we conduct substantially all of our operations in China and substantially all of our assets are located in China. In addition, all our senior executive officers reside within China for a significant portion of the time and some of them are PRC nationals. As a result, it may be difficult for you to effect service of process upon us or those persons inside China. It may also be difficult for you to enforce in U.S. courts judgments obtained in U.S. courts based on the civil liability provisions of the U.S. federal securities laws against us and our officers and directors as none of them currently resides in the United States or has substantial assets located in the United States. In addition, there is uncertainty as to whether the courts of the Cayman Islands or the PRC would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the United States or any state.

The recognition and enforcement of foreign judgments are provided for under the PRC Civil Procedures Law. PRC courts may recognize and enforce foreign judgments in accordance with the requirements of the PRC Civil Procedures Law based either on treaties between China and the country where the judgment is made or on principles of reciprocity between jurisdictions. China does not have any treaties or other forms of written arrangement with the United States that provide for the reciprocal recognition and enforcement of foreign judgments. In addition, according to the PRC Civil Procedures Law, the PRC courts will not enforce a foreign judgment against us or our directors and officers if they decide that the judgment violates the basic principles of PRC laws or national sovereignty, security or the public interest. As a result, it is uncertain whether and on what basis a PRC court would enforce a judgment rendered by a court in the United States.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the PRC State Council promulgated the Measures for the Management of Scientific Data, or the Scientific Data Measures, which 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 PRC 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. Currently, as the term "state secret" is not clearly defined, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad, or to our foreign partners in China.

If we are unable to obtain the necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to specific administrative penalties imposed by those government authorities.

Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results.

The U.S. government has made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies towards China. In January 2020, the "Phase One" agreement was signed between the United States and China on trade matters. However, it remains unclear what additional actions, if any, will be taken by the U.S. or other governments with respect to international trade agreements, the imposition of tariffs on goods imported into the U.S., tax policy related to international commerce, or other trade matters. While we have not started commercialization of drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our drug products, the competitive position of our drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. If any new tariffs, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders or ADS holders.

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside of the PRC with "de facto management body" within China is considered a "resident enterprise" and will be subject to the enterprise income tax on its global income at the rate of 25%. The implementation rules define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In 2009, the SAT issued the Circular of the State Administration of Taxation on Issues Relating to Identification of PRC-Controlled Overseas Registered Enterprises as Resident Enterprises in Accordance With the De Facto Standards of Organizational Management, or Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this Circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the SAT's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China and will be subject to PRC enterprise income tax on its global income if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in China; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and (iv) at least 50% of voting board members or senior executives habitually reside in China.

Our PRC counsel, JunHe LLP, has advised us that, based on its understanding of the current PRC Laws and Regulations, I-Mab should not be considered as a PRC resident enterprise for PRC tax income purposes. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body." If the PRC tax authorities determine that we are a PRC resident enterprise for enterprise income tax purposes, we could be subject to PRC tax at a rate of 25% on our worldwide income, which could materially reduce our net income, and we may be required to withhold a 10% withholding tax from dividends we pay to our shareholders that are non-resident enterprises (including the holders of our ADSs). In addition, non-resident enterprise shareholders (including our ADS holders) may be subject to PRC tax at a rate of 10% on gains realized on the sale or other disposition of ADSs or ordinary shares, if such income is treated as sourced from within China. Furthermore, if we are deemed a PRC resident enterprise, dividends payable to our non-PRC individual shareholders (including our ADS holders) and any gain realized on the transfer of ADSs or ordinary shares by such shareholders may be subject to PRC tax at a rate of 20% in the case of non-PRC individuals (which in the case of dividends may be withheld at source) unless a reduced rate is available under an applicable tax treaty. It is unclear whether non-PRC shareholders of our company would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. Any such tax may reduce the returns on your investment in the ADSs or ordinary shares.

Failure to renew our current leases or locate desirable alternatives for our leased properties could materially and adversely affect our business.

We lease properties for our offices and laboratories. We may not be able to successfully extend or renew such leases upon expiration of the current term on commercially reasonable terms or at all, and may therefore be forced to relocate our affected operations. This could disrupt our operations and result in significant relocation expenses, which could adversely affect our business, financial condition and results of operations. In addition, we compete with other businesses for premises at certain locations or of desirable sizes. As a result, even though we could extend or renew our leases, rental payments may significantly increase as a result of the high demand for the leased properties. In addition, we may not be able to locate desirable alternative sites for our current leased properties as our business continues to grow and failure in relocating our affected operations could adversely affect our business and operations.

Certain of our leasehold interests in leased properties have not been registered with the relevant PRC governmental authorities as required by relevant PRC laws. The failure to register leasehold interests may expose us to potential fines.

We have not registered certain of our lease agreements with the relevant government authorities. Under the relevant PRC laws and regulations, we may be required to register and file with the relevant government authority executed leases. The failure to register the lease agreements for our leased properties will not affect the validity of these lease agreements, but the competent housing authorities may order us to register the lease agreements in a prescribed period of time and impose a fine ranging from RMB1,000 to RMB10,000 for each non-registered lease if we fail to complete the registration within the prescribed timeframe.

We have granted, and may continue to grant, options and other types of awards under our share incentive plans, which may result in increased share-based compensation expenses.

We have adopted the Second Amended and Restated 2017 Employee Stock Option Plan (the "2017 Plan"), the Second Amended and Restated 2018 Employee Stock Option Plan (the "2018 Plan") and the 2019 Share Incentive Plan (the "2019 Plan"), for the purpose of granting share-based compensation awards to employees, directors and consultants to incentivize their performance and align their interests with ours. We recognize expenses in our consolidated financial statements in accordance with U.S. GAAP. As of February 29, 2020, options to purchase a total of 9,450,315 ordinary shares and 10,991,671 ordinary shares have been granted and outstanding under the 2017 Plan and 2018 Plan, respectively. As of February 29, 2020, no award has been granted or outstanding under the 2019 Plan. See "Item 6. Directors, Senior Management and Employees—Management—B. Compensation of Directors and Executive Officers—Share Incentive Plans."

We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we will continue to grant share-based compensation to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may have an adverse effect on our results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the grants under our currently effective share incentive plans from time to time. If we choose to do so, we may experience substantial change in our share-based compensation charges.

Fluctuations in exchange rates could have a material and adverse effect on our results of operations and the value of your investment.

The conversion of RMB into foreign currencies, including U.S. dollars, is based on rates set by the People's Bank of China. The RMB has fluctuated against the U.S. dollar, at times significantly and unpredictably. The value of RMB against the U.S. dollar and other currencies is affected by changes in China's political and economic conditions and by China's foreign exchange policies, among other things. We cannot assure you that RMB will not appreciate or depreciate significantly in value against the U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between RMB and the U.S. dollar in the future.

Any significant appreciation or depreciation of RMB may materially and adversely affect our revenues, earnings and financial position, and the value of, and any dividends payable on, our ADSs in U.S. dollars. For example, to the extent that we need to convert U.S. dollars we receive into RMB to pay our operating expenses, appreciation of RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, a significant depreciation of RMB against the U.S. dollar may significantly reduce the U.S. dollar equivalent of our earnings, which in turn could adversely affect the price of our ADSs.

Very limited hedging options are available in China to reduce our exposure to exchange rate fluctuations. To date, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by PRC exchange control regulations that restrict our ability to convert RMB into foreign currency. As a result, fluctuations in exchange rates may have a material adverse effect on your investment.

Certain PRC regulations may make it more difficult for us to pursue growth through acquisitions.

The Regulations on Mergers and Acquisitions of Domestic Enterprises by Foreign Investors, or the M&A Rules, adopted by six PRC regulatory agencies in 2006 and amended in 2009, established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. Such regulation requires, among other things, that the Ministry of Commerce, or MOFCOM, be notified in advance of any change of control transaction in which a foreign investor acquires control of a PRC domestic enterprise and involves any of the following circumstances: (i) any important industry is concerned; (ii) such transaction involves factors that impact or may impact national economic security; or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. Moreover, the Anti-Monopoly Law promulgated by the Standing Committee of National People's Congress which became effective in 2008 requires that transactions which are deemed concentrations and involve parties with specified turnover thresholds must be cleared by State Administration for Market Regulation (the "SAMR"), the successive authority of MOFCOM, before they can be completed.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We are a Cayman Islands holding company and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders and service any debt we may incur. If any of our PRC subsidiaries incur debt on its own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries, each of which is a wholly foreign-owned enterprise may pay dividends only out of its respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise is required to set aside at least 10% of its after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. At its discretion, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to a staff welfare and bonus fund. The reserve fund and staff welfare and bonus fund cannot be distributed to us as dividends.

Our PRC subsidiaries generate primarily all of their revenue in RMB, which is not freely convertible into other currencies. As result, any restriction on currency exchange may limit the ability of our PRC subsidiaries to use their RMB revenues to pay dividends to us.

The PRC government may continue to strengthen its capital controls, and more restrictions and a substantial vetting process may be put forward by SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends, or otherwise fund and conduct our business.

In addition, the PRC Enterprise Income Tax Law and its implementation rules provide that a withholding tax rate of up to 10% will be applicable to dividends payable by PRC companies to non-PRC-resident enterprises unless otherwise exempted or reduced according to treaties or arrangements between the PRC central government and governments of other countries or regions where the non-PRC-resident enterprises are incorporated.

PRC regulations relating to offshore investment activities by PRC residents may limit our PRC subsidiaries' ability to change their registered capital or distribute profits to us or otherwise expose us or our PRC resident beneficial owners to liability and penalties under PRC laws.

In July 2014, SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment Through Special Purpose Vehicles, or SAFE Circular 37. SAFE Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities as well as foreign individuals that are deemed as PRC residents for foreign exchange administration purpose) to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 further requires amendment to the SAFE registrations in the event of any changes with respect to the basic information of the offshore special purpose vehicle, such as changes of a PRC individual shareholder, name and operation term, or any significant changes with respect to the offshore special purpose vehicle, such as increase or decrease of capital contribution, share transfer or exchange, or mergers or divisions. SAFE Circular 37 is applicable to our shareholders who are PRC residents. If our shareholders who are PRC residents fail to make the required registration or to update the previously filed registration, our PRC subsidiaries may be prohibited from distributing their profits or the proceeds from any capital reduction, share transfer or liquidation to us, and we may also be prohibited from making additional capital contributions into our PRC subsidiaries.

In February 2015, SAFE promulgated a Notice on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment, or SAFE Notice 13, effective June 2015. Under SAFE Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound overseas direct investments, including those required under SAFE Circular 37, will be filed with qualified banks instead of SAFE. The qualified banks will directly examine the applications and accept registrations under the supervision of SAFE.

All of our shareholders who we are aware of being subject to the SAFE regulations have completed the initial registrations with the local SAFE branch or qualified banks as required by SAFE Circular 37. However, we may not be informed of the identities of all the PRC residents holding direct or indirect interests in our company, and we cannot provide any assurance that these PRC residents will comply with our request to make or obtain any applicable registrations or continuously comply with all requirements under SAFE Circular 37 or other related rules. The failure or inability of the relevant shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions, such as restrictions on our cross-border investment activities, on the ability of our wholly foreign-owned subsidiaries in China to distribute dividends and the proceeds from any reduction in capital, share transfer or liquidation to us. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits could be materially and adversely affected.

Any failure to comply with PRC regulations regarding our employee equity incentive plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

We and our directors, executive officers and other employees who are PRC citizens or who have resided in China for a continuous period of not less than one year and who will be granted restricted shares or options are subject to the Notice on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company, issued by SAFE in February 2012, according to which, employees, directors, supervisors and other management members participating in any share incentive plan of an overseas publicly listed company who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than one year, subject to limited exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain other procedures. In addition, an overseas entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests. Failure to complete the SAFE registrations may subject them to fines and legal sanctions and may also limit our ability to make payments under our equity incentive plans or receive dividends or sales proceeds related thereto, or our ability to contribute additional capital into our wholly foreign-owned enterprises in China and limit our wholly foreign-owned enterprises' ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our directors and employees under PRC law.

In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in China who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax. The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income taxes of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold applicable income taxes, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay or prevent us from making loans to our PRC subsidiaries or making additional capital contributions to our wholly foreigned-owned subsidiaries in China, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

We are an offshore holding company conducting our operations in China through our PRC subsidiaries. We may make loans to our PRC subsidiaries subject to the approval from governmental authorities and limitation on the available loan amount, or we may make additional capital contributions to our wholly foreign-owned subsidiaries in China.

Any loans to our wholly foreign-owned subsidiaries in China, which are treated as foreign-invested enterprises under PRC law, are subject to PRC regulations and foreign exchange loan registrations. For example, loans by us to our wholly foreign-owned subsidiaries in China to finance their activities cannot exceed statutory limits and must be registered with the local counterpart of SAFE. In addition, a foreign-invested enterprise shall use its capital pursuant to the principle of authenticity and self-use within its business scope. The capital of a foreign-invested enterprise shall not be used for the following purposes: (i) directly or indirectly used for payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; (ii) directly or indirectly used for investment in securities or investments other than banks' principal-secured products unless otherwise provided by relevant laws and regulations; (iii) the granting of loans to non-affiliated enterprises, except where it is expressly permitted in the business license; and (iv) paying the expenses related to the purchase of real estate that is not for self-use (except for the foreign-invested real estate enterprises).

SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming the Administration of Foreign Exchange Settlement of Capital of Foreign-invested Enterprises, or SAFE Circular 19, effective June 2015, in replacement of the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign-Invested Enterprises, the Notice from the State Administration of Foreign Exchange on Relevant Issues Concerning Strengthening the Administration of Foreign Exchange Businesses, and the Circular on Further Clarification and Regulation of the Issues Concerning the Administration of Certain Capital Account Foreign Exchange Businesses. According to SAFE Circular 19, the flow and use of RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company is regulated such that RMB capital may not be used for the issuance of RMB entrusted loans, the repayment of inter-enterprise loans or the repayment of banks loans that have been transferred to a third party. Although SAFE Circular 19 allows RMB capital converted from foreign currency-denominated registered capital of a foreign-invested enterprise to be used for equity investments within China, it also reiterates the principle that RMB converted from the foreign currency-denominated capital of a foreign-invested company may not be directly or indirectly used for purposes beyond its business scope. Thus, it is unclear whether SAFE will permit such capital to be used for equity investments in China in actual practice. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account, or SAFE Circular 16, effective on June 9, 2016, which reiterates some of the rules set forth in SAFE Circular 19, but changes the prohibition against using RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to non-associated enterprises. Violations of SAFE Circular 19 and SAFE Circular 16 could result in administrative penalties. SAFE Circular 19 and SAFE Circular 16 may significantly limit our ability to transfer any foreign currency we hold, including the net proceeds from our initial public offering, to our PRC subsidiaries, which may adversely affect our liquidity and our ability to fund and expand our business in China.

In light of the various requirements imposed by PRC regulations on loans to and direct investment in PRC entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans to our PRC subsidiaries or future capital contributions by us to our wholly foreign-owned subsidiaries in China. As a result, uncertainties exist as to our ability to provide prompt financial support to our PRC subsidiaries when needed. If we fail to complete such registrations or obtain such approvals, our ability to use foreign currency, including the proceeds we received from our initial public offering, to capitalize or otherwise fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

We and our shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributable to a PRC establishment of a non-PRC company.

On February 3, 2015, the SAT issued the Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Bulletin 7. Pursuant to this Bulletin, an “indirect transfer” of “PRC taxable assets,” including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC enterprise income tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax. When determining whether there is a “reasonable commercial purpose” of the transaction arrangement, factors to be taken into consideration include: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consist of direct or indirect investment in China or if its income mainly derives from China; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. On October 17, 2017, the SAT issued the Announcement of the State Administration of Taxation on Issues Concerning the Withholding of Non-resident Enterprise Income Tax at Source, or Bulletin 37, which came into effect on December 1, 2017. Bulletin 37 further clarifies the practice and procedure of the withholding of non-resident enterprise income tax.

Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors are not subject to the PRC enterprise income tax pursuant to Bulletin 7 where such shares were acquired in a transaction through a public stock exchange. However, the sale of ADSs or ordinary shares by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC enterprise income tax under Bulletin 7.

There are uncertainties as to the application of Bulletin 7. Bulletin 7 may be determined by the tax authorities to be applicable to the sale of the shares of our offshore subsidiaries or investments where PRC taxable assets are involved. The transferors and transferees may be subject to the tax filing and withholding or tax payment obligation, while our PRC subsidiaries may be requested to assist in the filing. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with Bulletin 7 or to establish that we and our non-resident enterprises should not be taxed under Bulletin 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial condition and results of operations.

The PRC tax authorities have the discretion under Bulletin 7 to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities make adjustments to the taxable income of the transactions under Bulletin 7 / Bulletin 37, our income tax costs associated with such potential acquisitions or disposals will increase, which may have an adverse effect on our financial condition and results of operations.

Recent litigation and negative publicity surrounding China-based companies listed in the U.S. may result in increased regulatory scrutiny of us and negatively impact the trading price of the ADSs and could have a material adverse effect upon our business, including our results of operations, financial condition, cash flows and prospects.

We believe that litigation and negative publicity surrounding companies with operations in China that are listed in the U.S. have negatively impacted stock prices for such companies. Various equity-based research organizations have published reports on China-based companies after examining, among other things, their corporate governance practices, related party transactions, sales practices and financial statements that have led to special investigations and stock suspensions on national exchanges. Any similar scrutiny of us, regardless of its lack of merit, could result in a diversion of management resources and energy, potential costs to defend ourselves against rumors, decreases and volatility in the ADS trading price, and increased directors and officers insurance premiums and could have a material adverse effect upon our business, including our results of operations, financial condition, cash flows and prospects.

Risks Related to Our ADSs

The trading price of our ADSs may be volatile, which could result in substantial losses to you.

The trading price of our ADSs ranged from US$9.30 to US$15.8 per ADS since the listing of ADSs on Nasdaq. The trading price of our ADSs can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control. In addition, the performance and fluctuation of the market prices of other companies with business operations located mainly in the PRC that have listed their securities in the United States may affect the volatility in the price of and trading volumes for our ADSs. Some of these companies have experienced significant volatility. The trading performances of these PRC companies' securities may affect the overall investor sentiment towards other PRC companies listed in the United States and consequently may impact the trading performance of our ADSs.

In addition to market and industry factors, the price and trading volume for our ADSs may be highly volatile for specific business reasons, including:

- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for a drug's use, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations, new products, acquisitions, strategic relationships, joint ventures or capital commitments by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- any adverse changes to our relationship with manufacturers or suppliers;
- the results of our testing and clinical trials;
- the results of our efforts to acquire or license additional drug candidates;
- variations in the level of expenses related to our existing drugs and drug candidates or pre-clinical, clinical development and commercialization programs;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- fluctuations in product revenue, sales and marketing expenses and profitability; manufacture, supply or distribution shortages;
- variations in our results of operations;
- announcements about our results of operations that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on results of operations;
- publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts;
- changes in financial estimates by securities research analysts;
- media reports, whether or not true, about our business, our competitors or our industry;
- additions to or departures of our management;
- fluctuations of exchange rates between the RMB and the U.S. dollar;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs;
- sales or perceived potential sales of additional ordinary shares or ADSs by us, our executive officers and directors or our shareholders;
- general economic and market conditions and overall fluctuations in the U.S. equity markets;
- changes in accounting principles; and
- changes or developments in the PRC or global regulatory environment.

In addition, the stock market, in general, and pharmaceutical and biotechnology companies have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ADSs, regardless of our actual operating performance. Further, the current volatility in the financial markets and related factors beyond our control may cause the market price of our ADSs to decline rapidly and unexpectedly.

We may face an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a significant decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatilities in recent years. If we were to face lawsuits, it could lead to substantial costs and a distraction of management's attention and resources, which could harm our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, or if they adversely change their recommendations regarding our ADSs, the market price for our ADSs and trading volume could decline.

The trading market for our ADSs will depend in part on the research and reports that securities or industry analysts publish about us or our business. If research analysts do not establish and maintain adequate research coverage or if one or more of the analysts who covers us downgrades our ADSs or publishes inaccurate or unfavorable research about our business, the market price for our ADSs would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for our ADSs to decline.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of our ADSs for return on your investment.

We currently intend to retain most, if not all, of our available funds and any future earnings to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our ADSs as a source for any future dividend income.

Our board of directors has complete discretion as to whether to distribute dividends, subject to our memorandum and articles of association and certain requirements of Cayman Islands law. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our directors. Under Cayman Islands law, a Cayman Islands company may pay a dividend out of either profit or share premium account of the company, provided that in no circumstances may a dividend be paid out of share premium if this would result in the company being unable to pay its debts as they fall due in the ordinary course of business. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. Accordingly, the return on your investment in our ADSs will likely depend entirely upon any future price appreciation of our ADSs. There is no guarantee that our ADSs will appreciate in value or even maintain the price at which you purchased the ADSs. You may not realize a return on your investment in our ADSs and you may even lose your entire investment in our ADSs.

Substantial future sales or perceived potential sales of our ADSs in the public market could cause the price of our ADSs to decline.

Sales of our ADSs in the public market, or the perception that these sales could occur, could cause the market price of our ADSs to decline. As of February 29, 2020, we had 133,006,644 ordinary shares issued and outstanding, including 18,804,225 ordinary shares represented by ADSs which are freely transferable without restriction or additional registration under the United States Securities Act of 1933, as amended, or the Securities Act. The remaining ordinary shares issued and outstanding will be available for sale, upon the expiration of the 180-day lock-up period beginning from the date of the prospectus of our initial public filing, subject to volume and other restrictions as applicable under Rules 144 and 701 under the Securities Act. Certain holders of our ordinary shares may cause us to register under the Securities Act the sale of their shares, subject to the 180-day lock-up period in connection with our initial public offering. Registration of these shares under the Securities Act would result in ADSs representing these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. Sales of these registered shares in the form of ADSs in the public market could cause the price of our ADSs to decline. Any or all of these shares may be released prior to the expiration of the lock-up period at the discretion of the representatives of the underwriters of our initial public offering. To the extent shares are released before the expiration of the lock-up period and sold into the market, the market price of our ADSs could decline.

The voting rights of holders of ADSs are limited by the terms of the deposit agreement, and you may not be able to exercise the same rights as our shareholders.

Holders of ADSs do not have the same rights as our shareholders. As a holder of our ADSs, you will not have any direct right to attend general meetings of our shareholders or to cast any votes at such meetings. As an ADS holder, you will only be able to exercise the voting rights carried by the underlying ordinary shares indirectly by giving voting instructions to the depositary in accordance with the provisions of the deposit agreement. Under the deposit agreement, you may vote only by giving voting instructions to the depositary. Upon receipt of your voting instructions, the depositary will try, as far as is practicable, to vote the ordinary shares underlying your ADSs in accordance with your instructions. If we ask for your instructions, then upon receipt of your voting instructions, the depositary will try to vote the underlying ordinary shares in accordance with these instructions. If we do not instruct the depositary to ask for your instructions, the depositary may still vote in accordance with instructions you give, but it is not required to do so. You will not be able to directly exercise your right to vote with respect to the underlying ordinary shares unless you withdraw the shares, and become the registered holder of such shares prior to the record date for the general meeting. When a general meeting is convened, you may not receive sufficient advance notice of the meeting to withdraw the shares underlying your ADSs and become the registered holder of such shares to allow you to attend the general meeting and to vote directly with respect to any specific matter or resolution to be considered and voted upon at the general meeting. In addition, under our memorandum and articles of association, for the purposes of determining those shareholders who are entitled to attend and vote at any general meeting, our directors may close our register of members and/or fix in advance a record date for such meeting, and such closure of our register of members or the setting of such a record date may prevent you from withdrawing the ordinary shares underlying your ADSs and becoming the registered holder of such shares prior to the record date, so that you would not be able to attend the general meeting or to vote directly. If we ask for your instructions, the depositary will notify you of the upcoming vote and will arrange to deliver our voting materials to you. We have agreed to give the depositary notice of shareholder meetings sufficiently in advance of such meetings. Nevertheless, we cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote the underlying ordinary shares represented by your ADSs. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for their manner of carrying out your voting instructions. This means that you may not be able to exercise your right to direct how the shares underlying your ADSs are voted and you may have no legal remedy if the shares underlying your ADSs are not voted as you requested. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting. Except in limited circumstances, the depositary for our ADSs will give us a discretionary proxy to vote the ordinary shares underlying your ADSs if you do not vote at shareholders' meetings, which could adversely affect your interests.

Under the deposit agreement for the ADSs, if you do not vote, the depositary will give us a discretionary proxy to vote the ordinary shares underlying your ADSs at shareholders' meetings unless:

- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting;
- a matter to be voted on at the meeting would have an adverse impact on shareholders; or
- the voting at the meeting is to be made on a show of hands.

The effect of this discretionary proxy is that you cannot prevent our ordinary shares underlying your ADSs from being voted, except under the circumstances described above. This may make it more difficult for shareholders to influence the management of our company. Holders of our ordinary shares are not subject to this discretionary proxy.

Your right to participate in any future rights offerings 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 rights available to you in the United States 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. Under the deposit agreement, the depositary will not make rights available to you unless both the rights and the underlying securities to be distributed to ADS holders are either registered under the Securities Act or exempt from registration under the Securities Act. 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 Securities Act. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

You may not receive cash dividends if the depositary decides it is impractical to make them available to you.

The depositary will pay cash dividends on the ADSs only to the extent that we decide to distribute dividends on our ordinary shares or other deposited securities, and we do not have any present plan to pay any cash dividends on our ordinary shares in the foreseeable future. To the extent that there is a distribution, the depositary of our ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses pursuant to the deposit agreement. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent. However, the depositary may, at its discretion, decide that it is inequitable or impractical to make a distribution available to any holders of ADSs. For example, the depositary may determine that it is not practicable to distribute certain property through the mail, or that the value of certain distributions may be less than the cost of mailing them. In these cases, the depositary may decide not to distribute such property to you.

You may be subject to limitations on transfer of your ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depositary may close its books from time to time for a number of reasons, including in connection with corporate events such as a rights offering, during which time the depositary needs to maintain an exact number of ADS holders on its books for a specified period. The depositary may also close its books in emergencies, and on weekends and public holidays. In addition, the depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason.

Certain judgments obtained against us by our shareholders may not be enforceable.

We are an exempted company incorporated under the laws of the Cayman Islands. We conduct our operations in China and substantially all of our assets are located in China. In addition, our directors and executive officers, and some of the experts named in this annual report, reside within China, and most of the assets of these persons are located within China. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the United States in the event that you believe that your rights have been infringed under the U.S. federal securities laws or otherwise. Even if you are successful in bringing an action of this kind, the laws of the Cayman Islands and of the PRC may render you unable to enforce a judgment against our assets or the assets of our directors and officers.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable outcomes to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that, subject to the depositary's right to require a claim to be submitted to the federal or state courts in the City of New York have jurisdiction to hear and determine claims arising under the deposit agreement and in that regard, to the fullest extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. Also, we may amend or terminate the deposit agreement without your consent. If you continue to hold your ADSs after an amendment to the deposit agreement, you agree to be bound by the deposit agreement as amended.

If we or the depositary were to oppose a jury trial demand based on such waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable state and federal law, including whether a party knowingly, intelligently and voluntarily waived the right to a jury trial. The waiver to right to a jury trial of the deposit agreement is not intended to be deemed a waiver by any holder or beneficial owner of ADSs of our or the depositary's compliance with the U.S. federal securities laws and the rules and regulations promulgated thereunder.

If you or any other holders or beneficial owners of ADSs bring a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under U.S. federal securities laws, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and/or the depositary. If a lawsuit is brought against us and/or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, in which the trial would be conducted according to different civil procedures and may result in different outcomes than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action.

Nevertheless, if this jury trial waiver provision is not enforced, to the extent a court action proceeds, it would proceed under the terms of the deposit agreement with a jury trial. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any substantive provision of the U.S. federal securities laws and the rules and regulations promulgated thereunder.

You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited, because we are incorporated under Cayman Islands law.

We are an exempted company incorporated under the laws of the Cayman Islands with limited liability. Our corporate affairs are governed by our memorandum and articles of association, the Companies Law (2020 Revision) of the Cayman Islands, which we refer to as the Companies Law, and the common law of the Cayman Islands. The rights of shareholders to take action against our directors, actions by our minority shareholders and the fiduciary duties of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from the common law of England, the decisions of whose courts are of persuasive authority, but are not binding, on a court in the Cayman Islands. The rights of our shareholders and the fiduciary duties of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a less developed body of securities laws than the United States. Some U.S. states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. In addition, Cayman Islands companies may not have standing to initiate a shareholder derivative action in a federal court of the United States.

Shareholders of Cayman Islands exempted companies like us have no general rights under Cayman Islands law to inspect corporate records or to obtain copies of lists of shareholders of these companies. Our directors have discretion under our articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest.

As a result of all of the above, our public shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as public shareholders of a company incorporated in the United States.

Our memorandum and articles of association contains anti-takeover provisions that could discourage a third party from acquiring us and adversely affect the rights of holders of our ordinary shares and the ADSs.

Our memorandum and articles of association contains provisions to limit the ability of others to acquire control of our company or cause us to engage in change of control transactions. These provisions could have the effect of depriving our shareholders of an opportunity to sell their shares at a premium over prevailing market prices by discouraging third parties from seeking to obtain control of our company in a tender offer or similar transaction. Our board of directors has the authority to issue preferred shares in one or more series and to fix their designations, powers, preferences, privileges, and relative participating, optional or special rights and the qualifications, limitations or restrictions, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights associated with our ordinary shares, in the form of ADS or otherwise. Preferred shares could be issued with terms calculated to delay or prevent a change in control of our company or make removal of management more difficult. If our board of directors decides to issue preferred shares, the price of our ADSs may fall and the voting and other rights of the holders of our ordinary shares and ADSs may be materially and adversely affected.

We are an emerging growth company within the meaning of the Securities Act and may take advantage of certain reduced reporting requirements.

We are an "emerging growth company," as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various requirements applicable to other public companies that are not emerging growth companies including, most significantly, not being required to comply with the auditor attestation requirements of Section 404 of Sarbanes-Oxley Act of 2002 for so long as we are an emerging growth company. As a result, if we elect not to comply with such auditor attestation requirements, our investors may not have access to certain information they may deem important.

The JOBS Act also provides that an emerging growth company does not need to comply with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or revised accounting standards. However, we have elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted for public companies. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

We are a foreign private issuer within the meaning of the rules under the Exchange Act, and as such we are exempt from certain provisions applicable to U.S. domestic public companies.

Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the securities rules and regulations in the United States that are applicable to U.S. domestic issuers, including:

- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q or current reports on Form 8-K;
- the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the selective disclosure rules by issuers of material nonpublic information under Regulation FD promulgated by SEC.

We will be required to file an annual report on Form 20-F within four months of the end of each fiscal year. In addition, we intend to publish our results on a quarterly basis as press releases, distributed pursuant to the rules and regulations of the Nasdaq Stock Market. Press releases relating to financial results and material events will also be furnished to the SEC on Form 6-K. However, the information we are required to file with or furnish to the SEC will be less extensive and less timely compared to that required to be filed with the SEC by U.S. domestic issuers. As a result, you may not be afforded the same protections or information that would be made available to you were you investing in a U.S. domestic issuer.

As an exempted company incorporated in the Cayman Islands, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from the Nasdaq Stock Market's corporate governance requirements; these practices may afford less protection to shareholders than they would enjoy if we complied fully with the Nasdaq Stock Market's corporate governance requirements.

As a Cayman Islands company listed on the Nasdaq Stock Market, we are subject to the Nasdaq Stock Market's corporate governance requirements. However, the Nasdaq Stock Market rules permit a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq Stock Market's corporate governance requirements. For example, neither the Companies Law nor our memorandum and articles of association requires a majority of our directors to be independent and we could include non-independent directors as members of our compensation committee and nominating committee, and our independent directors would not necessarily hold regularly scheduled meetings at which only independent directors are present. Currently, we do not plan to rely on home country practice with respect to our corporate governance. However, if we choose to follow home country practice in the future, our shareholders may be afforded less protection than they otherwise would under the Nasdaq Stock Market's corporate governance requirements applicable to U.S. domestic issuers.

There can be no assurance that we will not be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year, which could subject U.S. investors in our ADSs or ordinary shares to significant adverse U.S. income tax consequences.

We will be a passive foreign investment company, or PFIC, for any taxable year if either (i) 75% or more of our gross income for such year consists of certain types of "passive" income or (ii) 50% or more of the average quarterly value of our assets (generally determined on the basis of fair market value) during such year produce or are held for the production of passive income (the "asset test"). No assurance can be given with respect to our PFIC status for our taxable year ended December 31, 2019 or for the current taxable year or any future taxable year. The determination of whether we are or will become a PFIC is uncertain because it is a fact-intensive inquiry made on an annual basis that will depend, in part, on the composition of our income and assets. Fluctuations in the market price of our ADSs may cause us to be a PFIC for the current or subsequent taxable years because the value of our assets for purposes of the asset test may be determined by reference to the market price of our ADSs from time to time (which may be volatile for biopharmaceutical companies, such as ours, that have not yet achieved commercialization with respect to any of their products). The composition of our income and assets may also be affected by how, and how quickly, we use our liquid assets. Under circumstances where our revenue from activities that produce passive income increases relative to our revenue from activities that produce non-passive income, or where we determine not to deploy cash for active purposes, our risk of being a PFIC will substantially increase. Because there are uncertainties in the application of the relevant rules, it is possible that the IRS may challenge our classification or valuation of certain income and assets, each of which may result in our being or becoming a PFIC for the current or subsequent taxable years.

If we are a PFIC in any taxable year, a U.S. Holder (as defined in "Taxation—United States Federal Income Tax Considerations") may incur significantly increased U.S. income tax on gain recognized on the sale or other disposition of the ADSs or ordinary shares and on the receipt of distributions on the ADSs or ordinary shares to the extent such gain or distribution is treated as an "excess distribution" under the U.S. federal income tax rules and such holder may be subject to burdensome reporting requirements. Further, if we are a PFIC for any year during which a U.S. holder holds our ADSs or ordinary shares, we generally will continue to be treated as a PFIC for all succeeding years during which such U.S. holder holds our ADSs or ordinary shares. For more information see "Item 10. Additional Information—E. Taxation—United States Federal Income Tax Considerations—Passive Foreign Investment Company Considerations."

We expect to incur increased costs and become subject to additional rules and regulations as a result of being a public company, particularly after we cease to qualify as an "emerging growth company."

As a public company, we expect to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and the Nasdaq Global Market, impose various requirements on the corporate governance practices of public companies. As a company with less than US$1.07 billion in net revenues for our last fiscal year, we qualify as an "emerging growth company" pursuant to the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company's internal control over financial reporting and permission to delay adopting new or revised accounting standards until such time as those standards apply to private companies. However, we have elected to "opt out" of the provision that allows us to delay adopting new or revised accounting standards and, as a result, we will comply with new or revised accounting standards as required when they are adopted for public companies. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

We expect these rules and regulations to increase our legal and financial compliance costs and make some corporate activities more time-consuming and costly. After we are no longer an "emerging growth company," we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and the other rules and regulations of the SEC. We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. In addition, we will incur additional costs associated with our public company reporting requirements. It may also be more difficult for us to find qualified persons to serve on our board of directors or as executive officers. We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate with any degree of certainty the amount of additional costs we may incur or the timing of such costs.

In the past, shareholders of a public company often brought securities class action suits against the company following periods of instability in the market price of that company's securities. If we were involved in a class action suit, it could divert a significant amount of our management's attention and other resources from our business and operations, which could harm our results of operations and require us to incur significant expenses to defend the suit. Any such class action suit, whether or not successful, could harm our reputation and restrict our ability to raise capital in the future. In addition, if a claim is successfully made against us, we may be required to pay significant damages, which could have a material adverse effect on our financial condition and results of operations.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

We commenced our operations in November 2014, when our predecessor Third Venture Biopharma (Nanjing) Co., Ltd ("Third Venture") was established.

I-Mab was incorporated in June 2016 under the laws of the Cayman Islands as our offshore holding company. In July 2016, I-Mab established I-Mab Biopharma Hong Kong Limited ("I-Mab Hong Kong"), as its intermediary holding company. In August 2016, I-Mab Hong Kong established a wholly-owned PRC subsidiary, I-Mab Biopharma (Shanghai) Co., Ltd. ("I-Mab Shanghai"). In September 2016, the assets and operations of Third Venture were consolidated into I-Mab Shanghai.

In July 2017, I-Mab Hong Kong acquired a controlling interest in I-Mab Bio-tech (Tianjin) Co., Ltd. ("I-Mab Tianjin"), formerly known as Tasgen Bio-tech (Tianjin) Co., Ltd., a company focused on CMC management of biologics in China. Through an internal corporate restructuring, I-Mab Tianjin became the 100% owner of I-Mab Shanghai in September 2017 and I-Mab Hong Kong acquired the remaining interest in I-Mab Tianjin in May 2018, becoming the 100% owner of I-Mab Tianjin.

In February 2018, I-Mab Hong Kong established in Maryland, United States, a wholly-owned subsidiary I-Mab Biopharma US Limited ("I-Mab US"), as the hub for the discovery and development of the drug candidates in our Global Portfolio.

On January 17, 2020, our ADSs commenced trading on the Nasdaq Global Market under the symbol "IMAB." We raised from our initial public offering approximately US$103.7 million in net proceeds, after the underwriters exercise in part their over-allotment option to purchase additional ADSs.

Our principal executive offices are located at Suite 802, West Tower, OmniVision, 88 Shangke Road, Pudong District, Shanghai, People's Republic of China. Our telephone number at this address is +86 21-6057-8000. Our registered office in the Cayman Islands is located at Vistra (Cayman) Limited, P.O. Box 31119 Grand Pavilion, Hibiscus Way, 802 West Bay Road, Grand Cayman, KY1-1205, Cayman Islands.

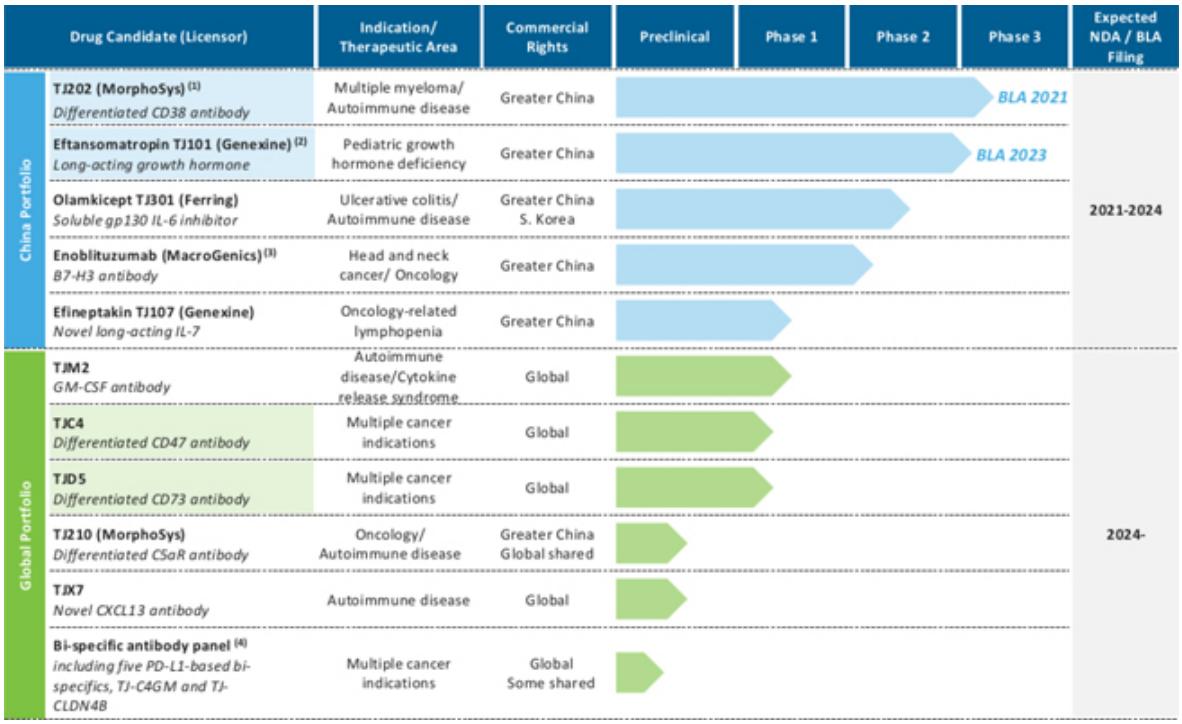
B. Business Overview

We are a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of novel or highly differentiated biologics to treat diseases with significant unmet medical needs, particularly cancers and autoimmune disorders.

We were founded to capture the opportunities presented by the confluence of two major developments—the emergence of an attractive and growing biologics market in China, and the revolutionary scientific breakthroughs in cancer and autoimmune disease medicines. We believe we are well-positioned to become a biotech leader in China because of our innovative discovery expertise, fit-for-purpose technology platforms, biomarker-enabled translational medicine capabilities, and clinical development capabilities. These integrated capabilities are further enhanced by our deep understanding of China's biologics regulatory framework and our direct access to extensive pre-clinical and clinical trial resources in China. To date, we have developed an innovative pipeline of more than 10 clinical and pre-clinical stage assets through our internal research and development efforts and in-licensing arrangements with global pharmaceutical and biotech companies.

Our Drug Pipeline

The chart below summarizes the development status of our drug pipeline.



Notes:

* (i) For TJ202, it has two ongoing registrational trials, a monotherapy trial and a combination therapy trial in multiple myeloma in Greater China, and we expect to initiate a Phase 1b trial in systemic lupus erythematosus ("SLE") in 2020; (ii) for TJ101, we are working towards submitting an IND application in 2020 for a Phase 3 registrational trial in China; and (iii) for enoblituzumab, we expect to submit an IND application in 2020 for a registrational trial or a Phase 2 trial.
* We were collaborating with Everest Medicines Limited ("Everest") to co-develop and commercialize TJ202 in Greater China for all indications in hematologic oncology. Everest was primarily responsible for sharing with us, by the proportion of 75% for Everest and 25% for us, the development costs of TJ202. On November 4, 2019, we and Everest terminated the collaboration agreement (including all the supplements and amendments thereto) with respect to the co-development and commercialization of TJ202 in Greater China. Upon the termination, Everest will not retain any rights or entitlements to develop or commercialize TJ202 or any economic interest in its commercialization. All intellectual property rights in respect of TJ202 arising from its development under the collaboration agreement are vested and owned by us, and we hold all intellectual property rights and have maximum flexibility to further develop, manufacture and commercialize TJ202 in Greater China. In consideration of the above arrangements, we issued a total value of US$37.0 million of ordinary shares (the "CPP Shares") to Everest, representing Everest's historical contribution to our collaboration and the associated time cost. The CPP Shares were issued concurrently with the completion of our initial public offering, at a per share price equal to the initial public offering price adjusted to reflect the ADS-to-ordinary share ratio.
** Our bi-specific antibody panel consists of (i) five PD-L1-based bi-specific antibodies, including TJ-L1C4 (PD-L1 and CD47), TJ-L1D5 (PD-L1 and CD73), TJ-L1H3 (PD-L1 and B7-H3), TJ-L14B (PD-L1 and 4-1BB) and TJ-L1I7 (anti-PD-L1 and IL-7 cytokine fusion), (ii) TJ-C4GM (anti-CD47 and GM-CSF cytokine fusion), and (iii) TJ-CLDN4B (Claudin 18.2 and 4-1BB).

China Portfolio

TJ202: A Potential Highly Differentiated CD38 Antibody for Multiple Myeloma and Autoimmune Diseases

Summary—

TJ202 (MOR202) is a fully human, highly differentiated monoclonal antibody directed against CD38. TJ202, if approved, is positioned as a potential highly differentiated anti-CD38 therapy for multiple myeloma ("MM"), either as a monotherapy or as a combination therapy with other anti-cancer agents. We aim to demonstrate the advantages of TJ202, including its short infusion time, low infusion reaction rate ("IRR") and potentially sustained efficacy, in our ongoing clinical trials in China. Additionally, as pathogenic CD38-positive B cells and plasma cells are strongly implicated in the disease progression of pathogenic antibody-mediated autoimmune diseases, we believe the therapeutic value of TJ202 can be extended to these diseases that have significant unmet medical needs. We have begun to explore its therapeutic application in systemic lupus erythematosus ("SLE") and later in other autoimmune diseases. In November 2017, we obtained an exclusive license from MorphoSys to develop TJ202 in Greater China. The development of TJ202 is driven by a fast-to-market strategy. We have started registrational trials for a third-line monotherapy and a second-line treatment trial in combination with lenalidomide, both in patients with MM in Greater China. We aim to submit a BLA for TJ202 as a third-line monotherapy in 2021, followed by another BLA submission for TJ202 as a second-line combination therapy. Additionally, we submitted an IND application to the NMPA in October 2019 and expect to initiate a clinical trial for TJ202 in SLE patients in 2020.

Therapeutic Options and Current Development—

Multiple Myeloma (MM)

The treatment options and investigational drugs under development in China include: (i) for small molecule drugs, two or three approved drugs known as doublets or triplets are used. VRD triplet (Velcade (bortezomib), Revlimid (lenalidomide) and dexamethasone) has recently been approved for overseas frontline treatment and is recommended in China in the 2017 version of treatment guideline. VCD triplet (Velcade, cyclophosphamide and dexamethasone) is the most widely adopted first-line treatment in China due to its lower cost. In 2017, lenalidomide and bortezomib were included in the National Reimbursement Drug List in China; (ii) with respect to CD38 antibody therapy, daratumumab (from Johnson & Johnson) received conditional NDA approval from the NMPA in July 2019, and isatuximab (from Sanofi) is in a Phase 3 trial in China; and (iii) for CAR-T therapy, several Phase 1 or 2 clinical trials are ongoing in China.

However, there is no curative treatment for MM. Although the currently marketed CD38 antibody in China is efficacious, it takes a long time to be administered by IV infusion (up to six hours) and causes a high infusion reaction rate ("IRR"). In clinical trials, approximately half of all patients experience an infusion reaction, symptoms of which may include fever, chills, nausea, bronchospasm, hypoxia, dyspnea, hypertension, laryngeal edema and pulmonary edema. Thus, there is a need for a safer and convenient-to-use drug. Such a drug may be combined with other therapeutic agents for better treatment effects in MM.

Systemic Lupus Erythematosus (SLE)

Patients with mild SLE are often given non-steroidal anti-inflammatory drugs, while more severe patients may need corticosteroids or immunosuppressants. Approved by the FDA in 2011 and by the NMPA in July 2019, Benlysta (belimumab), a B-lymphocyte stimulator (BLyS)-specific inhibitor developed by GSK, is currently the world's only biologic approved to treat SLE. However, there remains a significant unmet medical need beyond belimumab for SLE in China and the rest of the world. As dysregulated CD38-positive B cells and auto-antibodies produced by CD38-positive plasma cells and resulting immune complexes are at the core of the pathogenesis of SLE, direct inhibition and selective depletion of pathogenic B cells and plasma cells are believed to offer better treatment options. Our TJ202 has the potential to offer such a disease-modifying treatment option. In addition, as described below, the advantages of our TJ202 include convenience of use and a lower IRR, making it a more favorable treatment agent in the long-term clinical management of SLE if approved.

Advantages of TJ202—

TJ202, if approved, is a potentially highly differentiated CD38 monoclonal antibody and could be the second antibody therapy for MM to launch in China. A Phase 2a trial of TJ202 in MM showed a level of treatment effects comparable to that observed in trials of the currently marketed CD38 antibody. However, available trial data from MorphoSys and Johnson & Johnson indicate that with similar pre-medications of dexamethasone, anti-pyretics and anti-histamines, TJ202 required only a short infusion time of 0.5 to 2 hours, compared to 3.5 to 6.5 hours for the currently marketed CD38 antibody at the first infusion. Moreover, the IRR was as low as 7% for TJ202, compared to 48% for the currently marketed CD38 antibody. The advantages of TJ202 associated with infusion may be attributed to its lack of antibody CDC activity and are likely to translate into clinical benefits in terms of tolerability and convenience of use as well as economic benefits due to the cost and length of hospital stay. In addition, unlike the currently marketed CD38 antibody, TJ202 treatment does not down-regulate CD38 expression on the surface of bone marrow myeloma cells in vitro, maintaining sensitivity of malignant myeloma cells to repeated TJ202 treatments. As TJ202 is being considered for long-term treatment management of autoimmune diseases, we believe such clinical differentiation is critical.

For autoimmune diseases, TJ202 has advantages over other B cell-targeting therapies such as CD20 antibodies, as it specifically targets malfunctioned CD38 ^{high} B cells and pathogenic plasma cells involved in autoimmune diseases while CD20 antibodies target most B cells, including those involved in normal immune functions and regulatory functions, but not plasma cells producing pathogenic antibodies.

Mechanism of Action—

TJ202 binds to CD38 overexpressed on the surface of target cells and kills them by inducing antibody-dependent cellular cytotoxicity ("ADCC") and antibody-dependent cellular phagocytosis ("ADCP"). The target cells are the malignant plasma cells in MM and a group of dysregulated CD38 ^{high} B cells and plasma cells that produce pathogenic antibodies in autoimmune conditions such as SLE.

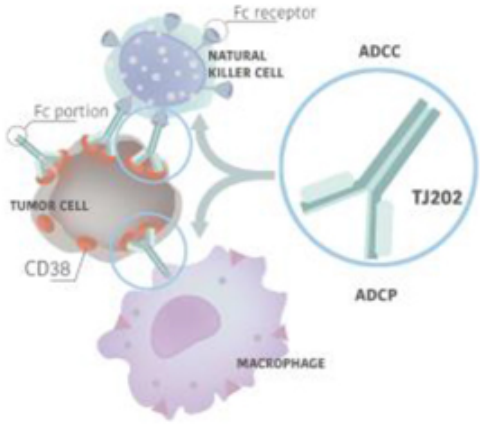


Figure: TJ202 kills CD38-bearing tumor cells by inducing ADCC and ADCP.

Summary of Clinical Results—

MorphoSys has conducted a Phase 1/2a study in adult patients with relapsed or refractory MM in Austria and Germany.

Study Design. The open-label, multicenter, dose-escalation study was designed to characterize the safety profile and preliminary efficacy of TJ202 in adults with relapsed or refractory MM. A 3+3 dose escalation design was used to establish the maximum tolerated dose ("MTD"), recommended dose and dosing regimen of TJ202 as monotherapy, weekly or bi-weekly, with or without dexamethasone ("DEX"), and in combination with pomalidomide ("POM") and DEX or lenalidomide ("LEN") and DEX standard regimens. The MTD and recommended dose and dosing regimens were to be confirmed in three confirmation cohorts of at least six evaluable subjects each. TJ202 dose levels in this study ranged from 0.01 mg/kg to 16.0 mg/kg, administered by intravenous ("IV") infusion.

The clinical study results as of the data cutoff date, December 31, 2017, are summarized as follows.

Safety. TJ202 was well tolerated in patients with RRMM, as a single agent and in combination with DEX, or with POM/DEX, or with LEN/DEX. The MTD of TJ202 was not reached. In the 56 patients from three groups receiving combination regimens, grade $\geq$ 3 adverse events ("AEs") were mainly in the hematological system reflected by a decrease of various blood cells. This was as expected, because of decreased bone marrow function due to the presence of myeloma as well as the expression of CD38 on various cell lineages of the myeloid and lymphoid compartments. Most of the hematological adverse events were transient and generally manageable.

TJ202 was administered as a two-hour IV infusion at first dose and infusion time could be reduced to as short as 30 minutes at subsequent doses without obvious safety concerns. Among all cohorts, infusion-related reactions, including tachycardia, pyrexia and hypersensitivity, occurred in 18 of 91 patients (19.8%) and were mostly mild to moderate. In the combination cohorts containing DEX, a very low IRR (4 out of 56 patients (7%)) was observed. These results compared favorably with the historical data of the currently marketed CD38 antibody.

Clinical Efficacy. Preliminary efficacy results were based on 56 patients from three groups treated with TJ202 combination therapies. No responses were observed for the monotherapy groups which were primarily serving for dose escalation. TJ202 in combination with low dose DEX, POM/DEX or LEN/DEX demonstrated an overall response rate ("ORR") of 28%, 48% and 65%, respectively. Durable responses were observed as median progression-free survival ("PFS") was of 8.4 months and 17.5 months for the DEX and the POM/DEX combination groups, respectively, and PFS levels were not reached for the LEN/DEX combination group, as there were not sufficient events of progression recorded.

Figure: Best overall response and ORR. Patients were treated with TJ202 (MOR202) in combination with low dose of DEX (40 mg for 75 years old and younger, or 20 mg for older than 75 years old), POM (4 mg) /Dex or LEN (25 mg)/Dex. Dex: dexamethasone; POM: pomalidomide; LEN: lenalidomide; ITT: intent to treat; NE: not evaluable; PD: progressive disease; SD: stable disease; MR: minimal response; PR: partial response; VGPR: very good partial response; CR: complete response; sCR: stringent complete response; ORR: overall response rate. (Source: MorphoSys)

The definitions of PD, SD, MR, PR, VGPR, CR and sCR and how these responses were measured for multiple myeloma are set forth in the table below. *(Source: International Myeloma Working Group Uniform Response Criteria (2006) and European Group for Blood and Marrow Transplantation Criteria)*

RESPONSE SUBCATEGORY	CRITERIA [A]
sCR	• CR as defined below plus Normal free light chain ratio (FLC) and Absence of clonal cells in bone marrow [b] by immunohistochemistry or immunofluorescence [c]
CR	• Negative immunofixation on the serum and urine and • Disappearance of any soft tissue plasmacytomas and • b
VGPR	• Serum and urine M-protein detectable by immunofixation but not electrophoresis or • ³ 90% reduction in serum M-protein plus urine M-protein level
PR	• ³ 50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ³ 90% or to • If the serum and urine M-protein were unmeasurable, a ³ 50% decrease in the difference between levels of involved and uninvolved free-light-chains instead of the M-protein criteria

RESPONSE SUBCATEGORY	CRITERIA [a]
	• In addition to the above-listed criteria, if present at baseline, a ³ 50% reduction in the size of soft tissue plasmacytomas was also required
MR [d,e]	• 25–49% reduction in level of serum M-protein • 50–89% reduction in 24-hour urinary M-protein, which still exceeds 200 mg/24 hours. If present at baseline, 25–49% reduction in the size of soft tissue plasmacytomas (by radiography or clinical examination) • No increase in the size or number of lytic bone lesions (development of a compression fracture did not exclude response)
SD [f]	• Not meeting criteria for CR, VGPR, PR, MR, or PD
PD	NOTE: Required any 1 or more of the following: Increase of ³ 25% from nadir in • Serum M-component and/or (absolute increase ³ 0.5 g/dL) [g] • Urine M-component and/or (absolute increase ³ 200 mg/24 hours) • Only in subjects without measurable serum and urine M-protein levels: the difference between involved and uninvolved FLC levels. Absolute increase >10 mg/dL. • Bone marrow plasma cell percentage: absolute % ³ 10% [h] • Definite development of new bone lesions or soft tissue plasmacytomas or definite increase in the size of existing bone lesions or soft tissue plasmacytomas • Development of hypercalcemia (corrected serum calcium >11.5 mg/dL or 2.65 mmol/L) that could be attributed solely to the plasma cell proliferative disorder

Notes:

a All response categories required 2 consecutive assessments made at any time before the institution of any new therapy; all categories also required no known evidence of progressive or new bone lesions if radiographic studies were performed. Radiographic studies were not required to satisfy these response requirements.

b Confirmation with repeat bone marrow biopsy not needed.

c Presence/absence of clonal cells was based upon the *k* / *l* ratio. An abnormal *k* / *l* ratio by immunohistochemistry and/or immunofluorescence required a minimum of 100 plasma cells for analysis. An abnormal ratio reflecting presence of an abnormal clone is *k* / *l* of >4:1 or

d MR also included subjects in whom some, but not all, the criteria for PR were fulfilled, provided the remaining criteria satisfied the requirements for MR.

e The response criterion MR did not apply to subjects who presented with serum FLCs only.

f Per the International Myeloma Working Group Uniform Response Criteria, stable disease was not recommended for use as an indicator of response; stability of disease is best described by providing the time to progression estimates.

g For progressive disease, serum M-component increases of ³ 1 g/dL were sufficient to define relapse if starting M-component was ³ 5 g/dL.

h Relapse from CR has the 5% cut-off versus 10% for other categories of relapse.

Pharmacodynamics . As a pharmacodynamic marker, serum myeloma (M) protein levels were used to evaluate severity and clinical response. The median relative change in M protein levels from baseline to post-baseline nadir for TJ202 in combination with low doses of DEX, POM/DEX or LEN/DEX was -13%, -58% and -81%, respectively. The data below show strong effects of TJ202 in reducing M protein levels.

Figure: The relative change in M protein levels from baseline to post-baseline nadir. Patients were treated with TJ202 (MOR202) in combination with low doses of DEX, POM/DEX or LEN/DEX. S: serum sample; U: urine sample. (Source: MorphoSys)

Pharmacokinetics ("PK") . The PK of TJ202 in humans was well characterized by a two-compartment model at dose levels greater than 4 mg/kg. At these doses, stable or even increasing trough levels could be observed over time suggesting the potential for full target occupancy, especially at the highest dose level (16 mg/kg). For most subjects, steady state at 16 mg/kg was observed after the fourth infusion. Terminal half-life at high-dose levels (^{3} 4 mg/kg) was at approximately two weeks. Pharmacokinetics of TJ202 were generally consistent across different individuals and dosing days and not affected by the co-medications.

Immunogenicity . No anti-drug antibody ("ADA") against TJ202 was observed as of the cut-off date. Thus, risk of ADA induction for TJ202 in humans is considered low.

Clinical Development Plan—

Immediately after in-licensing TJ202, we formulated a robust clinical development strategy with an aim for an NDA submission by 2021. With an approved IND, we have started a single-arm registrational trial with TJ202 and DEX as a third-line therapy for MM patients in Greater China using ORR as the primary endpoint (NCT03860038). Dosing of the first patient took place in March 2019. Data from this 82-patient study are expected to be the major package supporting registrational filing for conditional approval in 2021. In parallel, we started a registrational trial combining TJ202 with LEN and DEX as a second-line combination therapy in MM patients (NCT03952091). We plan to enroll 291 patients for full approval. Dosing of the first patient took place in Taiwan in April 2019. We have recruited a total of 32 patients for both registrational trials.

Our clinical development plan for SLE starts with a Phase 1b clinical trial to explore dose range, clinical safety and tolerability as well as TJ202's profiles of PK and pharmacodynamics ("PD") in SLE patients. Additionally, we submitted an IND application to the NMPA in October 2019.

TJ107 (Efineptakin): The First Long-acting Recombinant Human IL-7 with the Potential for Cancer Treatment-related Lymphopenia and Cancer Immunotherapy

Summary—

TJ107 (International Nonproprietary Name ("INN"): efineptakin) is the world's first and only long-acting recombinant human interleukin-7 ("rhIL-7"), which is being developed as a T lymphocyte-booster for cancer-related immunotherapy. Due to its advantages in terms of selective immune functions, improved stability, developability, and extended half-life, TJ107 is differentiated from an earlier generation of short-acting rhIL-7 and T cell growth factor (interleukin-2). In December 2017, we acquired exclusive rights from Genexine to develop and commercialize TJ107 in Greater China. We plan to position TJ107 first as a monotherapy or an oncology care product for cancer patients with cancer treatment-related lymphopenia (low blood lymphocyte levels) induced by chemotherapy or radiation therapy. This target indication covers a large population of cancer patients who develop cancer treatment-related lymphopenia, a condition that weakens the ability to receive continued chemotherapy or radiation therapy and leads to worsened disease prognosis and clinical outcome. Currently, there is no treatment available for this condition. Second, TJ107 is expected to show a therapeutic effect as a combination therapy with immune checkpoint inhibitors, i.e., PD-1/PD-L1 therapies, due to its inherent selective T cell-boosting properties. Pre-clinical studies have indicated that TJ107 exerted additional anti-tumor effect when combined with PD-1/PD-L1 therapies. If proven efficacious in clinical studies, we believe such a combination therapy, can potentially treat a large population of cancer patients who do not respond or respond poorly to PD-1/PD-L1 therapies. We are conducting a Phase 1b study in China to determine a suitable dose range for subsequent trials. We expect to start a Phase 2 trial in cancer patients in 2020.

Therapeutic Options and Current Development—

One of the target therapeutic indications of TJ107 is cancer treatment-related lymphopenia. Cancer patients who undergo chemotherapy and/or radiation therapy often develop cancer treatment-related lymphopenia, which further damages their already compromised immune systems and their ability to fight against cancers. According to the Frost & Sullivan Report, more than 85% of all cancer patients receive chemotherapy or radiation therapy, and 43% of these patients develop lymphopenia, which represents a significant unmet medical need, as currently no drug is available for the treatment of lymphopenia. Advanced solid tumor is another indication of TJ107 as a combination therapy with PD-1/PD-L1 treatments. As more than 60% cancer patients either do not respond or respond poorly to current PD-1/PD-L1 therapies, there are intense attempts to identify an effective agent that can work synergistically with PD-1/PD-L1 therapies to increase the probability of treatment success. TJ107 is believed to provide such a treatment option, which is supported by pre-clinical reports that IL-7 exhibits a synergistic effect with PD-1/PD-L1 antibodies in the treatment of cancers.

Advantages of TJ107—

TJ107 has an advantage over other T lymphocyte cytokines with therapeutic potential in oncology. Pre-clinical and clinical results generated so far indicate that TJ107 has a favorable immune function profile over recombinant human interleukin-2 ("rhIL-2") in that TJ107 activates and expands tumor-fighting CD4, CD8 and natural killer T cells but spares tumor-protecting Treg cells. By contrast, rhIL-2 is a well-known inducer of Tregs, which suppresses tumor-fighting effector T cells. Furthermore, rhIL-2 has a narrow therapeutic window and causes serious side effects such as capillary leak syndrome, breathing problems, serious infections, and seizures. A polyethylene glycol (PEG)-conjugated IL-2 variant recently developed by Nektar Therapeutics has yielded mixed results, indicating the complexity associated with using IL-2 as a cancer treatment. Owing to its preferred immune function and molecular profiles demonstrated in pre-clinical and Phase 1/2 clinical trials, we believe that TJ107 is a superior T cell cytokine investigational drug for cancer treatment-related lymphopenia and cancer immunotherapy.

TJ107, as an engineered rhIL-7, has the advantages of improved stability and half-life extension through Genexine's proprietary hybrid fragment crystallizable region ("hyFc"). Introducing a few hydrophilic amino acid residues to the N-terminus of IL-7 overcomes stability issues that hampered the development of previous rhIL-7 drug candidates. Furthermore, application of the hyFc technology enhances IL-7's function, increases its half-life (from 48 to 112 hours after a single subcutaneous ("SC") dose in clinical studies), and allows for a robust purification process. By contrast, the half-life of first-generation rhIL-7 was reported to be about 12 hours after SC dosing in human subjects. The hyFc in TJ107 is also non-cytolytic, so it will not damage the T cells to which it binds. Unlike TJ107, the previous rhIL-7 drug candidates adopt non-glycosylated (CYT 99-007) or glycosylated (CYT-107) forms of short-acting rhIL-7 and were developed by Revimmune Inc (formerly known as Cytheris SA). These molecules had low stability, low production yield, and a short half-life because IL-7 protein is intrinsically unstable and prone to aggregation. However, the preliminary clinical results from Phase 1 and Phase 2 trials in patients with AIDS did show an increase of T lymphocytes following treatment with CYT-107 (Thiebaut R et al., PLoS Comput Biol., 2014).

Mechanism of Action—

IL-7 is a cytokine essential for the survival and homeostatic proliferation of naive and memory T cells (see figure below). IL-7 is critically involved in restoring T cells to normal levels in the event of lymphopenia by stimulating T cell proliferation. IL-7 exerts its functions by binding to and activating the IL-7 receptor, which is expressed primarily on lymphocytes, including the lymphoid precursors, developing T and B cells, naive T cells, and memory T cells, but not on tumor-protecting Tregs. TJ107 as a monotherapy may enhance anti-tumor immunity by augmenting the number and functionality of T cells, whereas TJ107 in combination with an immune checkpoint inhibitor, cancer vaccine or CAR-T may improve the anti-tumor response by restoring T cell numbers, reconstituting T cell pools and reinvigorating exhausted T cells.

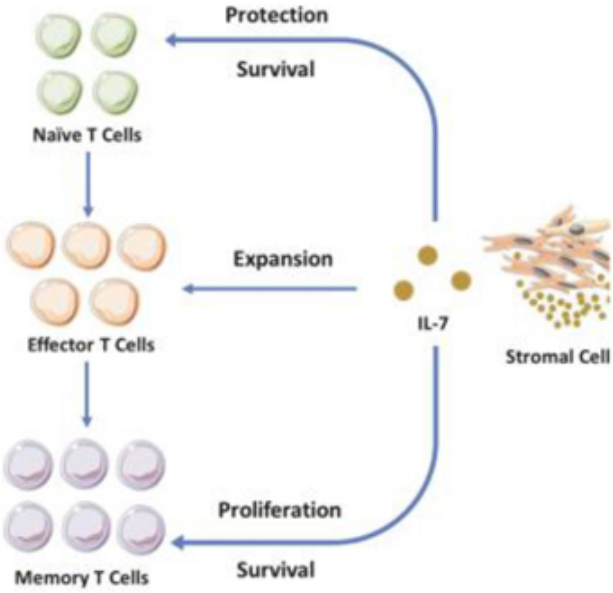


Figure: Role of IL-7 in T cell maintenance and proliferation.

Summary of Clinical Results—

A first-in-human Phase 1 trial has been conducted by Genexine in South Korea. This was a randomized, double-blind, placebo-controlled, single ascending dose study, to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic properties of 20 or 60 μg/kg TJ107 via SC or intramuscular ("IM") administration in healthy volunteers. Each dose group consisted of 10 subjects, eight of whom were administered TJ107 and two were given placebo via the same route of administration.

Safety. TJ107 was well-tolerated in all 30 subjects without serious adverse events. The most common adverse events were transient Grade 1 or 2 injection site skin reactions.

Pharmacodynamics ("PD") . Because IL-7 promotes the survival and proliferation of T cells, absolute lymphocyte count ("ALC") in the peripheral blood was used as a reliable and convenient PD marker for TJ107 (see figure below). ALC initially decreased transiently in all TJ107 groups. This effect is often termed margination, which is a physiological phenomenon common to many cytokines as a result of increased adherence of cytokine-stimulated white blood cells to the blood vessels and subsequent trafficking to tissues and lymphoid organs. ALC recovered in approximately seven days, reaching a maximum value at close to 21 days, before gradually declining. This result indicated that a single dose of TJ107 had a long-lasting effect of increasing lymphocyte levels. Overall, a greater increase in ALC was observed in Cohort 2 compared with Cohort 1, demonstrating a dose-dependent response. Additionally, a higher increase in ALC was observed in Cohort 3 compared with Cohort 2, which was consistent with the results of an animal study, where IM injection induced a more effective increase in lymphocytes than SC injection.

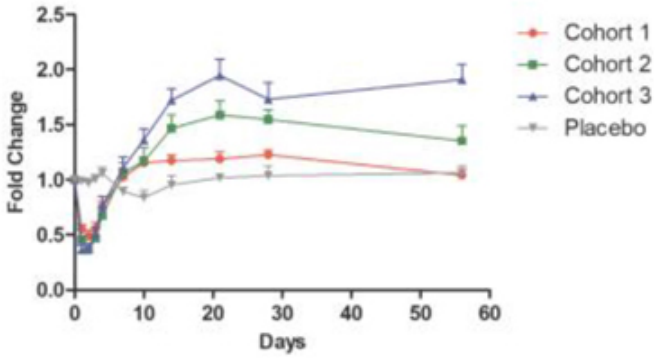


Figure: *Median fold changes of ALC following a single dose of TJ107 in humans. Cohort 1: 20 µg/kg, SC; Cohort 2: 60 µg/kg, SC; and Cohort 3: 60 µg/kg, IM. (Source: Genexine)*

TJ107 treatment resulted in a substantial increase in the number of CD4 and CD8 T cells, natural killer T cells, naive T cells, central memory, effector memory, and terminally differentiated effector memory T cells, without affecting the number of B cells, natural killer cells, monocytes or Tregs.

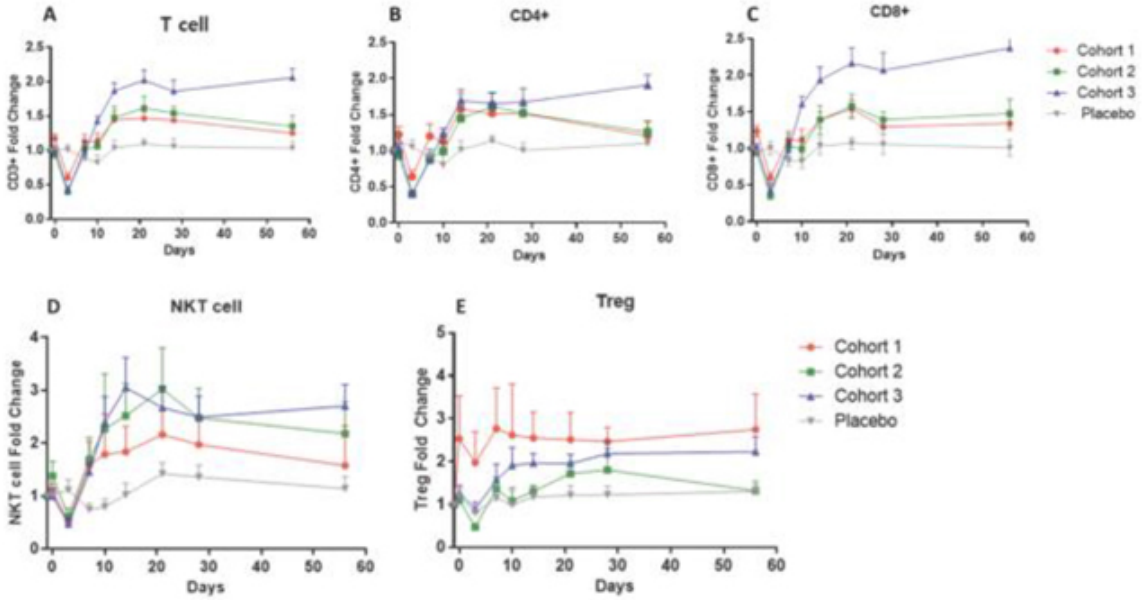


Figure: *Median fold changes of T cells and subsets following a single dose of TJ107 in human subjects. Cohort 1: 20 µg/kg, SC; Cohort 2: 60 µg/kg, SC; Cohort 3: 60 µg/kg, IM. (A) CD3+T cells, (B) CD4+T cells, (C)CD8 + T cells, (D) Natural Killer T cells, and (E) regulatory T cells (Treg). (Source: Genexine)*

Pharmacokinetics . TJ107 was slowly absorbed, particularly after SC administration, and was slowly removed, resulting in a half-life of 48 to 112 hours, longer than that reported for the first generation rhIL-7 (about 12 hours). Intramuscular TJ107 showed approximately two-fold greater exposure than SC administration at the same dose level of 60 µg/kg. The higher plasma exposure of TJ107 after IM administration was well-correlated with a more robust PD effect on ALC in Cohort 3.

Immunogenicity . ADAs were detected in 22 of 24 subjects treated with TJ107. One subject in Cohort 3 was positive for ADAs before treatment. Neutralizing antibodies were observed in 42% and 46% of the subjects within one to two months following administration, respectively, but only one person still harbored neutralizing ADAs five months after administration.

The clinical relevance of ADA was evaluated during long-term follow-up monitoring. ALC levels were maintained above the baseline values, endogenous IL-7 was maintained at normal levels, and no specific adverse events associated with ADAs were observed. These results are consistent with well-documented reports that a normal individual can harbor pre-existing auto-antibodies for cytokines such as IL-2, IL-3, IL-4, and IL-7, and that these anti-cytokine antibodies tend to serve as a reservoir and carrier of the cytokines in the blood, extending the half-life of these cytokines and preserving their functions.

Clinical Development Plan—

By leveraging the results of Genexine's ongoing clinical trials in South Korea and the United States, we aim to rapidly advance the clinical development of TJ107 for approval in Greater China. Currently, a Phase 1b trial in China is ongoing to investigate the safety, tolerability and PK/PD response of TJ107 in patients with advanced solid cancers. The clinical trial (NCT04001075) is designed to include: (i) dose escalation of TJ107 using a conventional "3 + 3" study design to identify a safe and active dose range and (ii) dose expansion to confirm the safety and obtain preliminary evidence of efficacy. We have finished dose escalation for the first two patient cohorts, and the safety and tolerability profile as well as the PK/PD response are consistent with other ongoing studies of TJ107.

After determining the recommended Phase 2 dose ("RP2D") in the Phase 1b trial, we expect to start a Phase 2 trial in cancer patients in 2020.

Genexine has initiated a dose-finding trial in combination with checkpoint inhibitors in patients with solid tumors. Meanwhile, Genexine is also sponsoring additional early-stage clinical trials in advanced solid tumors, including glioblastoma and high-risk skin cancer, in the United States and South Korea. The safety, pharmacology and preliminary efficacy data from these ongoing studies are expected to significantly facilitate our clinical development of TJ107 in Greater China.

TJ101 (Eftansomatropin): A Potential Highly Differentiated Long-Acting Growth Hormone for Growth Hormone Deficiency

Summary—

Eftansomatropin (TJ101), if approved, is a potential highly differentiated long-acting recombinant human growth hormone ("rhGH") (INN: eftansomatropin) being developed as a more convenient and effective therapy for growth hormone deficiency ("GHD"), for which there is substantial unmet medical need in China. TJ101 met the pre-set safety endpoints in three multi-regional clinical trials conducted in Europe and Asia and preliminary efficacy endpoints in pre-pubertal growth hormone naive pediatric growth hormone deficient ("PGHD") patients. In contrast to marketed short-acting rhGH such as Genotropin, TJ101 showed similar efficacy results in a weekly (vs. daily) regimen. Furthermore, TJ101 has not shown the safety concerns typically associated with approved pegylated drugs. We in-licensed the China rights to TJ101 from Genexine and are positioning TJ101 as a highly differentiated growth hormone replacement therapy because of its advantages over a daily regimen in terms of injection frequency (weekly vs. daily) and safety profile (natural protein-based vs. pegylated long-acting rhGH), especially in pediatric patients. We are preparing for a registrational Phase 3 trial in China to validate the efficacy, safety, pharmacodynamics, and pharmacokinetics of TJ101 in PGHD, with a plan for CTA (Clinical Trial Application) submission in 2020.

Therapeutic Options and Current Development—

Our current therapeutic indication is PGHD. The widely adopted treatment for PGHD is patient-specific growth hormone replacement therapy, which is given in a calculated weight-based dosing regimen. Currently, short-acting recombinant human growth hormone ("rhGH") is commonly used for the long-term treatment of children and adults with inadequate endogenous growth hormone secretion. There are certain safety concerns related to long-term use of pegylated drugs, such as potential renal toxicity, cellular vacuolation and formation of anti-polyethylene glycol antibodies. Approved by the NMPA in 2014, Jintrolong (developed by GeneScience) is currently the only marketed long-acting pegylated rhGH in China, according to the Frost& Sullivan Report. Other companies in China currently developing long-acting rhGH include Anhui Anke Biotechnology, Xiamen Amoytop Biotech, Generon Pharmaceutical Technology and Visen Pharmaceuticals. Our TJ101 is the only Fc-based long-acting rhGH ready for a Phase 3 clinical trial in China.

According to the Frost & Sullivan Report, only 3.7% of all PGHD patients in China were receiving growth hormone replacement therapy in 2018, which primarily consists of daily injections of rhGH before sleep. This dosing regimen puts a substantial burden on pediatric patients and their families because it requires drug preparation and needle injection every day, which is painful and extremely inconvenient, often resulting in poor patient compliance. More importantly, studies have shown that skipping just one or two doses in a week can markedly reduce the efficacy of the treatment. Therefore, there is a substantial unmet medical need for long-acting growth hormone therapies that are similarly efficacious but with reduced injection frequency, and the market potential for such a long-acting rhGH in China is largely untapped. In addition, recombinant human growth hormone therapy has been included in the National Reimbursement Drug List (NRDL) in China. Inclusion of a drug in the NRDL typically results in a much higher sales volume and significant sales growth despite a reduction in price.

Advantages of TJ101—

We believe that TJ101 has the following advantages: (i) when compared to the daily regimen of rhGH, TJ101 is expected to be a more convenient therapy with better patient compliance due to a reduced dosing frequency to either weekly or twice-monthly administration, while maintaining similar efficacy; and (ii) TJ101 has not shown safety concerns typically associated with pegylated drugs, such as potential renal toxicity, pre-existing or treatment-induced anti-PEG antibodies, and cellular vacuolation in macrophages, renal tubule cells and the choroid plexus epithelial cells.

Mechanism of Action—

Like endogenous growth hormone, TJ101 stimulates the production of insulin-like growth factor 1 (“IGF-1”) in the liver, which has growth-stimulating effects on a variety of tissues, including osteoblast and chondrocyte activities that stimulate bone growth. Thus, IGF-1 is a reliable pharmacodynamic marker and more importantly, the key mediator of TJ101’s growth-promoting activity. TJ101 is based on Genexine’s patented hyFc technology. The hyFc part consists of a portion of human immunoglobulin D (“IgD”) and G_4 (“IgG_4”). The former contains a flexible hinge, and the latter is responsible for half-life extension through neonatal Fc receptor (“FcRn”)-mediated recycling. Additionally, TJ101’s increased molecular weight (103 kilodalton) is expected to reduce renal clearance.

Figure: Schematic presentation of the structure of TJ101. CH2 & CH3: Constant regions 2 & 3 of antibody heavy chains, respectively; hGH: human growth hormone. (Source: Genexine)

Summary of Clinical Results—

Genexine has completed three clinical trials with TJ101, including one Phase 1 trial in healthy adult volunteers, one Phase 1b/2 multi-regional trial in adults with GHD, and one Phase 2 multi-regional trial in PGHD in Europe, altogether involving 32 healthy subjects and 99 patients with GHD and PGHD. Overall, TJ101 was shown to be well-tolerated, and clinical efficacy endpoint achieved by weekly or twice-monthly TJ101 administration was comparable to that of daily administration of Genotropin.

Phase 1 Clinical Trial—

The first-in-human trial of TJ101 was a randomized, double-blind, placebo-controlled single dose-ascending study in four groups of healthy subjects. A total of 32 subjects were enrolled, and 31 completed the study. TJ101 was shown to be well-tolerated at all dose levels studied (0.2–1.6 mg/kg). TJ101 was detectable in the blood until Day 7 for the 0.2 mg/kg dose group, Day 14 for the 0.4 and 0.8 mg/kg dose groups, and Day 21 for the 1.6 mg/kg dose group. A single subcutaneous ("SC") injection of TJ101 at dose levels of 0.4 mg/kg and higher increased IGF-1 and IGF-binding protein-3 ("IGFBP-3") levels for at least one week. No safety concerns were identified. TJ101 showed a half-life ranging from 69.2 to 138 hours.

Phase 2 Clinical Trial in PGHD—

Study Design . The Phase 2 trial in PGHD was a randomized, open-label, active-controlled study to assess the safety, tolerability, efficacy, pharmacokinetics, and pharmacodynamics of weekly and twice-monthly doses of TJ101, as compared to a daily injection of Genotropin, which is currently the standard of care for PGHD. Subjects were randomly assigned to receive one of three doses of TJ101 (0.8 mg/kg/weekly, 1.2 mg/kg/weekly or 2.4 mg/kg/twice monthly) or 0.03 mg/kg/daily of Genotropin for up to 24 months. The primary clinical endpoint was annualized height velocity (aHV) in centimeters (cm) per year (equivalent to annual growth rate), measured at six months. A total of 56 subjects were randomized at 27 centers in nine European countries and South Korea. Fifty two subjects completed the six-month treatment (through Visit 7), meeting the primary endpoint. Two subjects withdrew from the study before first drug administration, and two subjects discontinued due to treatment-related adverse events ("AEs"). Genexine and its co-developer Handok presented the latest interim results of the Phase 2 clinical trial for PGHD in March 2018 at the Endocrine Society's annual meeting.

Safety . No study drug-related serious adverse events ("SAEs") or death were observed. The tolerability of TJ101 was consistent with known properties of marketed products. The AE incidence rate was generally similar across the TJ101 cohorts treated with three different dose levels (ranging between 69.2% and 84.6%) and the Genotropin cohort (57.1%). A total of two (14.3%), three (23.1%), two (15.4%), and zero subjects experienced treatment-related AEs in the 0.8 mg/kg/week, 1.2 mg/kg/week, and 2.4 mg/kg/twice monthly TJ101 groups, and the 0.03 mg/kg/daily Genotropin group, respectively.

Two subjects withdrew from the study due to treatment-related AEs. One subject from Cohort 2 (1.2 mg/kg/week of TJ101) discontinued due to retinal vascular disorder. The Data and Safety Monitoring Board ("DSMB") reviewed this case independently, concluding that the retinal finding was more likely to be of completely different etiology than treatment-induced intracranial hypertension. One subject from Cohort 3 (2.4 mg/kg/twice monthly of TJ101) discontinued due to pseudopapilloedema (optic disc drusen), which was assessed by the principal investigator to be mild with continuous frequency and possibly related to the study drug.

Injection site reactions ("ISRs") were reported by 13 out of 40 subjects (32.5%) in the TJ101 cohorts. Pain was the most prominent and common symptom observed in 10 subjects. Also, six subjects reported redness, four reported itching, and one reported bruising, swelling and warmness. With respect to the Genotropin cohort, pain was the only ISR reported in 683 cases by 11 out of 14 subjects (78.5%). None of the ISRs led to discontinuation of treatment, and most of the reported ISRs posed no issue for the subjects and were resolved quickly. No safety signal was detected in laboratory parameters or vital signs for either TJ101 or Genotropin.

Pharmacokinetics . Half-life of TJ101 was 77.75–141.95 hours after a single dose and 43.92–55.66 hours (compared to 5.27 hours for Genotropin) after three months of multiple-dose administration.

Immunogenicity . Formation of treatment-emergent ADA with neutralizing property was reported in two subjects (one from Cohort 2 and one from Cohort 3) out of a total of 40 subjects randomized and dosed with TJ101. With respect to the Genotropin cohort, the presence of treatment-emergent ADA with neutralizing property was not observed in any subject.

Clinical Efficacy . Subcutaneous administration of TJ101 over the dose range of 0.8 mg/kg/week–2.4 mg/kg/twice monthly resulted in an increase in aHV over the six-month study period. Subjects who received TJ101 at 0.8 mg/kg weekly, 1.2 mg/kg weekly, and 2.4 mg/kg twice monthly showed growth rates of 11.50, 11.54, and 11.86 cm/year, respectively, while the growth rate in the control group treated with Genotropin was approximately 11.24 cm/year.

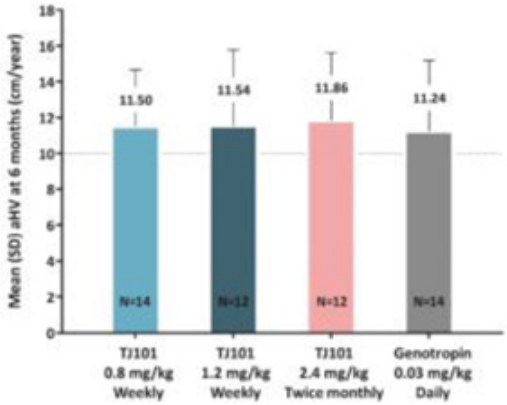


Figure: *The aHV at six months indicated comparable growth rates between all doses of TJ101 (both weekly and twice-monthly treatment) and the active comparator, Genotropin. (Source: Genexine)*

Pharmacodynamics. The growth-promoting effect of TJ101 was accompanied by elevated serum IGF-1 levels. This hormone is an important biomarker, which mediates growth hormone's biological effects. The Standard Deviation Score ("SDS"), which is a calculated score with reference to the normal age- and sex-matched IGF-1 levels, is a standardized parameter to compare IGF-1 levels across laboratories and populations. Mean IGF-1 SDS at the beginning of the study was below the lower limit of the normal range in all treatment arms. Following initiation of treatment, the IGF-1 SDS values quickly normalized by five days (Visit 2) and three weeks (Visit 3) after the initial treatment, respectively, for the TJ101 treatment arms and the Genotropin treatment arm. IGF-1 responses were maintained throughout the intended dosing interval, supporting both the weekly and twice monthly treatment regimens. IGF-1 mean peak levels were mostly within the upper limit of the physiologic range, which is considered safe in clinical practice.

Clinical Development Plan—

Based on Genexine's Phase 2 study in PGHD, we are preparing to conduct a registrational Phase 3, randomized, active-controlled, and multicenter study in China to assess the efficacy, safety, and pharmacokinetics of TJ101 in PGHD. The primary objective is to demonstrate non-inferiority of 1.2 mg/kg/week of TJ101 administered SC, based on aHV after 26 weeks of treatment, compared to the active control Jintropin, a daily rhGH marketed in China. We have finalized the study design with key opinion leaders, and our development plan and study design have been discussed with the NMPA through a face-to-face pre-IND meeting. We are working towards submitting a CTA application in 2020.

TJ301 (Olamkicept): A Potential Highly Differentiated IL-6 Blocker for Ulcerative Colitis and other Autoimmune Diseases

Summary—

TJ301 (INN: olamkicept) is the only clinical stage selective interleukin-6 ("IL-6") inhibitor that works through the trans-signaling mechanism. IL-6 is an important cytokine driver in the propagation and maintenance of chronic inflammation in autoimmune diseases. Compared to the approved antibody drugs that directly block IL-6 or IL-6 receptor ("IL-6R"), TJ301 is expected to provide a novel alternative for the treatment of IL-6 mediated inflammation without affecting some of the normal physiological functions of IL-6, e.g., acute immune response against infection and metabolic regulation. TJ301 demonstrated therapeutic effects in pre-clinical animal models of autoimmune diseases, including inflammatory colitis. Moreover, the safety and tolerability profile of TJ301 was studied in three clinical trials in Germany involving 128 subjects. We believe that TJ301 has the potential to become a highly differentiated therapy to target autoimmune diseases. We acquired an exclusive license from Ferring Pharmaceuticals to develop and commercialize TJ301 in Greater China and South Korea with an option of licensing worldwide rights. As part of our fast-to-market strategy for TJ301, we are conducting a Phase 2 clinical trial in ulcerative colitis ("UC") for the following reasons: (i) TJ301 was shown to be effective in animal models of colitis; (ii) an exploratory Phase 2a biomarker trial showed promising interim treatment effects of TJ301 in UC patients; and (iii) even though UC incidence is increasing rapidly, innovative biologic treatments for this disease are lacking in China. We expect to obtain topline data from this Phase 2 clinical trial by 2020. After clinical efficacy and differentiation are validated for UC, we plan to develop TJ301 in other inflammatory indications, in which IL-6 plays a role.

Therapeutic Options and Current Development—

Our current therapeutic indication for development is UC. UC and Crohn's disease ("CD") are the main types of inflammatory bowel disease ("IBD"), which cause chronic and often relapsing inflammation of the large and small intestines, respectively. Anti-inflammatory drugs, such as 5-aminosalicylic acids ("5-ASAs") and corticosteroids, are often used as initial treatment for UC. Immune system suppressors are also used to control inflammation in patients with UC, including azathioprine, mercaptopurine, and cyclosporine. Biologics that inhibit tumor necrosis factor alpha (TNF-α), including infliximab (Remicade), adalimumab (Humira), and golimumab (Simponi), are efficacious in some UC patients who fail to respond to conventional therapies. Entyvio, an integrin α4ß7 antibody that blocks lymphocytes from accumulating in the intestinal wall, is the first and, to date, the only non-anti-TNF-α biologics approved for UC. In China, Remicade is currently the only biologic approved for treatment of UC.

There is a substantial unmet medical need in UC for a treatment agent(s) that is efficacious and safe through pathways beyond the traditional drug targets. The incidence of UC is increasing rapidly, but UC patients, especially those with a moderate-to-severe disease, have few treatment options, which have limited efficacy and considerable side-effects. For example, Jak1/3 kinase inhibitors can carry the risk of serious infections and malignancies. TNF-α inhibitors also have inherent side effects and do not work in all patients. According to the Frost & Sullivan Report, approximately 45% patients with autoimmune diseases are considered treatment non-responders to TNF-α drugs and less than one third the UC patients taking TNF-α drugs achieve drug free remission. Thus, as the only clinical stage selective interleukin-6 ("IL-6") inhibitor that works through the trans-signaling mechanism, we believe TJ301 has the potential to become a highly differentiated IL-6 blocker for UC, if approved.

Advantages of TJ301—

The existing IL-6 or IL-6R blockers cause total inhibition of IL-6 signaling and are associated with significant adverse events in the clinic, such as infection, gastrointestinal perforation, metabolic disturbances, and insulin resistance. TJ301 is expected to provide a novel alternative as it works through a different mechanism, the trans-signaling pathway. This key advantage has been demonstrated in pre-clinical studies and three clinical trials conducted in Germany. The results indicated that TJ301 has no side effects on lipid, glucose or bone metabolism, and it has no agonistic activities that could activate receptors or trigger detrimental immune cascades. We expect that selective inhibition of IL-6 trans-signaling is an effective and safer approach to the treatment of chronic inflammation.

Mechanism of Action—

TJ301 is a homodimer of a fusion protein consisting of the extracellular domains of human glycoprotein130 ("gp130") and the fragment crystallizable (Fc) domain of human IgG1. Mimicking the function of endogenous soluble gp130, TJ301 works as a decoy by binding to a complex consisting of IL-6 and soluble IL-6 receptor ("sIL-6R"), thereby preventing TJ301 from stimulating the trans-signaling pathway in cells that do not express IL-6R. The gp130 part selectively binds the IL-6/sIL-6R complex with high affinity (Kd=130 pM), whereas the Fc part initiates dimerization and offers longer half-life for the molecule. TJ301 is not expected to affect the beneficial effects of IL-6, such as the acute immune response against infection mediated by the classical pathway.

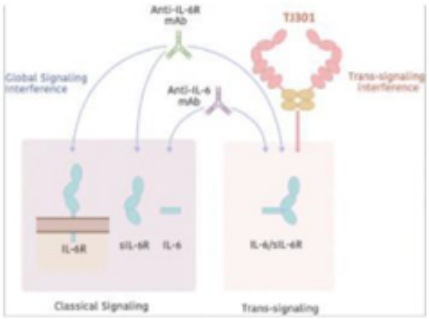


Figure: *Classical signaling and trans-signaling pathways of IL-6. Anti-IL-6R and anti-IL-6 block both pathways, whereas TJ301 blocks only trans-signaling. IL-6R: IL-6 receptor; sIL-6R: Soluble IL-6 receptor.*

Summary of Clinical Results—

Ferring Pharmaceuticals has completed two Phase 1 trials to evaluate TJ301's preliminary safety and clinical pharmacology. TJ301 was shown to be well-tolerated based on the clinical results collected from a total of 112 subjects exposed to the drug. In addition, a Phase 2a biomarker study in active IBD (known as the FUTURE study) has been completed in Germany with promising pharmacodynamic and clinical responses observed.

Phase 1 Clinical Trial: Single Dose Ascending Trial

Study Design. The first-in-human trial of TJ301 was a single dose, placebo-controlled, single-blind, randomized within dose, and parallel group dose-escalating trial. The trial recruited both healthy subjects and patients with Crohn's Disease ("CD") in clinical remission. The primary objective was to examine the safety, tolerability and pharmacokinetics after a single dose of TJ301. Several dose levels were tested, ranging from 0.75 mg to 750 mg, with each dose level including six subjects receiving TJ301 and two receiving placebo.

Pharmacokinetics. In healthy subjects and CD patients, TJ301 showed similar terminal half-life of 4.3 to 5.1 days. The maximum concentration (Cmax) in plasma and the area under curve ("AUC") of the plasma drug concentration-time curve were dose proportional. For SC administration of TJ301 (60 mg), the Cmax was approximately 1.0 µg/mL at 2.3 days, and the bioavailability was approximately 48%.

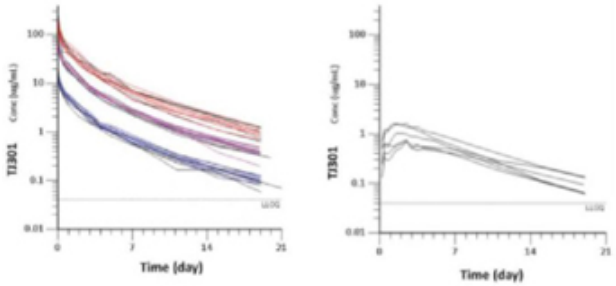


Figure: *Single dose pharmacokinetic profile of TJ301. Left, healthy subjects (colored lines) and IBD patients in remission (gray lines) received a single IV infusion at 75 mg (blue lines), 300 mg (magenta lines) or 600 mg (red lines) fixed doses. Right, healthy subjects received a single SC injection at 60 mg. LLOQ: lower limit of quantitation. (Source: Ferring Pharmaceuticals)*

Safety. TJ301 was well-tolerated when administered as a single IV dose at up to 750 mg and as a single SC dose at 60 mg. No apparent dose-related AE was observed. Infusion was discontinued in two subjects due to mild to moderate infusion-related reactions, with skin symptoms such as urticaria and swelling, which were rapidly resolved.

Only one healthy subject in the 300 mg group showed non-neutralizing treatment-emergent ADAs at the follow-up visit five to six weeks after administration.

Phase 1 Clinical Trial: Multiple Dose Ascending Trial

Study Design. This trial was a placebo-controlled, double-blind, and randomized dose-escalating trial in healthy subjects. A total of 24 healthy subjects were randomized into three dose groups and received four weekly infusions of TJ301 at 75 mg, 300 mg or 600 mg.

Pharmacokinetics. PK characteristics were similar on the first and last treatment days of the multiple dose-ascending trial and were similar to results in the single dose-ascending study.

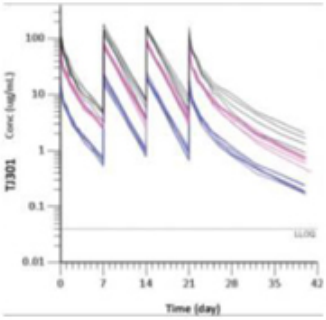


Figure: Multiple dose pharmacokinetic profile of TJ301. Healthy subjects received weekly IV infusions at 75 mg (blue lines), 300 mg (magenta lines) or 600 mg (gray lines) fixed doses. LLOQ, lower limit of quantitation. (Source: Ferring Pharmaceuticals)

Safety. There were only a few mild or moderate AEs reported across all treatment groups. One subject from the 600 mg group withdrew due to mild infusion-related reactions with urticaria and pruritus 30 minutes after administrating the first dose. No apparent dose-related trends or treatment-related change in vital signs, electrocardiogram or clinical chemistry parameters were observed. No ADAs were reported by any subject. Overall, TJ301 was well-tolerated when administered by IV at up to 600 mg once weekly for four weeks.

Overall Summary of Treatment-Emergent Adverse Events

	75 mg (N = 6)	300 mg (N = 6)	600 mg (N = 6)	Placebo (N = 6)	Total Active (N = 18)
	n (%) E	n (%) E	n (%) E	n (%) E	n (%) E
Any TEAE (1)	6 (100) 13	2 (33) 5	4 (67) 6	6 (100) 14	12 (67) 24
Serious TEAEs	0	0	0	0	0
Adverse Drug Reactions (1)	6 (100) 11	2 (33) 2	3 (50) 5	4 (67) 6	11 (61) 18
TEAEs Leading to Withdrawal	0	0	1 (17) 1	0	1 (6) 1
Deaths	0	0	0	0	0

Source: Ferring Pharmaceuticals

Note:

(1) Reasonably possibly related to treatment; N: number of subjects exposed; n: number of subjects with AE; %: n/N*100; E: number of AEs

Phase 2a Biomarker Study in Active IBD (FUTURE Study)

Study Design. This was an open-label exploratory study to assess the mechanisms of molecular activity (effects on biomarkers), safety and tolerability of TJ301 in adult patients with active IBD. Nine UC patients and seven CD patients were dosed with TJ301 (600 mg, IV, q2w) for up to 12 weeks followed by 42 days of safety follow-up. Patients enrolled had moderately to severe active UC or ileocolonic CD with median disease duration of 5.3 (UC) and 6.9 (CD) years and with immunologically active inflammation (C-reactive protein >5 mg/l), who had failed conventional therapies and had no prior biologics treatment.

The primary endpoint was the proportion of patients with reduced mucosal expression of a predefined set of inflammation-relevant genes (TNFA, IL1A, REG1A, IL8, IL1B and LILRA) as a composite score. Objective assessments included centrally read endoscopies, histology readings, and various explorative molecular parameters and inflammatory biomarkers. The trial was sponsored and conducted by the University Hospital Schleswig Holstein and Paul-Ehrlich Institute (EUDRA-CT 2016-000205-36), with financial and material support from Ferring Pharmaceuticals. The study has been completed, and the abstract of the results was presented at the United European Gastroenterology Week meeting in October 2019.

Safety. TJ301 was well-tolerated. Reported AEs were unspecific in nature and showed no signs of immune suppression. Five SAEs were observed, none of which were life-threatening or deemed to be related to TJ301.

Pharmacokinetics. After single and repeated IV administration of TJ301 (600 mg, Q2W) to patients with UC and CD, similar serum exposure was observed after the first and last dosing events, with respect to Cmax and total exposure over 14 days. Maximal serum drug concentration after each dosing was reached at the end of infusion. The mean terminal half-life of TJ301 after the last administration was approximately 5.1 days. Circulating biological activity of TJ301 was confirmed by whole-blood STAT3 phosphorylation assays in all patients. A minimal and transient ADA production was observed in three patients. ADAs were only detected at week 12 and week 15, but no longer detectable at week 18.

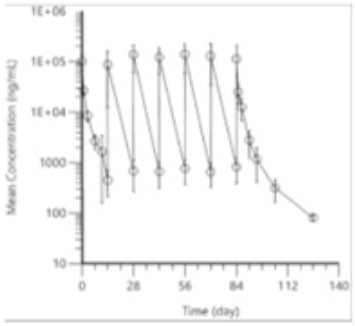


Figure: Time course of the mean serum concentration of TJ301.

Pharmacodynamics. In the assessment of the primary endpoint, it was observed that clinical remission was associated with a significant reduction of IL-1B, IL-8 and REG1A gene expression in the intestinal mucosa. Pathway analysis of blood transcriptome signatures showed an early molecular anti-inflammatory signature as early as four hours after treatment in all patients, irrespective of treatment outcome, which indicated a thorough inhibitory effect of IL-6 trans-signaling blockade on inflammatory pathways.

Clinical Efficacy . A preliminary clinical response was observed in both UC and CD patients, which appeared to be stronger in patients with UC than those with CD. Overall, 55% of UC patients (5/9) responded to TJ301, with 22% (2/9) reaching clinical remission, whereas 29% of CD patients (2/7) responded to TJ301, with 14% (1/7) reaching clinical remission. All three patients in clinical remission showed a fast and thorough induction of clinical, endoscopic, and immunologic remission within the first four weeks.

Clinical Development Plan—

We are positioning TJ301 as a differentiated IL-6 blocker for a number of autoimmune diseases. The first target indication is active stage UC that is not well-controlled by conventional therapies such as mesalazine. We have initiated a multi-regional Phase 2 clinical trial in Greater China and South Korea to assess the pharmacokinetics, safety, and efficacy of TJ301 in patients with active UC (NCT03235752). This is a randomized, double-blind, and placebo-controlled clinical trial with three treatment arms. We plan to enroll 90 patients. A total of 63 patients have been recruited. We expect to obtain preliminary data from this Phase 2 clinical trial by the second half of 2020.

Besides UC, we are evaluating the possibility of extending TJ301 to other autoimmune conditions where there is significant unmet medical need in China. We expect to initiate a second clinical trial for a chronic inflammatory disorder, such as systemic sclerosis and Castleman’s disease, in which IL-6 is implicated as a key pathogenic cytokine.

Enoblituzumab: The Most Advanced Clinical Stage Humanized B7-H3 Antibody as a Potential Immuno-oncology Treatment

Summary—

Enoblituzumab is a humanized antibody directed at B7-H3, a member of the B7 family of T cell checkpoint regulators. B7-H3 is a promising immuno-oncology drug target as it is widely expressed across multiple tumor types and plays a key role in regulating immune response against cancers. Increasing pre-clinical and clinical evidence suggests that antibodies targeting the two T cell checkpoint molecules—B7-H3 and PD-1—work synergistically in treating cancer. Given B7-H3's critical role, enoblituzumab has a wide range of cancer applications as either a monotherapy or in combination with PD-1 therapies. At the molecular level, enoblituzumab is engineered to possess an enhanced anti-tumor ADCC function and is at the forefront in global clinical development. Originally developed by MacroGenics, enoblituzumab has been evaluated in multiple clinical trials as a monotherapy or in combination with CTLA-4 or PD-1 therapies in patients with B7-H3-expressing cancers. Enoblituzumab is also being evaluated in a neoadjuvant Phase 2 study as a single agent in patients with intermediate and high-risk localized prostate cancer. The clinical studies so far have shown that enoblituzumab is well-tolerated, and it increased CD8 T cell infiltration in tumors with more focused T cell repertoires in patients treated with enoblituzumab as a monotherapy. Recent clinical studies conducted by MacroGenics indicate that combination therapy with enoblituzumab and pembrolizumab correlates with preliminary anti-tumor effects in recurrent or metastatic squamous cell carcinoma of the head and neck ("SCCHN") and non-small cell lung cancer ("NSCLC"). We recently acquired the development and commercial rights of enoblituzumab from MacroGenics for Greater China. We expect to submit an IND application in 2020 for a registrational trial or a Phase 2 trial after receiving NMPA pre-IND consultation comments. As more clinical and pre-clinical data become available, further clinical trials will be planned together with MacroGenics to extend enoblituzumab to other cancer indications in China and globally.

Therapeutic Options and Current Development—

Our initial therapeutic indication is head and neck cancer. Head and neck cancers occur in various parts of the head and neck, including the mouth, nose, throat and salivary glands. More than 90% of head and neck cancers are classified as SCCHN, which begin in the squamous cells that line the moist, mucosal surfaces inside the head and neck. The treatment principles and regimens for head and neck cancer in China are similar to those in the rest of the world. Treatment strategies often depend on the location and stage of the cancer, the patient's physical status, and response to prior treatments. Early-stage disease is primarily treated with surgical resection, while patients with locally advanced, recurrent or metastatic disease are typically treated with drug therapy. The combination of surgery and drug therapy, with or without radiation therapy, is the current standard of care for Stage 3 SCCHN patients with locally advanced disease. Platinum-based chemotherapy regimens are widely used as first-line therapies for Stage 4 and distant relapse patients. Erbitux (cetuximab from Eli Lilly and Merck KGaA) was approved in 2006 as a first-line treatment of locally advanced SCCHN in combination with radiation therapy. Regimens containing Erbitux, platinum-based chemotherapy, and 5-fluorouracil, known as EXTREME, are often considered as the standard of care for first-line treatment of distant relapse SCCHN. However, only about 35% of patients respond to EXTREME, and the resulting overall median survival is only 10.1 months. Furthermore, about half of the patients on first-line therapies need later-line therapies.

In addition, even second-line therapy is highly varied, including single-agent docetaxel or paclitaxel, Erbitux monotherapy, and Erbitux and paclitaxel combination therapy. In 2016, PD-1 inhibitors were approved globally as second-line therapies. Recently, Keytruda (pembrolizumab from Merck & Co), used as a single agent or in combination with chemotherapy, was approved by the FDA as first-line therapy for patients with metastatic or unresectable recurrent SCCHN. The average ORR for second-line therapies has been less than 15%.

As such, we believe that SCCHN patients, especially those with late stage or relapsed disease, need more efficacious treatments with fewer side effects, which represents a significant unmet medical need for immunotherapy and targeted therapy.

Advantages of Enoblituzumab—

Enoblituzumab is the most advanced clinical stage humanized B7-H3 antibody as a potential immuno-oncology treatment. The foregoing statement applies only to conventional therapeutic B7-H3 antibodies and does not include radio-labeled B7-H3 antibodies in development by Y-mabs Therapeutics. Targeting B7-H3 offers several advantages over other target options within the class of T cell checkpoint molecules. First, B7-H3 is a tumor-associated antigen that is over-expressed in a variety of solid tumors while its expression in normal tissues is rather limited, enabling the tumor killing mechanism of enoblituzumab. Second, B7-H3 is a unique checkpoint whose expression in tumors is associated with disease prognosis. For example, biomarker analysis of more than 400 NSCLC patients revealed that among all the elevated immune checkpoint inhibitors, including PD-1/PD-L1, PD-L2, B7-H3, TIM-3, BTLA and CTLA4, only B7-H3 is negatively correlated with clinical efficacies of neoadjuvant treatments (Lou et al., Clinical Cancer Research, 2016). Furthermore, recent studies have shown that when combined with a PD-1 antibody, a blockade of B7-H3 results in superior treatment effects in relevant cancer animal models while another study indicates that B7-H3 expression correlates with a lack of anti-PD-1 response (Yonesaka et al., Clinical Cancer Research, 2018). The advantages summarized above make B7-H3 a favorable tumor target for immuno-therapeutic intervention.

Mechanism of Action—

Enoblituzumab (MGA271) is an investigational humanized immunoglobulin (IgG1/kappa monoclonal antibody) that binds to B7 homolog 3 (B7-H3). This antibody consists of an engineered human IgG1 fragment crystallizable (Fc) domain that imparts increased affinity for the human activating Fc gamma receptor (Fc g R) IIIA (CD16A) and decreased affinity for the human inhibitory Fc g RIIB (CD32B). The engineered Fc domain confers enoblituzumab with enhanced target-specific antibody-dependent cellular cytotoxicity ("ADCC") in vitro and anti-tumor activity in preclinical studies. Therefore, enhanced cytolysis of B7-H3-expressing tumor cells is a mechanism that supports the development of this molecule as an antineoplastic agent.

In addition, data suggest that enoblituzumab impacts T-cell homeostasis in vivo. Cancer patients display a more narrowly focused T-cell repertoire following enoblituzumab treatment compared to their baseline repertoire distribution. Moreover, enhanced local T-cell infiltration has been observed in prostate cancer patients treated with enoblituzumab.

These data are consistent with the notion that enoblituzumab is capable of engaging both innate and adaptive immunity as mediators of its anti-tumor activity.

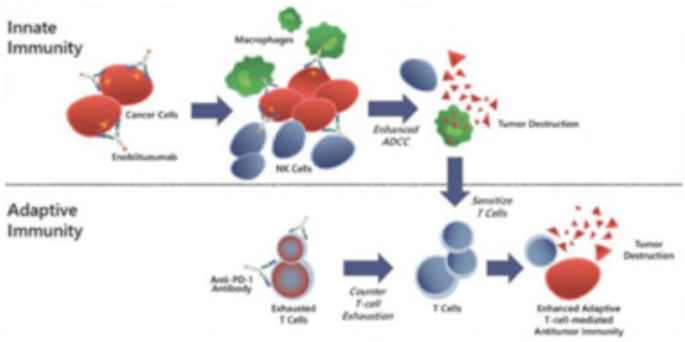


Figure: Enoblituzumab contributes to the coordination and engagement of innate and adaptive immunity to mediate tumor regression. Enoblituzumab binds to tumor cells, activates innate immune cells such as natural killer cells (NK cells) to kill cancer cells through ADCC. The released tumor antigens may then be presented by antigen-presenting cells, such as macrophages, which, in concert with PD-1 blockade, can promote tumor-specific T-cell immunity. (Source: MacroGenics)

Summary of Clinical Results—

Phase 1 Study of Enoblituzumab Monotherapy

Study Design. This was an open-label, multi-dose, single-arm, multi-center, and dose-escalation study to define safety, tolerability, maximum tolerated dose ("MTD"), PK, immunogenicity, and potential anti-tumor activity of enoblituzumab in patients with refractory cancers that express B7-H3 conducted by MacroGenics. In the dose escalation segment of the study, six doses (0.15–15 mg/kg QW) were evaluated in a conventional "3+3" design.

No MTD or dose-limiting toxicity ("DLT") was observed in the dose escalation phase, so the highest administered dose, 15 mg/kg, was used in the cohort expansion, in which patients received weekly infusions of enoblituzumab in eight-week cycles for up to 12 cycles. Tumor evaluation was carried out by both Response Evaluation Criteria in Solid Tumors ("RECIST") and immune-related response criteria ("irRC") with an initial response assessment after eight weeks. This entailed seven tumor-specific cohorts, including melanoma (post-checkpoint inhibitor failure, n=31), head and neck cancer (n=19), prostate cancer (n=34), triple-negative breast cancer (n=17), renal cell carcinoma (n=16), NSCLC (n=8), and bladder cancer (n=12).

Safety. Interim data analysis as of the data cut-off date of April 13, 2017, indicates that enoblituzumab is well-tolerated. Treatment-related AEs (per investigator assessment) were experienced by 134 out of 170 (78.8%) patients, most of which were infusion-related reactions (n=62, 36.5%), fatigue (n=54, 31.8%), nausea (n=32, 18.8%), and chills (n=24, 14.1%). Only three out of 179 patients (1.7%) had a treatment-related discontinuation, and 13 (7.3%) patients experienced treatment-related Grade 3 or higher AEs (fatigue, infusion-related reactions, and nausea), assessed based on Common Terminology Criteria for Adverse Events (CTCAE) criteria version 4.0. Mild to moderate infusion-related reactions were managed with low dose steroids or a decrease of the infusion rate. No severe immune-mediated toxicity was observed.

Pharmacokinetics. Preliminary analysis and population PK modeling based on 18 patients dosed at 15 mg/kg indicate that PK of enoblituzumab was characterized primarily by target-mediated drug disposition and was consistent with a typical human IgG1 with near-linear PK.

Efficacy. Evidence of decreased size of target and non-target lesions as well as extended time to progression were observed across a broad range of tumors, including heavily pretreated cancers. Three patients achieved PR (partial responses) by RECIST out of a total of approximately 71 patients being evaluated.

Phase 1 Study of Enoblituzumab in Combination with Pembrolizumab

Study Design. This is an open-label, dose escalation, cohort expansion, and efficacy follow-up study of enoblituzumab in combination with pembrolizumab conducted by MacroGenics. The dose escalation phase is designed to characterize the safety and tolerability of the combination and to define the maximum tolerated or maximum administered dose. Three dose levels of enoblituzumab (3, 10, 15 mg/kg, IV, QW) have been evaluated in combination with pembrolizumab (2 mg/kg, IV, Q3W). No MTD has been identified, and so the maximum administered dose of enoblituzumab (15 mg/kg) in combination with pembrolizumab was given to additional cohorts of patients enrolled during the cohort expansion phase. The efficacy follow-up period consists of the two-year period after administering the final dose of the study drug. All tumor evaluations are carried out by both RECIST and irRC.

A total of 133 patients with B7-H3-expressing melanoma, squamous cell carcinoma of the head and neck (SCCHN), non-small cell lung cancer (“NSCLC”), and urothelial cancer have been treated in the study. The interim results as of the data cut-off date, October 12, 2018, were presented at the 2018 Annual Meeting of the Society for Immunotherapy of Cancer (SITC), which showed an ORR (overall response rate) that compared favorably with historical experience with anti-PD-1 monotherapy in anti-PD-1/PD-L1 naive patients.

Safety. The combination of enoblituzumab and pembrolizumab demonstrated acceptable tolerability in patients treated to date. Grade 3 or higher AEs, assessed based on Common Terminology Criteria for Adverse Events (CTCAE) criteria version 4.0, occurred in 27.1% of all patients. Drug-related AEs of all grades included infusion-related reactions (n=73, 54.9%), fatigue (n=37, 27.8%), rash (n=14, 10.5%), and nausea (n=12, 9.0%). The incidence of immune-related AEs in the study was comparable to that observed in patients who received anti PD-1 monotherapy. Nine patients experienced drug-related AEs leading to treatment discontinuation. Drug-related AEs and immune-related AEs of special interest are summarized in the table below.

Drug-Related and Immune-Related Adverse Events
During Combination Treatment with Enoblituzumab and Pembrolizumab

	NO. (%) OF PATIENTS	
DRUG-RELATED AES (≥ 5% OF PATIENTS)	**ALL GRADES TOTAL (N=133)**	**≥ GRADE 3 (N=133)**
Any adverse event	115 (86.5)	36 (27.1)
Infusion-related reaction	73 (54.9)	9 (6.8)
Fatigue	37 (27.8)	2 (1.5)
Rash	14 (10.5)	1 (0.8)
Nausea	12 (9.0)	0
Pyrexia	12 (9.0)	0
Lipase increased	11 (8.3)	8 (6.0)
Arthralgia	10 (7.5)	0
Decreased appetite	9 (6.8)	2 (1.5)
Diarrhea	9 (6.8)	1 (0.8)
Hypothyroidism	8 (6.0)	0
Anemia	7 (5.3)	1 (0.8)
Pneumonitis	7 (5.3)	2 (1.5)
Chills	7 (5.3)	0

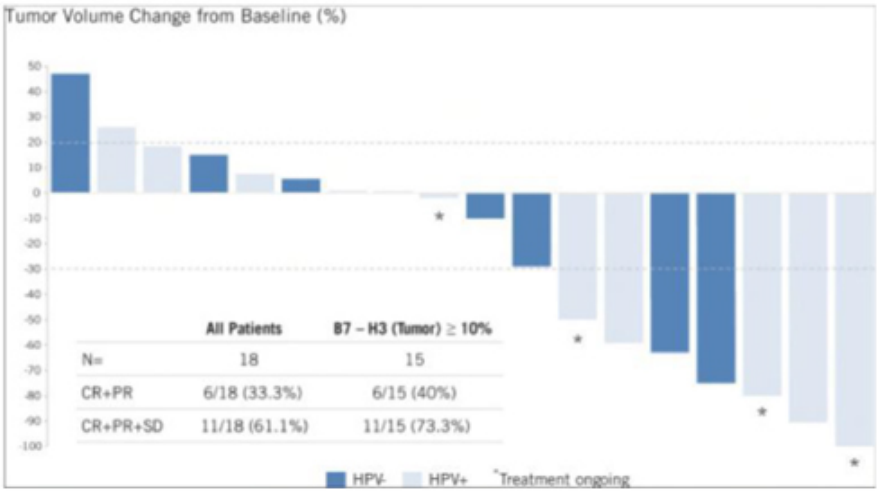
IMMUNE-RELATED ADVERSE EVENTS OF SPECIAL INTEREST (AESI)	NO. (%) OF PATIENTS ALL GRADES TOTAL (N=133)	[3] GRADE 3 (N=133)
Pneumonitis	5 (3.8)	2 (1.5)
Myocarditis	2 (1.5)	1 (0.8)
Diarrhea	1 (0.8)	1 (0.8)
Adrenal insufficiency	1 (0.8)	1 (0.8)
Colitis	1 (0.8)	0

- *Drug-related AEs:*
  - Leading to treatment discontinuation: 6.8% (9 patients)
  - Leading to death: 0.8% (1 patient with pneumonitis)
- *Nature of events consistent with enoblituzumab or pembrolizumab alone*

Source: MacroGenics.

Clinical Efficacy. As of October 12, 2018, the cut-off date of the most recent data analysis, preliminary results indicated that among the 18 response-evaluable SCCHN patients who had not previously received PD-1/PD-L1 therapies, six patients (33.3%) had confirmed partial responses ("PRs"). Among the subset of patients with 10% or higher B7-H3 tumor expression, six out of 15 (40.0%) had confirmed PRs (see figure below) compared to previously reported SCCHN patients treated with PD-1 monotherapy, which achieved ORRs ranging from 13% to 16%.

Anti-tumor Activity in Anti-PD-1/PD-L1-Naive SCCHN Patients

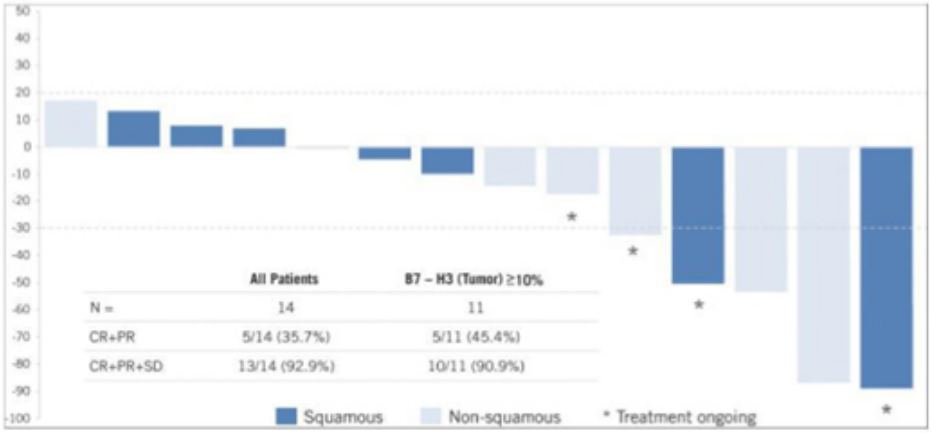


Source: MacroGenics

Among 14 response-evaluable NSCLC patients who had not previously received PD-1/PD-L1 therapies and were PD-L1 negative, i.e., PD-L1 less or equal to 1%, five patients (35.7%) had confirmed PRs (see figure below). Objective response rates ranging from 8% to 17% were reported in PD-L1 negative NSCLC patients treated with PD-1 monotherapy.

Anti-tumor Activity in PD-1-Naive NSCLC Patients Who are PD-L1 Negative (PD-L1

Tumor Volume Change from Baseline (%)



Source: MacroGenics

In the two figures above, CR (complete response) means the disappearance of all target lesions, with the reduction of all pathological lymph nodes to

Clinical Development Plan—

We plan to develop enoblituzumab as a second-line combination therapy with a PD-1 antibody in a registrational clinical trial (pending regulatory approval by the NMPA) or a Phase 2 trial in patients with recurrent or metastatic SCCHN. We have submitted a pre-IND consultation request to the NMPA in the first quarter of 2020. After receiving feedbacks from the NMPA, we expect to submit an IND application in 2020 for a registrational trial or a Phase 2 trial. The primary efficacy endpoint of this study will be objective response rate (ORR) performed by central review. In addition, we are planning to explore enoblituzumab development in a variety of B7-H3 expressing solid tumors. MacroGenics plans to combine enoblituzumab and a PD-1 antibody with and without chemotherapy in a two-part Phase 2/3 study for first-line treatment of patients with recurrent or metastatic SCCHN not curable by localized therapy. We expect to participate in the Phase 3 global study if initiated.

Global Portfolio

TJM2: A GM-CSF Monoclonal Antibody for Rheumatoid Arthritis and CAR-T-related Therapies

Summary—

TJM2 is an internally discovered neutralizing antibody against human granulocyte-macrophage colony-stimulating factor (“GM-CSF”), an important cytokine that plays a critical role in chronic inflammation and destruction in autoimmune diseases such as rheumatoid arthritis (“RA”). TJM2 is expected to be the first clinical stage GM-CSF monoclonal antibody in China. TJM2 is a humanized IgG1 that displays high affinity binding to GM-CSF and blocks its signaling and downstream effects. TJM2 is being developed for the treatment of autoimmune and inflammatory diseases, including RA, cytokine release syndrome (“CRS”) and neuroinflammation from CAR-T therapy. We have completed a single-dose first-in-human study in healthy volunteers in the United States. We have received IND approval from the NMPA for a multiple-dose Phase 1b study in Chinese patients with RA and may expand to other autoimmune and inflammatory indications with high unmet medical need, where GM-CSF is known as a pathogenic cytokine in disease activity and progression. TJM2 is expected to be the first compound of its class to enter clinical trial in China in 2020. If approved, it is expected to provide an effective treatment option as a disease-modifying anti-rheumatic drug (“DMARD”) therapy.

Therapeutic Options and Current Development—

Our current therapeutic indication is RA, a systemic chronic inflammatory disease considered to be one of the most prevalent immune-mediated inflammatory diseases. RA is nearly always polyarticular and causes joint destruction, deformity, and loss of function. Extra-articular manifestations include cardiopulmonary diseases, eye diseases, Sjogren's syndrome, rheumatoid vasculitis and neurological diseases. Current therapies for RA in China include traditional Chinese medicine, corticosteroids, and DMARDs, including immunosuppressants and targeted therapies such as TNF inhibitors. Although the market for RA has become more competitive in China, new medicines targeting different pathways with greater clinical efficacy and safety remain a significant unmet need. Our GM-CSF antibody targets an entirely different disease pathway and has these desired characteristics to treat RA.

Clinical evidence supporting the role of a GM-CSF antibody in RA is highlighted in a few recent global studies. For example, both otilimab (MOR103), a GM-CSF antibody from MorphoSys and GSK, and mavrilimumab, a GM-CSF receptor antibody from Medimmune, have shown an early onset of clinical responses in Phase 2 proof-of-concept trials with RA patients. In addition to RA, attempts to develop a GM-CSF antibody for treating other autoimmune diseases, such as ankylosing spondylitis, are being studied by Amgen and Takeda. These autoimmune conditions involve the same autoimmune cell types, including macrophages, and neutrophils and the same connective tissues such as bones, joints, and tendons. Given the large patient population affected and the burden of these diseases, we are keen to explore the therapeutic role of TJM2 in treating these diseases, if initial studies in RA patients meet primary end-points.

The therapeutic role of TJM2 goes beyond autoimmune diseases. A recent study indicates that GM-CSF plays a critical role in serious side effects associated with chimeric antigen receptor (CAR)-T therapy, such as cytokine release syndrome ("CRS") and neurotoxicity. As CAR-T therapy has become an effective treatment option for certain cancer types, finding a treatment solution for CAR-T-related toxicities that occur frequently and can turn into a serious and potentially fatal condition becomes an urgent need. These severe toxicities add to the morbidity and mortality of CAR-T therapy. CRS is caused by a massive release of circulating cytokines by expanding CAR-T cells, and GM-CSF is one of the key cytokines of CRS. Currently, there are no effective therapies to prevent CRS or neurotoxicity. Tocilizumab, an IL-6 receptor antagonist, is approved for severe CRS with limited therapeutic coverage. Recent studies indicate that neutralizing GM-CSF *in vivo* may ameliorate and potentially prevent CRS and neuroinflammation without affecting CAR-T cell activity. Humanigen recently teamed up with Kite to evaluate lenzilumab, a GM-CSF antibody, as a preventive or treatment agent in association with Yescarta, an approved CD19-directed CAR-T therapy. In parallel with an RA clinical trial, we are seeking opportunities to co-develop TJM2 as a treatment option for CRS associated with CAR-T therapy.

Advantages of TJM2—

Based on reported clinical findings with front-runner GM-CSF antibodies compared to other RA biologics that are clinically used, we have the following expectations:

- Fast onset of therapeutic effect . *Because GM-CSF acts at a relatively early stage in the inflammatory cascade, GM-CSF blockade is expected to take effect after just a few initial doses and provide quick symptomatic relief to patients. This fast onset of clinical responses in RA has been shown in Phase 2 clinical trials on otilimab and mavrilimumab (NCT01023256 and NCT01050998);*
- Convenience and increased patient compliance . *Given the favorable development profile (high affinity, excellent PK, clean immunogenicity and concentrated formulation) exhibited by TJM2 thus far, the clinically active dose for TJM2 is expected to be low, which is advantageous for chronic maintenance of the disease by subcutaneous administration. This provides convenience to the patients and will likely increase patient compliance; and*

- Analgesic effect on inflammatory pain . *Because the GM-CSF receptor is also expressed on sensory neurons and is involved in RA-associated inflammatory pain, GM-CSF blockade is expected to provide relief for inflammatory pain, which provides additional clinical benefits to patients. This analgesic effect has been shown in a Phase 2 clinical trial on mavrilimumab (NCT01706926).*

Mechanism of Action—

GM-CSF is a central driver cytokine in orchestrating an innate immune response during inflammation. It is responsible for myeloid cell proliferation and functions, such as chemotaxis, adhesion, phagocytosis, and microbial killing. Importantly, GM-CSF can polarize macrophages into a pro-inflammatory M1 phenotype and is known to induce an inflammatory cascade involving other pro-inflammatory cytokines such as TNF, IL-1, IL-6, IL-12, and IL-23. It is evident that GM-CSF plays a crucial role in the pathogenesis and disease progression of multiple autoimmune conditions. The action of GM-CSF is mediated by binding of its cognate receptor on target cells and subsequent phosphorylation of signal transducer and activator of transcription 5 (“STAT5”).

TJM2 specifically binds to human GM-CSF with high affinity and can block GM-CSF from binding to its receptor, thereby preventing downstream signaling and target cell activation. As a result, it can effectively inhibit inflammatory responses mediated by macrophages, neutrophils, and dendritic cells, leading to reduced tissue inflammation and damage.

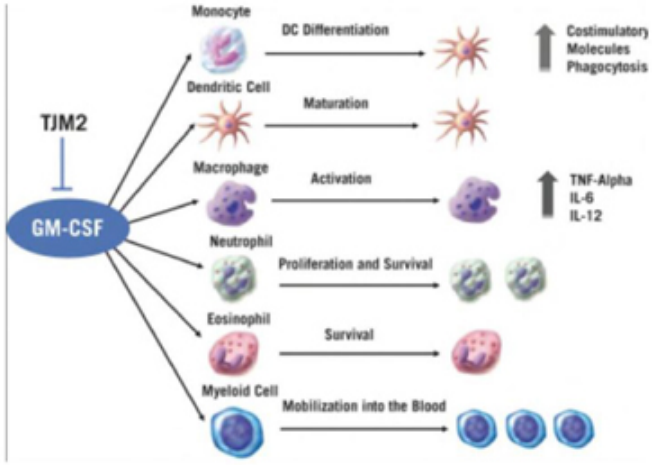


Figure: Role of GM-CSF in orchestrating coordinated immune response.

Summary of Pre-clinical Results—

A series of nonclinical studies have been conducted to evaluate the pharmacology, PK, and toxicology profiles of TJM2. TJM2 could potently bind to human and monkey GM-CSF but not rodent GM-CSF. TJM2 neutralized GM-CSF in a number of pharmacological studies *in vitro* and *in vivo* . TJM2 demonstrated linear PK behavior in single dose IV and SC studies in monkeys with a half-life characteristic of IgG and a low ADA potential. Weekly TJM2 treatment significantly reduced arthritis score and clinical symptoms in monkeys with established collagen-induced arthritis (a model of RA). In a GLP-compliant multilevel four-week repeat-dose general toxicology study in cynomolgus monkeys, the no observed adverse effect level (“NOAEL”) was considered to be 60 mg/kg. The nonclinical studies performed to date have demonstrated an acceptable pharmacological profile to allow TJM2 to progress to clinical studies in healthy volunteers.

Pharmacokinetics in Cynomolgus Monkeys

The systemic exposure in monkeys after a single IV injection of TJM2 appeared to increase proportionally with doses from 5, 25 to 50 mg/kg. The mean half-life (T1/2) was 217–241 hours, the mean maximum observed concentration (Cmax) ranged 112–1220 µg/mL, and the mean exposure (AUC0-last) ranged 14800–124000 µg*h/mL. TJM2 also exhibited linear PK behavior following a single subcutaneous ("SC") injection from 5, 25 to 50 mg/kg, with the mean T1/2 being 215–242 hours and the mean bioavailability ranging from 73 to 79%. No apparent sex difference was observed. The elimination rate of TJM2 was independent of the dose route. ADAs were of low titers and detected only in one animal before dosing and on Day 42 post-IV dose, which did not affect the PK profile. ADA was clean for the SC administration. These results indicate that TJM2 is not a strong immunogen to cynomolgus monkeys.

Pharmacodynamics in Cynomolgus Monkeys

Type II collagen-induced arthritis ("CIA") is a recognized animal model for RA, and drugs approved for RA have shown efficacy in this model. Monkeys were immunized with collagen to induce the disease. Once the animals exhibited signs of disease (joint swelling), weekly injections of vehicle control or 40 mg/kg TJM2 were initiated. TJM2 significantly decreased the severity of CIA as measured by arthritis score over the entire treatment period, which correlated with the decrease in STAT5 phosphorylation in PBMCs 24 hours after treatment.

Repeat-Dose Toxicology Study in Cynomolgus Monkeys

A GLP-compliant four-week repeat-dose toxicology study with a 30-day recovery was conducted in cynomolgus monkeys via weekly IV administrations at 20, 60 or 200 mg/kg.

The TK parameters were similar following the first and fourth dose, indicating no apparent accumulation after repeat administration. No apparent sex difference was observed. All samples were detected as ADA-negative throughout the study period. No TJM2-related death or moribund sacrifices occurred. Possible TJM2-related observation was limited to pulmonary granulomas observed in one male animal given 200 mg/kg dose. Minimal congestion and alveolar protein observed in one male animal given 20 mg/kg dose during the recovery period had uncertain relation to TJM2 and was not considered adverse. No other TJM2-related findings were noted. The NOAEL was considered to be 60 mg/kg, with corresponding mean Cmax and AUC0-t following the fourth dose of 2010 µg/mL and 117000 µg*h/mL for males, and 1930 µg/mL and 119000 µg*h/mL for females, respectively.

Summary of Clinical Results—

Based on the pre-clinical results, we initiated a first-in-human study in healthy volunteers in the United States (NCT03794180). This study has now been completed with a clinical study report (CSR) available.

Study design. This randomized, double-blind, placebo-controlled, and single dose-ascending study was designed to assess the safety, tolerability, PK/PD, and immunogenicity of TJM2 (referred to as TJ003234) in healthy volunteers. We have enrolled and completed dosing of four planned cohorts at 0.3, 1, 3 and 10 mg/kg dose levels, with each cohort consisting of eight subjects randomized into six receiving TJM2 and two receiving placebo IV infusions.

Safety. TJM2 was well tolerated following a single IV dose up to 10 mg/kg in healthy subjects with no MTD reached. There were no interruptions in dosing or early withdrawals. Fourteen males and 18 females participated in the study. The majority of AEs were mild to moderate in nature. No serious adverse events were reported during the study. Overall, 8 of the 24 subjects who received TJM2 and 3 of the 8 subjects on placebo reported treatment-related treatment-emergent adverse events (TEAEs). The most common AEs experienced by subjects dosed with TJM2 were headache (25%) and protein urine (25%). These AEs were also the most common AEs reported by subjects receiving placebo (37.5% and 37.5%, respectively).

Pharmacokinetics. Serum concentrations of TJM2 (TJ003234) were determined by anti-idiotypic antibody capture immunoassay and PK parameters were analyzed by noncompartmental analysis. Results showed that over the dose range of 0.3 mg/kg to 10 mg/kg, both Cmax and exposure increased in an approximately dose-proportional manner, with Cmax increased from 5.75 µg/mL to 260 µg/mL and AUC0-last increased from 90.5 day*µg/mL to 3780 day*µg/mL (see *Figure* below). In addition, t1/2 was approximately 3 weeks across the tested dose range. Clearance of TJM2 decreased with increasing dose. Volume of distribution decreased slightly with increasing dose. In terms of immunogenicity, two subjects in the 3 mg/kg TJM2 cohort and 1 placebo subject were positive for ADA. No subject in the 10 mg/kg dose level was positive for ADA.

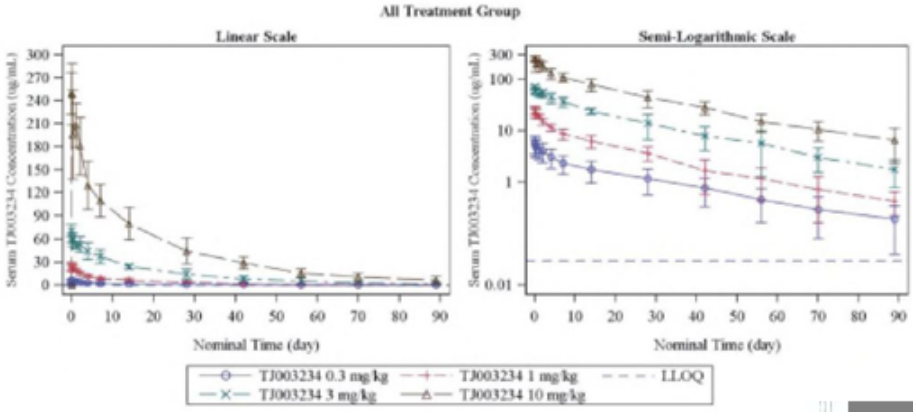


Figure: *Mean±SD concentration-time plots of serum TJM2 (TJ003234) levels. Linear scale, left; semi-log scale, right. LLOQ, lower limit of quantitation.*

Pharmacodynamics . Four hours after dosing, the induction of pSTAT5 by *ex vivo* GM-CSF stimulation in the monocyte population was inhibited by at least 70% compared to the placebo following a single dose of TJM2 for all dose groups. TJM2 inhibited GM-CSF-stimulated pSTAT5 levels by more than 90% in subjects in the 3 mg/kg and 10 mg/kg cohorts at 4 h to up to 2 weeks after dosing, suggesting the saturation of the pSTAT5 inhibition by the treatment at doses of 3 mg/kg and above.

Clinical Development Plan—

Data from this first-in-human study support continued development of TJM2. We have received IND approval from the NMPA for a multiple-dose Phase 1b study in patients with RA to be initiated in the first half of 2020. We also intend to investigate the efficacy of TJM2 in reducing or preventing CRS and neurotoxicity associated with CAR-T therapy through collaborations.

In addition, we are developing TJM2 to treat cytokine storm in severe and critically ill patients caused by the coronavirus disease (COVID-19). We have recently received IND clearance from the FDA for a double-blinded, placebo-controlled, three-arm randomized study that evaluates the safety and efficacy of TJM2 in reducing cytokine levels, including GM-CSF, in severe patients infected with SARS-CoV-2 who appear to have severe clinical complications caused by CRS. We have also submitted an IND application in South Korea, with plans to expand into other hardest-hit countries. The results from these planned COVID-19 studies will also be used to further evaluate the potential therapeutic role of TJM2 in reducing or preventing cytokine storm and neurotoxicity associated with CAR-T therapy.

TJC4: A Potential Highly Differentiated CD47 Antibody for Immuno-Oncology

Summary—

TJC4 is a fully human CD47 monoclonal antibody that we have discovered and developed internally for cancer immunotherapy. CD47 has emerged as one of the most promising immuno-oncology targets. Unlike other immuno-oncology targets being explored, the CD47-SIRPα pathway is involved in tumor progression by delivering a “don’t eat me” signal to tumor-engulfing macrophages, thereby protecting tumors from natural attacks by macrophages. Blockade of this pathway by CD47 antibody represents one of the most effective tumor killing mechanisms. However, due to the inherent epitope sharing between tumor cells and normal red blood cells (“RBCs”), the first-wave of clinical stage CD47 antibodies were found in clinical trials to bind to RBCs and cause significant hematologic adverse effects, such as severe anemia, which has hampered the development of these CD47 antibodies as a potential cancer therapy.

We developed TJC4 by design to possess a unique property or differentiation, to minimize binding to RBCs while retaining anti-tumor activities in line with other antibodies of the same class. This key differentiation is achieved through additional RBC counter-screening to select rare antibody clones that bind to CD47 with high affinity but do not bind to or bind minimally to RBCs. The proportion of RBC-sparing CD47 antibody leads among all CD47 antibody leads we identified after screening was 0.5%. TJC4 has been validated in a series of *in vitro* and *in vivo* pre-clinical studies, which have consistently shown a unique RBC-sparing profile comprised of minimal RBC binding, lack of hemagglutination and no significant adverse hematologic changes in cynomolgus monkeys even when used at a high dose (100 mg/kg). Our pre-clinical data thus far indicate that TJC4, if approved, is a potentially highly differentiated anti-tumor CD47 antibody with the advantage of minimizing hematologic side effects. We have obtained the IND approval from the FDA and the NMPA, respectively. We have initiated a Phase 1 clinical trial in the United States to study the safety profile, especially the hematologic profile, of TJC4 and to assess its pharmacokinetics, pharmacodynamics and early anti-tumor signals in cancer patients. We expect to obtain single-agent safety data of TJC4 in2020. In parallel, we have initiated a Phase 1/2a clinical trial of TJC4 in China in patients with relapsed or refractory AML/MDS. In addition, we are collaborating with Merck Sharp & Dohme Corp, or MSD, in a Phase 1 clinical trial in the United States for the combination therapy of TJC4 and MSD's PD-1 inhibitor KEYTRUDA (pembrolizumab) of multiple types of solid tumors. We have not initiated any research and development activities under such collaboration arrangement as of the date of this annual report.

Therapeutic Options and Current Development—

We plan to evaluate the therapeutic role of TJC4 in a variety of solid tumors, such as cancers of the ovary, lung, liver, pancreas, breast and colon, and hematological malignancies such as AML/MDS, lymphoblastic leukemia, and NHL. Although PD-1/PD-L1 therapies represent a new paradigm in cancer treatment, less than 40% of cancer patients have a clinically meaningful response to PD-1/PD-L1 treatment. As a result, targeting other immune components or cells involved in the immune system's anti-tumor mechanism has become an area of active pursuit in the field of immuno-oncology. TJC4 is one such innovative and promising therapeutic antibody, which is capable of mobilizing macrophage functions for effective and direct tumor-killing. Currently, a number of CD47 antibodies are in clinical development by biotech companies including Forty-Seven, Inc., Celgene, Surface Oncology and Arch Oncology. The most advanced asset, 5F9 from Forty-Seven, Inc., is in Phase 2 clinical studies for multiple cancer indications. However, almost all clinical trials with CD47 antibodies so far have shown significant hematologic adverse effects, likely due to inherent RBC-binding properties of generic CD47 antibodies, and as a result, some clinical studies had to be either terminated or managed with extra cautions.

Advantages of TJC4—

TJC4 has similar sub-nanomolar binding affinity as other CD47 antibodies and exhibits comparable anti-tumor activity. The key advantage of TJC4 is its minimal binding to RBCs, thus potentially avoiding or minimizing inherent hematologic adverse effects typically seen in other CD47 antibodies in clinical trials. This differentiated property of TJC4 is due to its unique epitope interaction as revealed by crystallography, which appears different from those recognized by other CD47 antibodies currently in clinical development based on publicly available information. The differentiation of TJC4 is highlighted in a series of pre-clinical studies summarized as the following: (i) TJC4 displays only minimal RBC-binding even at high antibody concentrations by flow cytometry; (ii) TJC4 does not induce RBC agglutination even in a high dose range; and (iii) most importantly, TJC4 does not cause significant hematologic changes or systemic toxicologic effects even at high doses in multiple cynomolgus monkey studies, including a pivotal 4-week GLP toxicity study. Taken together, TJC4 has a potentially better clinical safety profile and may be used in a broader patient population doses to explore its anti-tumor potential compared to other clinical stage competitor molecules.

	Company 1	Company 2	Company 3	I-Mab
Affinity	$8x10^{-9}$	$4x10^{-9}$	$8x10^{-10}$	$5x10^{-10}$
RBC binding	++	++	++	Minimal
RBC clumping	++	-	-	-
Anti-tumor activity	++	++	++	++
Phase 1	Anemia	Anemia NHL *on-going* AML *stopped*	Anemia *Suspended*	1st patient cohort dosed in U.S. Clinical trials planned China
Phase 2	On-going (combo)			

Table: Differentiated product profile of TJC4. (Sources for comparator antibodies: American Society of Hematology publication, PLOS One publication, World Intellectual Property Organization and company data)

Mechanism of Action—

TJC4 blocks the interaction between CD47 expressed on cancer cells and SIRPa expressed on macrophages, leading to increased phagocytosis of cancer cells by macrophages. Blockade of CD47 by TJC4 may also promote the development of anti-tumor T cell responses, resulting from increased tumor antigen presentation by professional antigen-presenting cells such as macrophages and dendritic cells. In addition to stimulating the phagocytosis of cancer cells, CD47 blockade was shown to involve other anti-tumor mechanisms, such as the enhancement of ADCC, direct induction of apoptosis (programmed cell death) of cancer cells, induction of differentiation of cancer stem cells, and inhibition of metastasis.

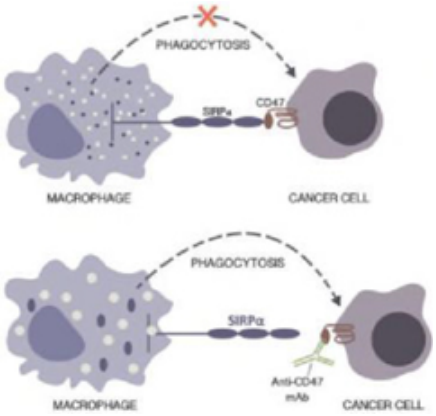


Figure: Targeting the CD47/SIRP α myeloid-specific immune checkpoint. CD47 is highly expressed on many different types of cancers. SIRP α is an inhibitory receptor expressed on macrophages and other myeloid immune cells. When CD47 binds to SIRP α , it causes the inhibition of phagocytosis. CD47 antibodies disrupt the CD47/SIRP α axis and enable the phagocytosis of cancer cells.

Summary of Pre-clinical Results—

CD47-related In Vitro and In Vivo Anti-tumor Activities

TJC4 exhibits high-affinity binding to human CD47 protein and CD47-expressing tumor cells at the nanomolar level and effectively blocks interaction of CD47 with its receptor SIRPα. As compared with other CD47 antibodies currently under clinical development, TJC4 demonstrated comparable potency in the enhanced macrophage-mediated phagocytosis of Raji tumor cells (see Figure A below) and comparable anti-tumor activity in the HL-60 leukemia and Raji xenograft models (see Figure B below). Moreover, when combined with rituximab, TJC4 exhibited a markedly enhanced inhibition on tumor growth in a diffuse large B cell lymphoma (DLBCL) animal model, through the synergistic effect of both agents (see Figure C below).

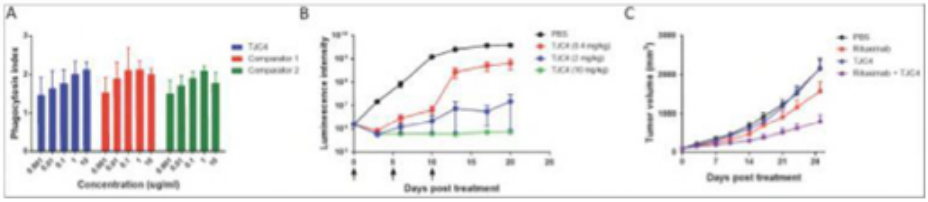


Figure: In vitro and in vivo anti-tumor activity of TJC4. (A) In vitro phagocytosis of Raji cells by primary human macrophages in the presence of different doses of TJC4 or comparator CD47 antibodies. (B) In vivo anti-tumor activity of TJC4 mono-treatment in Raji xenograft model. (C) In vivo anti-tumor activity of TJC4 (5 mg/kg, BIW) in combination with Rituximab (5 mg/kg, BIW) in the DLBCL model.

Assessment of Potential CD47-related In Vitro and In Vivo Hematologic Effects—

First, in a representative flow cytometric analysis (see Figure A below), TJC4 showed minimal binding to human RBCs compared to comparator CD47 antibodies used at the same concentration (1 μg/ml). The minimal binding of TJC4 to RBCs was confirmed when compared with other CD47 antibodies across multiple concentrations in another flow cytometric experiment (see Figure B below).

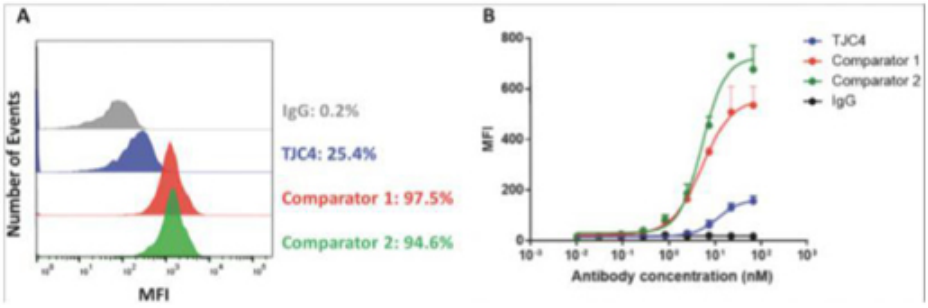


Figure: Binding of CD47 monoclonal antibodies to RBCs. (A) Representative graph of the staining of human RBCs with CD47 monoclonal antibodies or control IgG (1 μg/ml); (B) Dose dependent binding of CD47 monoclonal antibodies with human RBCs from different healthy donors (n = 3). MFI: mean fluorescence intensity.

Second, as CD47 is expressed on normal RBCs, binding of CD47 antibodies to the surface of RBCs could cross-link the RBCs into lattices and prevent them from precipitating into compact pellets, which is a phenomenon termed hemagglutination. Our results showed that TJC4 did not induce RBC agglutination across a wide range of antibody concentrations, while a comparator antibody caused significant hemagglutination starting at a concentration of 0.3 μg/ml. Results from a representative experiment are shown below.

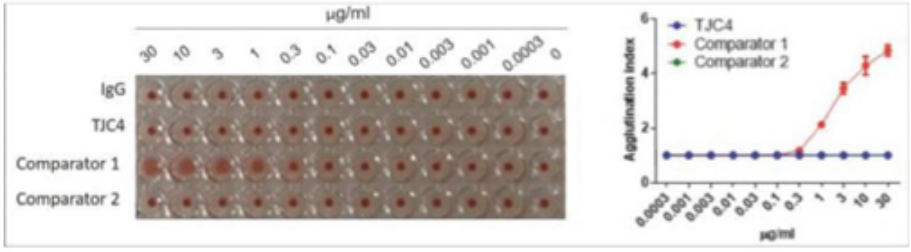


Figure: Hemagglutination by CD47 monoclonal antibodies. Left: representative graph of hemagglutination (haze appearance) or lack thereof (precipitate) by different concentrations of control IgG, TJC4, and comparator antibodies. Right: quantification through an index determined by the area of RBC occupation in the presence of the test antibodies, normalized to that of IgG control.

Thirdly, *in vivo* safety studies were performed in cynomolgus monkeys to assess the effects of TJC4 on the hematology parameters. Whereas a single bolus IV injection of the comparator antibody caused a significant drop in the number of RBCs and hemoglobin ("HGB") levels, treatment with TJC4 at a dose of 10 mg/kg did not significantly affect the number of RBCs, HGB levels or reticulocyte or platelet counts (see figure below).

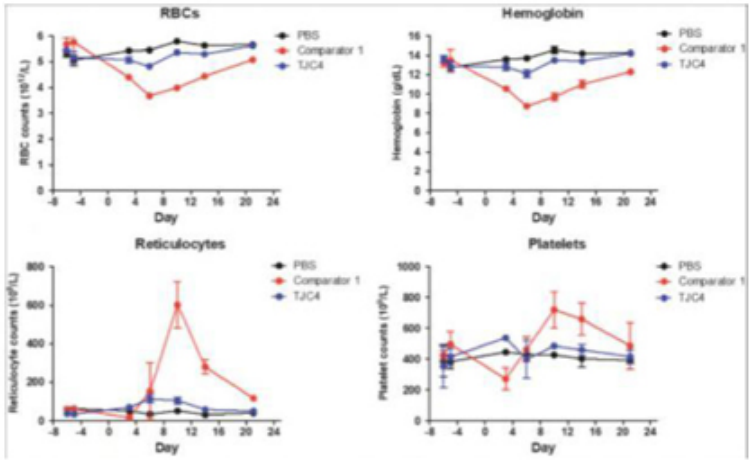


Figure: Hematological parameters in non-human primates treated with a single dose of CD47 antibodies. On Day 0, naive cynomolgus monkeys were IV injected with PBS control (n=2), TJC4 (n=2, 10 mg/kg) or a comparator antibody (n=2, 10 mg/kg). Blood cells were counted, twice before drug injection (baseline) and at 3, 6, 10, 14 and 21 days post-injection.

Moreover, in a four-week GLP toxicology study, TJC4 treatment did not induce significant overall toxicologic changes. Only mild decreases in the number of RBCs, HGB and hematocrit were found, which reached nadir at Day 4 post-first administration and then gradually recovered to the normal range following administration. The changes were not dose-dependent. Compared with the placebo control, the average decrease of RBCs in the treated animals was approximately 6% to 9% with only one animal showing an 18% drop at a dose of 30 mg/kg. No RBC-associated changes were noted in histopathologic examinations or in bone marrow smears (including erythrocytic series). Therefore, NOAEL was defined at 100 mg/kg.

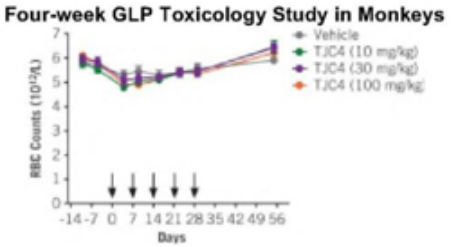


Figure: No anemia in non-human primates (male) at a high dose range.

Key preclinical data from above have been published as a poster presentation (#4063) at American Society of Hematology 2019 Annual Meeting.

Clinical Development Plan—

We have recently initiated a Phase 1 clinical trial in patients with advanced cancer in the United States. The clinical trial (NCT03934814) is designed to assess the safety of TJC4, in particular, the hematologic safety profile, including changes in hemoglobin levels and RBC counts. The clinical trial includes typical dose escalation schemes up to 30 mg/kg and cohort expansions in cancer patients. We expected to obtain single-agent safety data of TJC4 in 2020. In the same clinical trial, we also intend to evaluate the pharmacokinetics, pharmacodynamics and preliminary efficacy signals of TJC4 as a single agent and in combination with a PD-1 inhibitor or rituximab in patients with advanced solid tumors and relapsed or refractory lymphoma. In parallel, we have initiated a Phase 1/2a clinical trial of TJC4 as a monotherapy in China in patients with relapsed or refractory AML/MDS. The first patient was dosed in April 2020. In addition, we are collaborating with Merck Sharp & Dohme Corp, or MSD, in the same Phase 1 clinical trial in the United States for the combination therapy of TJC4 and MSD's PD-1 inhibitor KEYTRUDA (pembrolizumab) under a collaboration agreement in cancer patients with several types of solid tumors after completing a single-agent dose escalation. We have not initiated any research and development activities under such collaboration arrangement as of the date of this annual report. The goals of our global and China clinical development plans are to explore the potential in both hematologic malignancies and solid tumor indications, including but not limited to AML/MDS, ovarian cancer and gastric cancer, in both the United States and China.

TJD5: A Potential Highly Differentiated CD73 Antibody for Cancer Treatment

Summary—

TJD5 is an internally developed, humanized inhibitory antibody against human CD73. CD73 is a homodimeric enzyme expressed in tumors and plays a critical role in suppressing immune cells in tumor micro-environment. TJD5 displays sub-nanomolar binding affinity to CD73 and inhibits its nucleotidase activity. *In vitro* , TJD5 completely reversed the AMP- or tumor cell-mediated suppression of T cells. *In vivo* , when combined with a PD-L1 antibody, TJD5 exhibited a superior or synergistic inhibitory effect on tumor growth. The key differentiation of TJD5 when compared to some of the other clinical stage antibodies of the same class, is related to its novel epitope, which works through a unique intra-dimer binding mode, resulting in a complete inhibition of the enzymatic activity and avoiding the aberrant pharmacological property known as the "hook effect." With this particular mode of action, TJD5, if approved, has the potential to become a highly differentiated CD73 antibody. We have initiated a Phase 1 clinical trial in cancer patients in partnership with TRACON Pharmaceuticals in the United States. Safety data from dose escalation cohorts of TJD5 in combination with atezolizumab (a PD-L1 inhibitor) provided by Roche under a clinical supply agreement among Roche, TRACON and us, are expected in 2020. We obtained IND approval from the NMPA for TJD5 in September 2019. In China, we will collaborate with Shanghai Junshi Biosciences Co., Ltd, or Junshi, for the combination therapy of TJD5 with Junshi's PD-1 monoclonal antibody toripalimab in cancer patients with various types of solid tumors.

Therapeutic Options and Current Development—

Despite recent breakthroughs with PD-1/PD-L1 therapies, clinical non-response rates to such treatments remains high in cancer patients (exceeding 60%). This non-responsiveness to these standard treatments is partly due to the fact that T cells within an inhibitory tumor environment are suppressed and fail to respond to stimulation induced by PD-1/PD-L1 therapies. CD73, which converts extracellular adenosine monophosphate ("AMP") to adenosine, is implicated in one of the protective mechanisms of tumors that evade immune attack by creating an adenosine-rich microenvironment inhibitory to immune cells. Pre-clinical studies have indicated that the inhibition of CD73 renders T cells more responsive to PD-1/PD-L1 therapies by altering the tumor micro-environment, resulting in a superior anti-tumor effect. As CD73 is widely expressed in various cancers, a combination therapy of TJD5 with a PD-1/PD-L1 antibody may increase the likelihood of treatment success in cancer patients who do not respond to standard PD-1/PD-L1 therapies. The potential cancer indications of TJD5 include thyroid cancer, lung cancer, colorectal cancer, stomach cancer, urothelial cancer, endometrial cancer, head and neck cancer, breast cancer, ovarian cancer, and melanoma, in which CD73 is widely expressed.

A number of global companies are running active clinical development programs with CD73 antibodies. MEDI-9447 from Medimmune and BMS-986179 from Bristol-Myers Squibb are the two most advanced CD73 antibodies, which are in Phase 1/2 clinical trials. BMS-986179 is being studied as a single agent and in combination with nivolumab (a PD-1 antibody) for the treatment of advanced colorectal, esophageal, gastric, ovarian, and pancreatic cancers. MedImmune is testing MEDI-9447 for the treatment of solid tumors as a single agent or in combination with durvalumab (a PD-L1 antibody) or chemotherapy. NZV-930 (from Novartis) and CPI-006 (from Corvus) have entered Phase 1 clinical trials for the treatment of solid tumors.

Advantages of TJD5—

Extracellular AMP can be generated from ATP, cyclic AMP and nicotinamide adenine dinucleotide ("NAD") through separate biochemical pathways, all of which converge to CD73 to generate adenosine. Thus, CD73 antibody is expected to block adenosine generation more completely than other related targets. Further, CD73 antibody works through a substrate non-competitive fashion and has advantages over small molecule inhibitors targeting the adenosine pathway through a substrate competing fashion. More importantly, TJD5, if approved, is potentially highly differentiated among the clinical stage CD73 antibodies as it binds to a novel epitope in the C-terminal domain of CD73 without causing a "hook effect."

TJD5 has the following key advantages: (i) TJD5 exhibits a typical dose-response curve without the "hook effect" and with a complete inhibition of both soluble and surface-bound CD73 and (ii) TJD5 has a non-competitive inhibitory effect that is not blunted by high levels of CD73 enzyme substrates, which would be expected for small-molecule competitive blockers. These pharmacological properties may translate into efficient target inhibition in tumors and superior anti-tumor activity, especially in an adenosine-rich micro-environment.

Mechanism of Action—

Adenosine is a potent immunosuppressive signaling molecule abundant in the tumor microenvironment. CD73 is the rate-limiting enzyme that generates adenosine from extracellular AMP. TJD5 allosterically inhibits the CD73 enzyme by preventing the inactive CD73 dimer from changing into the active conformation in a substrate non-competitive manner. This results in a decrease in adenosine production in the tumor micro-environment, increasing T cell anti-tumor activity.

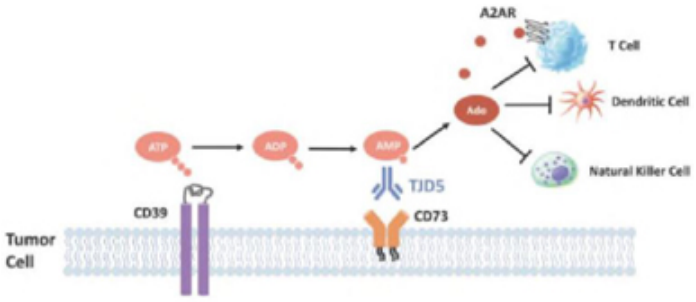


Figure: Schematic diagram of CD73-catalyzed adenosine (Ado) generation and immunosuppression by Ado in the tumor microenvironment.

Summary of Pre-clinical Results—

Inhibition of CD73 by TJD5. As shown in the figure below, TJD5 displayed complete inhibition of soluble CD73 enzymatic activity (IC50= 0.22 n *M*) without the "hook effect" in contrast to the comparator molecule, which at higher concentrations caused a paradoxical rebound of enzymatic activity presumably due to its inter-dimer binding mode.

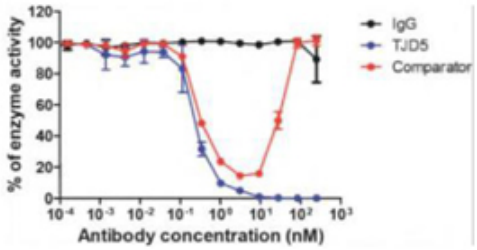


Figure: Inhibition of soluble CD73 enzymatic activity by CD73 antibodies.

Restoration of T Cell Activity by TJD5 In Vitro. We observed that AMP inhibited interferon gamma (IFN- g) production by CD4 or CD8 T cells through adenosine generation, mimicking the suppressive tumor microenvironment where AMP is abundantly produced. However, this suppression could be reversed by TJD5 in a concentration-dependent manner. Moreover, in an experimental system where CD73 ^{high} human ovarian cell line SK-OV-3 and human T cells were co-cultured, addition of TJD5 restored T cell activity as measured by IFN g production in a concentration-dependent manner.

In Vivo Anti-tumor Activity of TJD5. TJD5 monotherapy showed a moderate anti-tumor effect in a mouse xenograft model bearing A375 melanoma cells. To examine whether TJD5 can enhance the anti-tumor activity of the PD-L1 antibody, we evaluated the therapeutic effects of TJD5 used as a single agent and in combination with a PD-L1 antibody in the same A375 melanoma model. The combination treatment group resulted in 68% inhibition of tumor growth which is significantly better than the vehicle and TJD5 monotherapy.

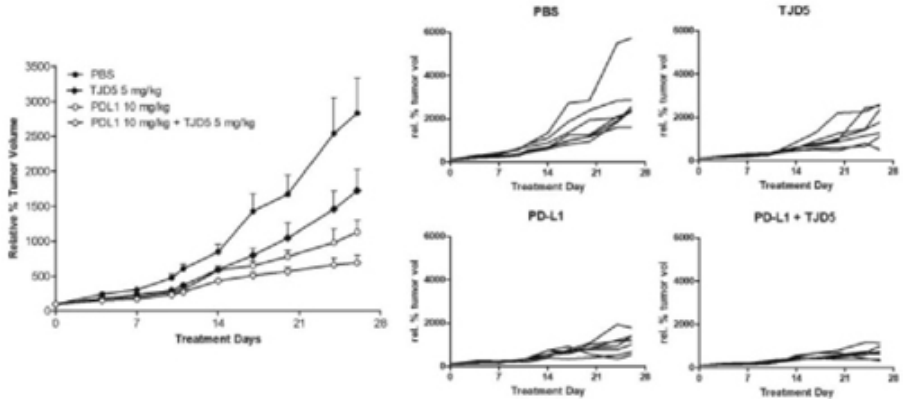


Figure: In vivo anti-tumor activity of TJD5 and anti-PD-L1 in A375 melanoma xenograft model. Mice were treated with PBS control, anti-PD-L1 (10 mg/kg), TJD5 (5 mg/kg) or a combination of anti-PD-L1 and TJD5 twice a week for three weeks. Tumor volumes as percentages relative to baseline (day 0) for each treated group (n=7 per group) (left) and for each individual mouse (right) were plotted.

Pharmacokinetics of TJD5 in Cynomolgus Monkeys . Following a single IV injection of TJD5 at 5, 25 and 50 mg/kg, the mean Cmax ranged dose-proportionally from 136 to 1430 µg/mL, and the systemic exposure indicated by the AUC0-last increased in a non-linear manner, ranging from 4020 to 135000 hr*µg/mL. Mean half-life was 44.9 hours, 61.5 hours and 104 hours, respectively, reflecting decreased clearance of TJD5 with increasing dose. No apparent sex difference was observed in the main PK parameters. Positive ADAs against TJD5 were detected in the majority of the animals, without an apparent impact on systemic exposure.

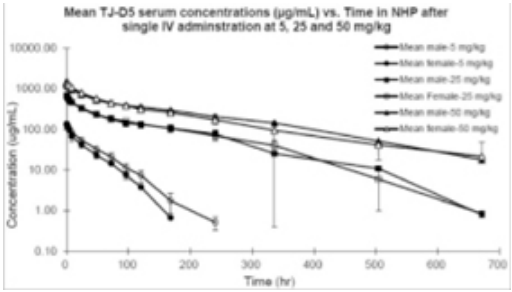


Figure: Concentration-time profile of TJD5 in cynomolgus monkeys.

Repeat-dose Toxicology Study of TJD5 in Cynomolgus Monkeys. A four-week GLP toxicity study was conducted in cynomolgus monkeys followed by a six-week recovery period to evaluate the potential toxicity of TJD5. Forty cynomolgus monkeys were randomly assigned into four groups (5/sex/group) and given five weekly doses of TJD5 at 20, 60 or 200 mg/kg via IV injection. Systemic exposures (Cmax and AUC0-t) generally increased dose-proportionately, and the Day 22 values were generally higher than those on Day 1, with mean accumulation ratios (AR) ranging between 1.65 and 2.19. No apparent sex difference was observed. Positive TJD5 antibodies were detected in the majority of animals following repeat administration at all doses, while no significant impact was observed on the TK profiles.

The only TJD5-related effect was decreased monocyte chemoattractant protein 1 (MCP-1) on Day 1 (24 or 48 hours post-dosing) in treated animals. Due to a lack of corresponding findings or impact on the well-being of the animals, this effect was not considered adverse. No abnormality was observed in other study endpoints, including safety pharmacology parameters and immunotoxicity. The no observed adverse effect level (NOAEL) was defined at 200 mg/kg. This dose level corresponded to the mean Cmax and AUC values of 6890 μg/mL and 594000 μg*hr/mL in males, respectively, and 6450 μg/mL and 501000 μg*hr/mL in females, respectively, on Day 22 of the dosing phase.

Clinical Development Plan—

The current clinical development plan is to develop TJD5 in the United States and China in parallel. In the United States, we have initiated a Phase 1 clinical trial of TJD5 in combination with atezolizumab (a PD-L1 inhibitor) provided by Roche under a clinical supply agreement among Roche, TRACON and us, in patients with advanced solid tumors in partnership with TRACON Pharmaceuticals, Inc., which will be responsible for conducting the current Phase 1 clinical trial in the United States (TJD5 is referred to as TJ004309, NCT03835949). Eleven patients have been dosed so far. Safety data of TJD5 from dose escalation cohorts are expected in 2020. In China, we have obtained the IND approval from NMPA and plan to begin a clinical trial to evaluate the safety, tolerability, PK/PD, and potential efficacy primarily in patients with solid tumors, including lung cancer. We are collaborating with Shanghai Junshi Biosciences Co., Ltd, or Junshi, for the combination therapy of TJD5 with Junshi's PD-1 monoclonal antibody toripalimab in cancer patients with various types of solid tumors.

Pre-clinical Assets (Monoclonal antibodies)

TJ210 and TJX7 are monoclonal antibodies currently at the pre-clinical stage, moving towards IND submission in the United States by 2020.

TJ210: A Potential Highly Differentiated Antibody Targeting Myeloid Derived Suppressor Cells in Cancers and Autoimmune Diseases—

TJ210 is a fully human, high affinity antibody against human C5aR1 for the treatment of cancers and potentially autoimmune diseases. Tumors produce large amounts of complement factor C5a to attract C5aR1-expressing myeloid derived suppressor cells ("MDSCs"), M2 macrophages and neutrophils. These myeloid cells critically contribute to an immunosuppressive microenvironment as part of the evading mechanism of tumors and are associated with poor prognosis and resistance to PD-1/PD-L1 therapies in many cancers. Inhibition of C5a or its receptor C5aR in mice leads to markedly reduced MDSCs and has an inhibitory effect on tumor growth in various tumor-bearing animal models. The C5aR-blocking antibody has been shown to have significant therapeutic activity when combined with PD-1 therapies in PD-1-resistant tumor models. TJ210 exerts strong anti-tumor activity by blocking the activation and migration of C5aR1-expressing myeloid cells and has a highly differentiated potential, if approved, as it binds to a novel epitope and possesses superior functional properties. Compared to the only competitor antibody from Innate Pharma, TJ210 shows a more potent anti-tumor effect, especially when C5a concentrations are high, and binds to C5a receptors in both humans and monkeys, making pre-clinical safety assessment possible. In addition, TJ210 has therapeutic potential in multiple inflammatory and autoimmune indications, in which the role of the C5a/C5aR axis has been validated. We partnered with the original developer of TJ210, MorphoSys, for Greater China rights and shared global rights. TJ210 is progressing towards IND submission by 2020 in the United States, and we plan to work jointly with MorphoSys to develop this asset.

TJX7: A Novel CXCL13 Antibody for Autoimmune Diseases—

TJX7 is an internally discovered novel humanized neutralizing antibody targeting the CXCL13 chemokine. CXCL13, through its receptor CXCR5, plays a key role in forming germinal centers, which are critical for immune response. The role of CXCL13 in forming germinal centers is to guide the migration of germinal center B cells and follicular T cells within the lymphoid organs and facilitate their interaction, maturation and function. One of the key pathogenic features in autoimmune diseases is related to the aberrant formation of ectopic germinal centers formed in affected organs, contributing to chronic inflammation and tissue destruction. Elevated serum CXCL13 levels, CXCR5-expressing T cells and pathogenic germinal center B cells and even ectopic germinal center formation are found in multiple autoimmune diseases, including Sjögren's syndrome, RA, multiple sclerosis, and SLE. TJX7 is being developed for the treatment of autoimmune disorders and has been shown to bind to CXCL13 with sub-nanomolar affinity, effectively blocking the interaction between CXCL13 and CXCR5 and the downstream signaling. TJX7 has been shown to completely inhibit the migration of primary human tonsil B cells. Pharmacodynamic studies in mice and cynomolgus monkeys have confirmed TJX7's inhibitory effects on germinal center formation and antibody production. Results generated so far indicate that TJX7 may provide a new therapeutic angle in the treatment of autoimmune diseases as it acts uniquely at the core of tissue pathologies. TJX7 is currently under CMC and pre-clinical development.

Pre-clinical Assets (Bi-Specific Antibody Panel)

PD-L1-based Bi-specific Antibodies . As previously discussed, this panel of PD-L1-based bi-specific antibodies is designed according to the scientific rationale that a PD-L1 antibody, when engineered with a selected second immune component such as a cytokine or another antibody, is able to convert "cold tumors," which typically do not respond to PD-1/PD-L1 inhibitors, to "hot tumors," which are more sensitive to PD-1/PD-L1 therapies. Such PD-L1-based bi-specific antibodies are expected to increase the probability of treatment success in patients who do not respond to PD-1/PD-L1 treatment. Based on this concept, we have generated a panel of bi-specific antibodies using our proprietary PD-L1 antibody sequence as the backbone (the first signal), linked to a second component (the second signal) of selected immune properties. The second signals for this panel of bi-specific antibodies include IL-7 cytokine (expanding T effector cells), 4-1BB and B7-H3 antibodies (activating T cells synergistically with PD-L1) and CD47 antibody (adding the macrophage killing mechanism). We strive to validate all bi-specific antibodies through a series of robust *in vitro* and *in vivo* studies for proof-of-concept, thus providing a solid basis for further development. Collectively, we have demonstrated that the second paired component must be structurally integrated with the tumor-engaging anti-PD-L1 backbone to concentrate and function effectively inside tumors, which cannot be achieved by simply combining two free agents.

"Fortified" Bi-specific Antibodies for Specific Cancer Therapeutic Purposes. TJ-C4GM is a "fortified" version of the CD47 antibody, which is specifically designed for the treatment of solid tumors through the CD47-mediated macrophage killing mechanism. As the majority of tumor-associated macrophages adopt an anti-inflammatory and tumor-promoting M2 phenotype rather than a pro-inflammatory M1 phenotype, they are less efficient in phagocytosis in response to CD47 blockade. Thus, treatment of solid tumors with the CD47 antibody may exhibit limited efficacy. TJ-C4GM is a novel molecule composed of TJC4 with an engineered GM-CSF moiety fused at the C-terminus of the antibody heavy chain. GM-CSF is a potent cytokine known to convert tumor-resident M2 macrophages into tumor-engulfing M1 macrophages, which enables TJ-C4GM to exert a better phagocytic effect in solid tumors. These unique functional properties of TJ-C4GM are confirmed in a series of *in vitro* and *in vivo* tumor animal models, in which TJ-C4GM exerts superior anti-tumor activity against solid tumors, which cannot be achieved by TJC4 or GM-CSF used either alone or in combination. TJ-C4GM is currently at the CMC and pre-clinical development stage.

TJ-CLDN4B is a bi-specific antibody targeting both Claudin18.2 (CLDN18.2), a tumor antigen preferentially expressed in gastric and pancreatic cancers, and 4-1BB, a co-stimulatory molecule on T cells. CLDN18.2 is a tight junction molecule normally expressed only on epithelial cells of the gastric mucosa, which is inaccessible by antibodies under normal conditions, making it a highly attractive tumor target. Although a CLDN18.2 monoclonal antibody (claudiximab) was active in a Phase 2 trial, only the CLDN18.2 high-expressing tumors seemed to be susceptible. In collaboration with ABL Bio, we developed a bi-specific antibody, TJ-CLDN4B, which provides two key advantages over current CLDN18.2 antibodies and 4-1BB agonistic antibodies. First, TJ-CLDN4B is capable of binding to tumor cells even with low levels of CLDN18.2 expression, making it more suitable for a broader patient population. Second, only upon tumor cell engagement by TJ-CLDN4B are T cells activated. In contrast, other pan-activating 4-1BB antibodies that activate T cells regardless of tumor engagement are prone to liver toxicity as seen in clinical studies. In a humanized mouse model, TJ-CLDN4B suppressed tumor growth to a greater extent than anti-CLDN18.2 or anti-4-1BB alone or in combination. TJ-CLDN4B is currently at the CMC and pre-clinical development stage.

Licensing and Collaboration Arrangements

A. In-Licensing Arrangements

Licensing Agreement with MorphoSys (MOR202/TJ202)

In November 2017, we entered into a license and collaboration agreement with MorphoSys AG (“MorphoSys”) with respect to the development and commercialization of MOR202/TJ202, MorphoSys´s proprietary investigational antibody against CD38 (the “CD38 product”).

Under this agreement, MorphoSys granted to us an exclusive, royalty-bearing, sublicensable license to exploit MOR202/TJ202 for any human therapeutic or diagnostic purpose in the licensed territory, namely Greater China.

Pursuant to this agreement, we granted to MorphoSys an exclusive license to our rights in any inventions that we make while exploiting MOR202/TJ202 under this agreement, solely to exploit MOR202/TJ202 outside of Greater China.

We also received the right to sublicense to affiliates and third parties acting as contract manufacturers, contract research organizations, distributors or wholesalers without prior written consent, as well as the right to sublicense to other third parties with the prior written consent of MorphoSys, not to be unreasonably withheld, delayed or conditioned.

We are solely responsible for the development and commercialization of MOR202/TJ202 in Greater China, and must use commercially reasonable efforts as we develop and commercialize MOR202/TJ202.

Pursuant to this agreement, we paid to MorphoSys an upfront license fee of US$20.0 million. We also agreed to make milestone payments to MorphoSys, conditioned upon the achievement of certain development, regulatory and commercial milestones, in the aggregate amount of US$98.5 million. Such milestones include first patient dosed in human clinical trials, marketing approval, and first annual net sales of CD38 products covered by the agreement in excess of a certain amount. As of the date of this annual report, we have made milestone payments of US$8.0 million to MorphoSys.

In addition, we are required to pay tiered low-teens royalties to MorphoSys on a country-by-country and product-by-product basis during the term, commencing with the first commercial sale of a relevant licensed product in Greater China. The end of the royalty term is linked to (i) the expiration, invalidation or abandonment of relevant patent claims, (ii) 10 years from the date of first commercial sale of such CD38 product, and (iii) marketing exclusivity for such relevant licensed product. To date, we have not paid any royalties to MorphoSys. Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect until the expiration of our last payment obligation under the agreement. This agreement may be terminated by either party for the other party’s uncured material breach, bankruptcy or insolvency. In addition, we have the right to terminate the agreement for convenience at any time after a certain specified time period upon a notice period that varies based upon the stage of development. MorphoSys has the right to terminate the agreement if we challenge its patents. To the extent that we terminate for convenience or MorphoSys terminates for our material breach, bankruptcy, insolvency or patent challenge, among other things, all licenses and rights granted by MorphoSys to us will automatically terminate and the licenses and rights granted by us to MorphoSys will survive. In the event of such termination, we must also grant to MorphoSys an exclusive, royalty-bearing, sublicensable license under certain of our intellectual property relating to the licensed product to exploit MOR202/TJ202 for any human therapeutic or diagnostic purpose in Greater China.

Assignment and License Agreement with Genexine (TJ101)

In October 2015, I-Mab Bio-tech Tianjin Co., Ltd., known as Tasgen Bio-tech (Tianjin) Co., Ltd. at the time (which subsequently became our subsidiary following the Acquisition) ("I-Mab Tianjin"), entered into an intellectual property assignment and license agreement with Genexine, Inc. ("Genexine"), further amended in December 2017, with respect to four licensed products, namely GX-H9 (TJ101), GX-G3 (TJ102), GX-G8 and GX-P2 and one assigned product, GX-G6 (TJ103). Under this agreement, Genexine (i) granted to I-Mab Tianjin an exclusive, non-transferable, sublicensable license to use and otherwise exploit certain intellectual property to engage in pre-clinical and clinical development, manufacturing, sale and distribution of the above-mentioned licensed products for (A) the treatment of any disease with respect to GX-H9 and GX-G3 in China (which, for clarity excludes, Hong Kong, Macau and Taiwan), (B) the treatment of chemically induced diarrhea, with respect to GX-G8 anywhere in the world and (C) the treatment of rheumatoid arthritis and lupus (not including psoriasis) with respect to GX-P2 anywhere in the world and further (ii) assigned to I-Mab Tianjin a certain Chinese patent and related know-how related to the assigned product (TJ103) and granted I-Mab Tianjin an exclusive license to exploit the assigned intellectual property to engage in pre-clinical and clinical development, manufacturing, sale and distribution of the assigned product (TJ103) for the treatment of any disease in China (which, for clarity, excludes Hong Kong, Macau and Taiwan). I-Mab Tianjin will also receive an exclusive license to any improvements that Genexine develops or acquires related to any of the aforementioned products.

Under this agreement, I-Mab Tianjin paid an aggregate upfront license fee of US$13.0 million in relation to the patents, patent applications, know-how, data and information in connection with the four licensed products and a purchase fee of US$7.0 million in connection with the assigned product (TJ103). I-Mab Tianjin also agreed to make certain milestone payments, including milestone payments in the aggregate amount of US$40.0 million for GX-H9, US$25.0 million for TJ103 and US$15.0 million for GX-G3, conditioned upon the achievement of certain net sales targets. As of the date of this annual report, we have made upfront license payment of US$0.1 million and milestone payments of US$0.7 million to Genexine.

The term of this agreement is 30 years unless terminated earlier in accordance with the terms thereof. This agreement may be terminated by either party for the other party's uncured material breach, bankruptcy or insolvency, in the event of force majeure or a PRC regulatory requirement to make material alteration or modification to the contractual rights or obligations of this agreement which has the effect of preventing the parties from achieving their business objectives, or upon the termination of a certain subscription agreement or a certain joint venture agreement entered into by I-Mab Tianjin and Genexine in October 2015 (provided that the termination of such subscription agreement or joint venture agreement was not due to the material breach of the party electing to terminate this agreement). Genexine has the right to terminate the agreement if we fail to use commercially reasonable efforts to obtain regulatory approvals for commercializing the licensed product in the agreed period due to our own fault or if we cease to pursue clinical development or product registration or to conduct licensed activities on a reasonable scale as approved by our board of directors. During the term of this agreement, if I-Mab Tianjin develops or acquires any improvement, modification or alteration to the licensed products, I-Mab Tianjin will become the sole legal owner of such improvements, modifications and alterations and has full power, right and authority to grant licenses or transfer ownership of the same. I-Mab Tianjin is required to promptly notify Genexine in writing giving details of any such improvements, modifications or alterations and provide Genexine with such explanations or trainings to enable Genexine to legally and effectively use the same. Additionally, I-Mab Tianjin shall grant to Genexine a fully paid up, royalty-free, exclusive license to use any such improvements, modifications and alterations anywhere outside of the territory for which I-Mab Tianjin is licensed under this agreement.

Licensing Agreement with Genexine (GX-I7/TJ107)

In December 2017, we entered into an intellectual property license agreement with Genexine with respect to GX-I7, a long-acting IL-7 cytokine. Under this agreement, Genexine granted to us an exclusive, sublicensable and transferable license to use and otherwise exploit certain intellectual property (including improvements subsequently developed or acquired by Genexine) in connection with the pre-clinical and clinical development, manufacturing, sale and distribution of GX-I7 to treat cancers in the field of oncology in China, Hong Kong, Macau and Taiwan.

Under this agreement, we paid an upfront license fee of US$12.0 million to Genexine. We also agreed to make milestone payments in the aggregate amount of US$23.0 million, conditioned upon the achievement of certain development milestones, including completion of Phase 2 and Phase 3 clinical studies and NDA or BLA approval in any of China, Hong Kong, Macau or Taiwan.

Further, we agreed to make milestone payments in the aggregate amount of US$525.0 million, conditioned upon the achievement of certain cumulative net sales of GX-I7 up to US$2,000 million. We also are required to pay Genexine a low-single-digit percentage royalty in respect of the total annual net sales of GX-I7. The aforesaid milestones and royalties (other than the upfront payment) will be reduced by 50% following the entry of a generic version of GX-I7 in China, Hong Kong, Macau and Taiwan without the consent or authorization of us or any of our sublicensees. As of the date of this annual report, no milestone payments or royalties are due under this agreement.

Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect until the later of (i) the expiry of the last to expire patent of the licensed intellectual property that includes a valid claim for China, Hong Kong, Macau or Taiwan. and that covers the composition of GX-I7; and (ii) 15 years from the date of the first commercial sale of GX-I7. This agreement may be terminated by either party for the other party's uncured material breach, bankruptcy or insolvency, in the event of force majeure or regulatory requirement to make material alteration or modification to the contractual rights or obligations of this agreement which has the effect of preventing the parties from achieving their business objectives, or by mutual agreement of both parties. Genexine has the right to terminate the agreement if we fail to use commercially reasonable efforts to obtain regulatory approvals or other registrations necessary for commercializing the licensed product in the agreed period due to our fault or if we cease to pursue clinical development or product registration or to conduct licensed activities on a reasonable scale as agreed ("Development and Commercialization Termination Events"). Such Development and Commercialization Termination Events expressly include our failure to reach certain development milestones or commercially launch the licensed product in the agreed period. To the extent that we terminate as a result of a regulatory requirement to make material alteration or modification to the contractual rights or obligations of this agreement or Genexine terminates for our material breach, bankruptcy or insolvency, force majeure, or the Development and Commercialization Termination Events, we cannot develop, manufacture, market, promote, sell, offer for sale, distribute or otherwise make available any competing product for a certain period after such termination.

During the term of this agreement, if we develop or acquire any improvement, modification or alteration to the licensed product, we will own such improvements, modifications or alterations and provide Genexine details thereof, whether patentable or not. Additionally, we shall grant to Genexine a fully paid up, royalty-free. exclusive license (with a right to sublicense) to use any such improvements, modifications or alterations anywhere outside of China, Hong Kong, Macau and Taiwan.

Licensing Agreement with Ferring (TJ301)

In November 2016, we entered into a license and sublicense agreement with Ferring International Center SA ("Ferring") with respect to (i) FE301, an interleukin-6 inhibitor, and (ii) all pharmaceutical formulations in finished packaged form containing FE301 covered by certain patents or patent applications. Under this agreement, Ferring granted to us an exclusive, sublicensable license (excluding any non-exclusive license that Ferring granted to Conaris Research Institute AG under a licensing agreement entered into in November 2008) under certain Ferring intellectual property to research, develop, make, have made, import, use, sell and offer to sell FE301 (and the licensed products containing FE301) in China, Hong Kong, Macau, Taiwan and South Korea. We also have an option to receive an exclusive, sublicensable license under certain Ferring intellectual property to research, develop, make, have made, import, use, sell and offer to sell FE301 (and the licensed products containing FE301) in the countries in North America, the European Union and Japan that are mutually agreed upon by the parties.

We are required to use commercially reasonable efforts to obtain approval of FE301 and to promote, market, distribute and sell it in China, Hong Kong, Macau, Taiwan, and South Korea. Such activities are to be at our own cost and expense.

Under this agreement, we paid to Ferring an upfront license fee of US$2.0 million. We also agreed to make milestone payments to Ferring, in the aggregate amount of US$14.5 million, conditioned on the achievement of certain development milestones in the licensed territory, including completion of Phase 1b and Phase 2a clinical studies and the submission and approval of the new drug application. Further, if we exercise our option to receive a license in any of the mutually agreed upon countries in North America, the European Union and Japan, we are required to pay to Ferring an additional US$3.0 million as an upfront license fee (upon the exercise of the option), and milestone fees up to the aggregate amount of US$30.0 million, conditioned upon the licensed product achieving certain development milestones in certain countries in the option territory. As of the date of this annual report, no milestone payments are due under this agreement.

In addition, we agreed to pay Ferring tiered royalties ranging from the mid-single-digit to high-single-digit percentages of annual net sales for countries in China, Hong Kong, Macau, Taiwan, and South Korea, and from the high-single-digits to 10% of annual net sales for the mutually agreed upon countries in North America, the European Union and Japan. To date, we have not paid any royalties to Ferring.

The royalty term commences with the first commercial sale of the licensed product in the relevant country and ends upon the later of (i) 15 years from the date of launch, and (ii) the expiry of the last to expire patent of Ferring that includes a valid claim covering the development, making, using or selling of the licensed compound or licensed product in the licensed territory and/or option territory. Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect until the later of the expiry of the royalty term, and the first date on which we are not conducting any necessary and outstanding clinical study with respect to the licensed product or seeking to obtain any necessary and pending regulatory approval for the licensed product, if applicable. This agreement may be terminated by either party for the other party's uncured material breach, bankruptcy or insolvency. In addition, in the event that the original licensor terminates its license to Ferring governing any of the intellectual property sublicensed to us under this agreement, Ferring has the right to terminate this agreement with respect to such sublicenses in which case both parties will discuss in good faith how to resolve and mitigate to mutual satisfaction. To the extent that Ferring terminates for our material breach, bankruptcy or insolvency, among other things, all licenses and rights granted by Ferring to us will automatically terminate and the licenses and rights we granted to Ferring will survive and automatically become irrevocable with the right to sublicense.

During the term of the licensing agreement, if we develop or acquire any improvement, modification, enhancement or addition to the licensed product, we will own and retain all rights, title and interest therein, and grant to Ferring a non-exclusive, fully paid, royalty-free, worldwide license thereto.

License and Collaboration Agreement with MacroGenics (enoblituzumab)

In July 2019, we entered into a license and collaboration agreement with MacroGenics, Inc. for development and commercialization of an Fc-optimized antibody known as enoblituzumab that targets B7-H3, including in combination with other agents, such as the anti-PD-1 antibody known as MGA012, in the People's Republic of China, Hong Kong, Macau and Taiwan.

Under this agreement, MacroGenics granted to us an exclusive, sublicensable, royalty-bearing license to MacroGenics' patents and know-how to develop and commercialize the enoblituzumab product, and a combination regimen of enoblituzumab and MGA012, in Greater China during the term of the agreement.

In exchange for these rights, in addition to certain financial consideration, we grant to MacroGenics a royalty-free, sublicensable, license outside of Greater China, to our patents and know-how that are related to the enoblituzumab product or useful or necessary for MacroGenics to develop or commercialize the enoblituzumab product or a product containing MGA012, and combinations thereof. The license is (i) non-exclusive with respect to the enoblituzumab product, and (ii) exclusive with regard to MGA012.

Unless prohibited by applicable laws and regulations, which include all international, national, federal, state, regional, provincial, municipal and local government laws, rules, and regulations that apply to either us or MacroGenics or to the conduct of the collaboration under this agreement (including Good Manufacturing Practice, Good Clinical Practices, General Biological Products Standards, and the laws, rules and regulations of the International Conference on Harmonisation, the United States, China, Hong Kong, Macau, and Taiwan, each as may be then in effect, as applicable and amended from time to time), we will co-own all clinical data generated pursuant to this agreement in any clinical trial conducted solely in Greater China, and, to the extent that such joint ownership is not legally permitted, MacroGenics will be the sole and exclusive owner of such clinical data. MacroGenics will solely and exclusively own all other clinical data generated pursuant to this agreement. We are not aware of any applicable laws or regulations that would prohibit us from jointly owning such clinical data and, to our knowledge, we currently qualify for such joint ownership with MacroGenics under this agreement.

Pursuant to this agreement, we paid MacroGenics an upfront payment of US$15.0 million. We also agreed to pay MacroGenics development and regulatory milestone fees of up to US$135.0 million and tiered double-digit royalties (ranging from mid-teens to twenty percent) based on annual net sales in the territories. As of the date of this annual report, no milestone payments or royalties are due under this agreement.

We are responsible for, and must use commercially reasonable efforts, to develop and commercialize the enoblituzumab product (which includes the enoblituzumab product in combination with MGA012) in Greater China. This includes conducting all clinical studies required for approval, participating in a planned, global Phase 3 trial (or another mutually agreeable global clinical trial) of the enoblituzumab combination product, the conduct of at least two Phase 2 or Phase 3 trials each targeting B7-H3 expressing patient populations, and submissions to regulatory authorities in Greater China. MacroGenics is responsible for, and must use commercially reasonable efforts to, develop and commercialize the enoblituzumab product (which includes the enoblituzumab product in combination with MGA012) in the rest of the world.

We are responsible for all development costs in Greater China. MacroGenics is responsible for all development costs in the rest of the world, except that we are responsible for 20% of the costs incurred in (i) activities supporting global clinical trials in which we participate, (ii) certain CMC activities for material intended to be used in clinical trials in Greater China, and (iii) companion diagnostic development and validation for indications being studied in Greater China.

Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect, on a country-by-country and region-by-region basis, until the later of (i) the twelfth (12th) anniversary of the first commercial sale of an enoblituzumab product in such country or region, (ii) the expiration of the last-to-expire MacroGenics patent licensed under this agreement, which will occur in October 2036, and (iii) the expiration of the latest data exclusivity period for the enoblituzumab product in such country or region. Since there is currently no data exclusivity protection period in China, Hong Kong, Macau or Taiwan, this agreement will remain in effect until the later of clauses (i) and (ii). This agreement may be terminated by either party for the other party's uncured material breach, safety reasons or force majeure. In addition, we have the right to terminate the agreement for convenience at any time after a certain specified time period upon advance notice to MacroGenics. MacroGenics has the right to terminate the agreement if we challenge its patents. To the extent that we terminate for convenience or MacroGenics terminates for our material breach, patent challenge or safety reasons, all licenses and rights granted by MacroGenics to us will automatically terminate and the licenses and rights granted by us to MacroGenics will survive and automatically become exclusive and worldwide. To the extent that we terminate for MacroGenics' material breach or safety reasons, among other things, all licenses and rights granted by MacroGenics to us will automatically terminate. The licenses and rights granted by us to MacroGenics will also automatically terminate to the extent we terminate for MacroGenics' material breach. To the extent we terminate for safety reasons, such licenses and rights will terminate only with respect to the licensed territory and will otherwise survive outside the licensed territory.

Other In-Licensing Arrangements

In November 2018, we entered into a license and collaboration agreement with MorphoSys for MorphoSys's proprietary antibody (MOR210/TJ210) directed against C5aR (the "C5aR Agreement"). Under this agreement, MorphoSys granted to us an exclusive, royalty-bearing license to explore, develop and commercialize MOR210/TJ210 in Greater China and South Korea. I-Mab will perform and fund all global development activities related to the development of MOR210/TJ210 in Greater China and South Korea, including all relevant clinical trials (including in the U.S. and China) and all development activities required for IND filing in the US as well as CMC development of manufacturing processes. As of the date of this annual report, we have made an upfront payment of US$3.5 million to MorphoSys and no milestone payments or royalties are due under this agreement. MorphoSys retains rights in respect of development and commercialization of MOR210/TJ210 in the rest of the world. Additionally, MorphoSys maintains the right to conduct activities in Greater China and South Korea that enable MorphoSys to exploit MOR210/TJ210 outside of those countries. Pursuant to the C5aR Agreement, we are required to use commercially reasonable efforts as we develop and commercialize MOR210/TJ210 in Greater China and South Korea. This agreement may be terminated by either party for the other party's uncured material breach, bankruptcy or insolvency. In addition, we have the right to terminate the agreement for convenience at any time after a certain specified time period upon a notice period that varies based upon the stage of development and for safety reasons. MorphoSys has the right to terminate the agreement if we challenge its patents. To the extent that we terminate for convenience or MorphoSys terminates for our material breach, bankruptcy, insolvency or patent challenge, among other things, all licenses and rights granted by MorphoSys to us will automatically terminate and the licenses and rights granted by us to MorphoSys will survive. In the event of such termination, in addition to other obligations, we must grant to MorphoSys an exclusive, royalty-bearing, sublicensable license under certain of our intellectual property relating to the licensed product to exploit MOR210/TJ210 in Greater China and South Korea.

B. Out-Licensing Arrangements

Licensing Agreement with ABL Bio

In July 2018, we entered into a license and collaboration agreement with ABL Bio (the "ABL Bio License"), as amended from time to time. Under the ABL Bio License, we granted to ABL Bio exclusive, worldwide (excluding Greater China, royalty-bearing rights to develop and commercialize a bispecific antibody (the "BsAb") using certain of our monoclonal antibody sequences. ABL Bio has developed expertise in the area of bispecific antibodies for cancer treatment and has developed proprietary intellectual property around the BsAb technology, and the license allows ABL Bio to further develop and commercialize the BsAb based on monoclonal antibodies licensed from us under the ABL Bio License. ABL Bio granted to us an exclusive, royalty-free, sublicensable license under its interest in the BsAb and related know-how (including improvements thereto) to exploit the licensed BsAb in Greater China.

Under the ABL Bio License, we and ABL Bio each are responsible for using commercially reasonable efforts to develop the licensed products through the completion of in vivo studies, and ABL Bio is responsible for using commercially reasonable efforts thereafter. We agreed to split costs fifty-fifty (50:50) with ABL Bio through the completion of in vivo studies, with ABL Bio responsible for all costs and activities following that time. ABL Bio is responsible for all development and commercialization activities, subject to our input through a joint committee comprised of an equal number of our and ABL Bio's representatives (though ABL Bio has final decision-making authority).

In consideration of the license, ABL Bio paid us an upfront fee of US$2.5 million and agrees to make milestone payments in the aggregate amount of US$97.5 million conditioned upon achieving certain clinical development and sales milestones. Further, ABL Bio agreed to pay us royalties at mid-single-digit percentages in respect of the total annual net sales of the licensed BsAb product.

In addition, ABL Bio granted to us an exclusive, royalty-free, sublicensable license to use its BsAb technology solely to exploit the licensed BsAb product for all indications in Greater China.

We also agreed that, during the term of the ABL Bio License, neither we nor ABL Bio would develop independently from the other a bispecific antibody that uses the same pair of antibodies as the bispecific antibody molecules created under the ABL Bio License.

The ABL Bio License will continue to be in effect until expiration of the last payment obligation thereunder, unless earlier terminated according to its terms. The ABL Bio License may be terminated by either party for the other party's uncured material breach or in the event that the other party challenges its patents. In addition, after a certain specified time period, ABL Bio may terminate the ABL Bio License upon a notice period that varies based upon the stage of development.

Upon expiration (but not termination) of the ABL Bio License, we and ABL Bio will each retain our respective licenses granted under the ABL Bio License. If the ABL Bio License is terminated pursuant to ABL Bio's right to terminate at will or due to ABL Bio's material breach, all rights and obligations (including all licenses granted) shall terminate and upon our request, we and ABL Bio will negotiate in good faith regarding our takeover of the exploitation of the BsAb product outside of Greater China in exchange for reasonable compensation. Such negotiation will include, among other things, ABL Bio's assignment of assets related to the licensed BsAb product and the continuation of the licenses granted to us under the ABL Bio License.

Licensing Agreement with CSPC Entity

In December 2018, we entered into a product development agreement (the "CSPC Agreement") with an entity controlled by CSPC Pharmaceutical Group Limited (01093.HK) ("CSPC entity"). Under the CSPC Agreement, we granted to CSPC entity exclusive, non-transferable, non-irrevocable and sublicensable rights under our patent rights in China to develop and commercialize TJ103 for treating type 2 diabetes mellitus and any other potential therapeutic applications. CSPC entity's right to sublicense is conditioned on our prior written consent, which we cannot unreasonably withhold, other than sublicense to CSPC entity's affiliates. CSPC entity is a comprehensive pharmaceutical and drug manufacturing company, with an increasing focus on its research and development of new products focusing the therapeutic area of oncology, among others.

Under the CSPC Agreement, CSPC entity is responsible for using commercially reasonable efforts to develop, obtain market approval and commercialize the licensed products, while we are responsible for using commercially reasonable efforts to transfer the manufacturing technology of the licensed products to CSPC entity and assist or guide CSPC entity in the continued optimization of such manufacturing technology thereafter. CSPC entity has final decision-making authority with respect to product development (though the research plan shall be jointly developed by both parties and any changes to the plan shall be discussed and approved by the joint development committee) and commercialization.

We also agreed that, during the term of the CSPC Agreement, we shall not develop, either for ourselves or for third parties, any other hyFc platform technology-based long-acting recombinant GLP-1 Fc fusion proteins that may be in a competitive position with TJ103.

In consideration of the license, CSPC entity paid us an upfront fee of RMB15.0 million and agreed to make milestone payments in an aggregate amount of RMB135.0 million conditioned upon achieving certain clinical development and regulatory approval milestones, including completion of Phase 2 and Phase 3 clinical studies and obtaining NDA approval or market approval. Further, we will also be entitled to tiered royalties ranging from mid-single-digit percentages to 10 percent in respect of the total annual net sales of the products after their commercialization in China. The royalty term shall terminate at the later of: (i) the expiry date of the underlying patents of the licensed products with application numbers 201410851771.1 and 201580071643.8 (final grant of rights requested relating to GLP-1) in China, whichever is later; and (ii) the ten-year anniversary of the initial commercialization of the product developed under the CSPC Agreement. We expect any patents that may issue under the aforementioned patent application numbers 201410851771.1 and 201580071643.8 will expire between 2034 and 2035, before taking into account any extension that may be obtained through patent term extensions or adjustments, or term reduction due to filing of terminal disclaimers.

Unless terminated earlier in accordance with the terms thereof, the CSPC Agreement will remain in effect until the termination of the royalty term. This agreement may be terminated by either party for the other party's uncured material breach, bankruptcy or insolvency or force majeure. We have the right to terminate the agreement if CSPC entity fails to use commercially reasonable efforts to obtain regulatory approvals for commercializing the licensed product in the period stipulated by its board of directors due to its own fault or if CSPC entity ceases to pursue clinical development or product registration as determined by its board of directors. CSPC entity has the right to terminate the agreement if we fail to resolve certain intellectual property disputes relating to TJ103 within six months after signing.

During the term of the CSPC Agreement, CSPC entity shall have exclusive, royalty-free rights in China to any work product generated by us, and be responsible for any patent application and maintenance costs of such work product. CSPC entity shall have all rights to any work product generated by itself under the CSPC Agreement.

Other Out-Licensing Arrangements

In April 2017, our subsidiary I-Mab Shanghai entered into a technology transfer agreement (the "HDYM License") with Ningbo Hou De Yi Min Information Technology Co., Ltd. ("HDYM") and Hangzhou HealSun Biopharm Co., Ltd. ("HealSun") with respect to PD-L1 humanized monoclonal antibodies. HealSun is a portfolio company of Lepu Biotech (□□□□). Under the HDYM License, I-Mab Shanghai agreed to grant to HDYM exclusive (even to I-Mab Shanghai itself), worldwide and sublicensable rights to develop, manufacture, have manufactured, use, sell, have sold, import, or otherwise exploit certain PD-L1 related patents, patent applications, know-hows, data and information of I-Mab Shanghai, relevant cell lines as well as any PD-L1 monoclonal antibody arising from such cell lines for the treatment of diseases. Further, I-Mab Shanghai and its cooperative party HealSun agreed to provide subsequent research and development services on such intellectual property to HDYM, including the selection and examination of innovative PD-L1 humanized monoclonal antibodies, cultivation and selection of stable cell lines, establishment of cell bank, research and development of manufacturing processes and preparation of samples, toxicological and pharmacological testing, pre-clinical pharmaceutical experiment report drafting, and application for and registration of clinical trials. If any party breaches the agreement and fails to cure, the non-breaching parties may terminate this agreement. In addition, in the event that the development of the licensed product encounters insurmountable technical difficulties, this agreement may be terminated by mutual agreement of all parties. To the extent that the agreement is terminated for HDYM's breach, all licenses and rights granted by us to HDYM will automatically terminate and be re-assigned to us. To the extent that the agreement is terminated due to material difficulty, HDYM will have all rights to dispose of any development data and technology held by HealSun and us under this agreement and neither HealSun or us may use such development data and technology without HDYM's consent.

In March 2020, we entered into a strategic partnership with Kalbe Genexine Biologics ("KG"), a joint venture of Kalbe Farma Tbk ("Kalbe") and Genexine. Under the terms of the agreement, KG will receive a right of first negotiation for an exclusive license for the commercialization of two I-Mab-discovered product candidates: TJD5, a highly differentiated anti-CD73 antibody in Phase 1 development for advanced solid tumors, and an I-Mab product candidate to be agreed upon by both parties. With the agreement, KG will have a right of first negotiation for exclusive rights to commercialize these two product candidates in the ASEAN (Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam) and MENA (Algeria, Bahrain, Djibouti, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Libya, Malta, Morocco, Oman, Qatar, Saudi Arabia, Syria, Tunisia, United Arab Emirates, Palestine, and Yemen) regions, as well as Sri Lanka. If and when we and KG enter into the definitive licensing agreement for TJD5, we will be eligible to receive from KG an aggregate amount of up to approximately $340 million, including an upfront payment and subsequent payments conditional upon achieving certain development and commercial milestones. KG will pay us tiered royalties in the low to mid-teen percentages on net sales from the ASEAN and MENA regions, as well as Sri Lanka.

C. Collaboration Arrangements

Collaboration Agreement with Everest

In January 2018, we entered into a collaboration agreement with Everest whereby both parties agreed to collaborate to co-develop MorphoSys' proprietary CD38 antibody (TJ202 or the CD38 product) and commercialize the CD38 product in Greater China for all indications in hematologic oncology.

Under the agreement, we and Everest established a joint steering committee with equal representation from each party to, among other things, coordinate and oversee the development and commercialization regarding the CD38 product. All decisions of the joint steering committee shall be made by unanimous vote. We have final decision-making authority on matters related to the development of the CD38 product, provided that Everest has the right to opt out of sharing of development cost increases for new work or clinical trials added to the initial development plan and budget. Everest has final decision-making authority on matters related to the commercialization of the CD38 product.

Under the agreement, we are primarily responsible for using commercially reasonable efforts to carry out the development, manufacture and supply of the CD38 product, and we are also responsible for seeking regulatory approval of the CD38 product. Everest is primarily responsible for sharing with us, by the proportion of 75% for Everest and 25% for us, the development costs of the CD38 product, including payments due to MorphoSys under the License and Collaboration Agreement, dated November 30, 2017, between us and MorphoSys. We are not required to make any upfront, milestone or royalty payments to Everest under this agreement.

The joint steering committee will decide whether we or Everest shall be responsible for conducting the commercialization of the CD38 product pursuant to the commercialization plan approved by the committee. If Everest is selected to be responsible for commercialization, we shall grant an exclusive royalty-free license to Everest to commercialize the CD38 product for all indications in hematologic oncology in Greater China.

We and Everest will share the CD38 product's profit and loss in proportion to the costs that each of us incur in developing the product. The parties will also split out-license revenue according to the proportion of development costs incurred, with us getting an additional five percent (5%) share and Everest receiving five percent (5%) less. Everest cannot share in any profit from the commercialization of CD38 product until it has fulfilled its payment obligations under this agreement.

If we want to develop the CD38 product for indications other than hematologic oncology in Greater China, we must first provide notice of such intent to Everest and, at their election, negotiate with them in good faith regarding such rights.

The agreement shall continue as effective so long as we and Everest continue to develop the CD38 product for any indications in hematologic oncology in Greater China. This agreement may be terminated by either party for the other party's uncured material breach, bankruptcy or insolvency. In addition, if we fail to initiate or conduct any material development activities in relation to any therapeutic, prophylactic or palliative CD38 product for a period of three months (other than as a result of a regulatory requirement), Everest will have the right to terminate this agreement.

Upon any termination of the agreement, the terminating party has the right to continue the development and commercialization of CD38 product. If Everest is the rightful terminating party, we shall reasonably cooperate with Everest to, among other things, (i) assign the MorphoSys license to Everest (subject to the terms and conditions of such license); (ii) grant to Everest an exclusive license to all intellectual property rights we own or control to further develop, manufacture, and commercialize the CD38 product; and (iii) transfer the development, manufacture and commercialization of the CD38 product to Everest, including providing reasonable technical assistance and assigning to Everest any agreement with third party vendors pertaining to the development, manufacture and commercialization of the CD38 product. In addition, the terminating party that elects to continue the development and commercialization of the CD38 product shall be solely responsible for the cost and expense of such development and commercialization after termination. In the event that such continuing party successfully develops and commercializes the CD38 product, it shall pay to the other party a percentage of the product profit and out-license income generated therefrom in accordance with the terms of this agreement.

On November 4, 2019, we and Everest Medicines Limited, or Everest, terminated the collaboration agreement (including all the supplements and amendments thereto) with respect to the co-development and commercialization of TJ202 in Greater China. Upon the termination, Everest will not retain any rights or entitlements to develop or commercialize TJ202 or any economic interest in its commercialization. All intellectual property rights in respect of TJ202 arising from its development under the collaboration agreement are vested and owned by us, and we hold all intellectual property rights and have maximum flexibility to further develop, manufacture and commercialize TJ202 in Greater China. In consideration of the above arrangements, we issued a total value of US$37.0 million of ordinary shares (the "CPP Shares") to Everest, representing Everest's historical contribution to our collaboration and the associated time cost. The CPP Shares were issued concurrently with, and subject to, the completion of our initial public offering within 180 days from termination of the collaboration agreement, at a per share price equal to the initial public offering price adjusted to reflect the ADS-to-ordinary share ratio. The total value of US$37.0 million was calculated based on the sum of (1) US$33.7 million, which equals cumulative paid-in contributions historically made by Everest under the collaboration agreement; and (2) a negotiated US$3.3 million time cost of the foregoing historical contribution in light of our exclusive rights over the commercialization of TJ202 after this termination. At the initial offering price of US$14.00 per ADS (or US$6.09 per ordinary share), Everest was issued 6,078,571 ordinary shares and became a minority shareholder of our company upon the completion of our initial public offering. Our issuance of ordinary shares to Everest is being made pursuant to an exemption from registration with the U.S. Securities and Exchange Commission under Regulation S of the U.S. Securities Act of 1933, as amended, or the Securities Act. Everest has agreed not to, directly or indirectly, sell, transfer or dispose of any CPP Shares for a period of 180 days after the date of the prospectus of our initial public offering.

Other Collaboration Arrangements

In July 2018, we entered into a collaboration agreement with ABL Bio whereby both parties agreed to collaborate to develop three PD-L1-based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include the PRC, Hong Kong, Macau, Taiwan and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement. This agreement may be terminated by either party for the other party's uncured material breach or in the event that the other party challenges its patents. Also, if a party encounters insurmountable technical difficulties and risks, which cannot be resolved by such party within a certain period thereafter despite all reasonable efforts, such party will have the right to terminate this agreement and will no longer have the right to develop the licensed product. As of the date of this annual report, ABL Bio has paid us$2.5 million upfront payment to us.

In September 2018, we entered into a collaboration and platform technology license agreement with WuXi Biologics Ireland Limited ("WuXi Biologics"), whereby both parties agreed to collaborate in the research and development of at least three bispecific antibodies for our company to commercialize them worldwide. Such bispecific antibodies shall be created using our proprietary monoclonal antibodies and WuXi Biologics' proprietary WuXiBody platform technology for generating bispecific antibodies, shall be developed and manufactured through the exclusive service of WuXi Biologics. This agreement may be terminated by either party for the other party's uncured material breach, bankruptcy or insolvency. WuXi Biologics has the right to terminate this agreement if we challenge its patents. We have the right to terminate this agreement if we decide to end the development and commercialization of the licensed product in the licensed territory due to scientific, technical, or commercial reasons. As of the date of this annual report, we have made an up-front payment of US$0.9 million to Wuxi Biologics and no milestone payments or royalties are due under this agreement. In April 2019, we extended our existing partnership with WuXi Biologics (Shanghai) Co., Ltd. ("WuXi Biologics Shanghai"). We entered into a long-term, strategic collaboration agreement with WuXi Biologics Shanghai to facilitate the CMC development and GMP manufacturing of both clinical and commercial supplies of certain of our monoclonal and bispecific antibodies and fusion products, leveraging WuXi Biologics' and its affiliates' expertise in this area and supporting our pre-existing collaboration and platform technology license agreement with WuXi Biologics.

In November 2018, we entered into collaboration agreements with TRACON Pharmaceuticals, Inc. ("TRACON"), whereby we and TRACON agreed to (1) collaborate to co-develop our proprietary CD73 antibody, TJD5 and (2) collaborate to co-develop up to five BsAbs. Both agreements may be terminated by either party for the other party's uncured material breach, bankruptcy or insolvency or for safety reasons. In addition, the agreement in respect of TJD5 may be terminated by us: (i) for convenience within a certain period upon completing different clinical stages subject to certain payments and royalties, based on the clinical stage, that would be owed to TRACON upon the exercise of such termination for convenience; (ii) in the event that TRACON causes the Phase 1 study timeline to be delayed beyond the agreed extension periods; or (iii) if we decide to end the development of the collaborative product prior to its first commercial sale. Further, prior to the first commercial sale, TRACON may deem this agreement to be terminated by us if it reasonably believes that we have discontinued all meaningful development of the collaborative product for at least 12 months and certain other conditions are met. As of the date of this annual report, no payments or royalties are due under this agreement. Additionally, in March 2019, we agreed with TRACON and F. Hoffmann-La Roche Ltd ("Roche") on a clinical supply agreement for Roche to supply atezolizumab for use in clinical studies under the collaboration agreement with TRACON.

Competition

Our industry is highly competitive and subject to rapid and significant change. While we believe that our management's research, development and commercialization experience provide us with competitive advantages, we face competition from global and China-based biopharmaceutical companies, including specialty pharmaceutical companies, generic drug companies, biologics drug companies, academic institutions, government agencies and research institutions.

For our Global Portfolio drug candidates, we expect to face competition from a broad range of global and local pharmaceutical companies. Many of our competitors have significantly greater financial, technical and human resources than we have, and mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer or less costly than our current or future drug candidates, or obtain regulatory approval for their products more rapidly than we may obtain approval for our drug candidates.

Intellectual Property

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for our drug candidates and other commercially important products, technologies, inventions and know-how, as well as on our ability to defend and enforce our patents including any patent that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of other parties.

As of December 31, 2019, our owned patent portfolio consist of (i) five issued patents, including two issued in the U.S., one issued in the PRC and two issued in Korea; and (ii) 166 pending patent applications, including 17 PCT patent applications, 12 U.S. patent applications, 15 PRC patent applications and 122 patent applications in other jurisdictions. Our owned patents and patent applications primarily relate to the drug candidates in our Global Portfolio. Furthermore, as of December 31, 2019, we in-licensed the Greater China and Korea rights relating to (i) 20 issued patents, including 12 issued in the PRC, one issued in Korea, five issued in Hong Kong and two issued in Taiwan; and (ii) 27 pending patent applications, including two PCT patent applications, 12 PRC patent applications, seven Hong Kong patent applications, three Taiwan patent applications and three Korean patent application. The in-licensed patents and patent applications primarily relate to TJ202, TJ101, TJ301, enoblituzumab and TJ107.

TJ202	As of December 31, 2019, we exclusively licensed from MorphoSys eight issued patents (including five issued in the PRC, two issued in Hong Kong and one issued in Taiwan) and six pending patent applications (including three in the PRC and three in Hong Kong) relating to TJ202. The licensed patents include composition of matter patents in China, Hong Kong and Taiwan. The patents (including patent applications if issued) in this portfolio are expected to expire between 2025 and 2037, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
TJ101	As of December 31, 2019, we (i) exclusively licensed from Genexine two pending PRC patent applications directly relating to TJ101 and (ii) exclusively licensed from Genexine three issued patents in the PRC relating to a hyFc platform that develops TJ101. The licensed patents include composition of matter patents in China. The patents (including patent applications if issued) in this portfolio are expected to expire between 2028 and 2037, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
TJ301	As of December 31, 2019, we exclusively licensed from Ferring two issued patents in the PRC and Korea relating to TJ301 and four patient applications in the PRC and Korea relating to TJ301. The licensed patents include composition of matter patents. These patents are expected to expire between 2027 and 2035, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
Enoblituzumab	As of December 31, 2019, we exclusively licensed from MacroGenics six issued patents (including two issued in the PRC, three issued in Hong Kong and one issued in Taiwan) and eight pending patent applications (including two in the PRC, four in Hong Kong and two in Taiwan) relating to enoblituzumab. The patents (including patent applications if issued) in this portfolio are expected to expire between 2023 and 2036, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
TJ107	As of December 31, 2019, we (i) exclusively licensed from Genexine one pending PRC patent application directly relating to TJ107 and (ii) exclusively license from Genexine three issued patents in the PRC relating to a hyFc platform that develops TJ107. The patents (including patent applications if issued) in this portfolio are expected to expire between 2028 and 2036, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.

TJM2	As of December 31, 2019, we owned one PCT patent application that relates to TJM2 and it has entered national phases in China, the United States and 22 other jurisdictions. We expect that any patent that may issue under this application will expire in 2037, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
TJC4	As of December 31, 2019, we owned two PCT patent applications and one of them has entered national phases in the PRC, the United States and 22 other jurisdictions. We expect that any patents that may issue under these applications will expire between 2037 and 2039, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.
TJD5	As of December 31, 2019, we owned one PCT patent application and it has entered national phases in the PRC, the United States, and 23 other jurisdictions. We expect that any patent that may issue under this application will expire in 2038, before taking into account any extension that may be obtained through patent term extension or adjustment, or term reduction due to filing of terminal disclaimers.

The term of a patent depends upon the laws of the country in which it is issued. In most jurisdictions, a patent term is 20 years from the earliest filing date of a non-provisional patent application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to inventions are effective for twenty years, and utility models and designs are effective for ten years from the date of application. There are no patent term adjustments or patent term extensions available in the PRC for issued patents.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our partners, collaborators, scientific advisors, employees, consultants and other third parties, and invention assignment agreements with our consultants and employees. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. If any of the partners, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements or otherwise discloses our proprietary information, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result.

Additionally, as of December 31, 2019, we had (i) three registered trademarks in Hong Kong, four registered trademarks in the PRC, 16 trademark applications in the PRC and six trademark applications in the United States; (ii) nine domain names in the PRC, including *www.i-mabbiopharma.com* , four domain names in Hong Kong and two domain names in the United States and (iii) 12 software copyrights in the PRC.

For more information on these and other risks related to intellectual property, see “Item 3. Key Information—D. Risk Factors—Risks Related to Our Intellectual Property.”

Enterprise Social Responsibility

Having a positive impact on the communities in which we operate is an integral part of our business, and we maintain that as our core values. We aim to make a significant positive contribution to society around the world, through the transformational medicines that we research, develop, manufacture and sell. We are committed to reflecting ethical, social and environmental concerns in our business decisions. Our products must improve people’s lives and ensure a profitable and sustainable future for our business. We also understand that stakeholders, including employees, need to be reassured of the sound ethical basis for our business.

Our focus on making a contribution to improving healthcare and alleviating suffering is evidenced by our efforts on coping with the COVID-19 outbreak. We are initiating the development of TJM2 to treat cytokine storm in severe and critically ill patients caused by COVID-19. Cytokine storm is characterized by surge of high levels of circulating inflammatory cytokines and is an overreaction of the immune system in patients infected with SARS-CoV-2. Recent studies revealed that high levels of GM-CSF, along with a few other cytokines, are critically associated with severe clinical complications in COVID-19 patients. Research data provide the rationale to use TJM2 as a potential treatment for cytokine storm associated with COVID-19, because the antibody effectively neutralizes circulating GM-CSF to control acute inflammatory responses, and it may also exhibit potential advantages over conventional IL-6 antibodies. We have received IND clearance from the FDA, and our IND application is under review in South Korea. Our study will commence initially in the United States with plans to expand into other hardest-hit countries. In addition, at the peak of the COVID-19 outbreak, we donated personal protective equipment and funds worth a total of RMB800 thousand to support medical personnel and hospitals in Wuhan. We also donated US$50 thousand to BayHelix, a non-profit organization focused on global life sciences and healthcare community, for the purpose of supporting relief of COVID-19 in the United States. Meanwhile, we took the health and safety of our employees as our top priority and have implemented company-wide self-protection policies for employees to either working remotely or onsite with protective masks and sanitization.

Regulation

This section sets forth a summary of the most significant rules and regulations that affect our business activities in China and the United States.

PRC Regulation

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the principal PRC laws, rules and regulations that we believe are relevant to our business and operations.

Regulations on Company Establishment and Foreign Investment

Company Law

The establishment, operation and management of companies in China is governed by the PRC Company Law, which was passed by the Standing Committee of the National People's Congress (the "NPC"), on December 29, 1993 and came into effect on July 1, 1994 and was latest revised or amended on October 26, 2018, respectively. In light of the PRC Company Law, companies established in the PRC are either in the form of a limited liability company or a joint stock company. The PRC Company Law applies to both PRC domestic companies and foreign-invested companies, unless otherwise provided in the relevant foreign investment laws and regulations.

Foreign Investment Law

On March 15, 2019, the NPC approved the PRC Foreign Investment Law, which became effective on January 1, 2020 and replaced the three old rules on foreign investment in China, namely, the PRC Equity Joint Venture Law, the PRC Cooperation Joint Venture Law and the Wholly Foreign-Owned Enterprise Law, together with their implementation rules and ancillary regulations. The Foreign Investment Law establishes the basic framework for the access to, and the promotion, protection and administration of foreign investments in view of investment protection and fair competition. According to the Foreign Investment Law, "foreign investment" refer to investment activities directly or indirectly conducted by one or more natural persons, business entities, or other organizations of a foreign country (collectively referred to as "foreign investor") within China, and "investment activities" include the following activities: (i) a foreign investor, individually or together with other investors, establishes a foreign-invested enterprise within China; (ii) a foreign investor acquires stock shares, equity shares, shares in assets, or other similar rights and interests of an enterprise within China; (iii) a foreign investor, individually or together with other investors, invests in a new construction project within China; and (iv) investments in other means as provided by the laws, administrative regulations or the State Council.

Regulations Relating to Foreign Investment

On December 26, 2019, the State Council promulgated the Implementation Rules to the Foreign Investment Law, which became effective on January 1, 2020. The implementation rules further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

Furthermore, PRC-based investments by foreign investors shall also be regulated by the Catalogue for the Guidance of Foreign Investment Industries (2017 Revision) issued on June 28, 2017 and effective from July 28, 2017, and the Special Management Measures (Negative List) for the Access of Foreign Investment (2018) issued on June 28, 2018 and effective from July 28, 2018. According to the aforesaid catalogue and management measures, foreign-invested industries fall into four categories, namely, "encouraged," "permitted," "restricted" and "prohibited," and certain ownership requirements, requirements for senior executives and other special management measures shall apply to foreign investors with regard to the access of foreign investments in certain categories. The Special Management Measures (Negative List) for the Access of Foreign Investment (2019) and the Catalogue of Industries for Encouraging Foreign Investment (2019 Version), which became effective on July 30, 2019, further reduce restrictions on the foreign investment and replaced the Special Management Measures (Negative List) for the Access of Foreign Investment (2018).

On December 30, 2019, the MOFCOM and SAMR jointly promulgated Measures for Information Reporting on Foreign Investment, which became effective on January 1, 2020. Pursuant to the Measures for Information Reporting on Foreign Investment, where a foreign investor carries out investment activities in China directly or indirectly, the foreign investor or the foreign-invested enterprise shall submit the investment information to the competent commerce department.

M&A Rules

According to the Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors jointly issued by the MOFCOM, the State Assets Supervision and Administration Commission of the State Council, the State Administration of Taxation (the "SAT"), the State Administration for Industry and Commerce (now known as the State Administration for Market Regulation), the China Securities Regulatory Commission and the State Administration of Foreign Exchange (the "SAFE"), on August 8, 2006 and amended by the MOFCOM on June 22, 2009, among other things, (i) the purchase of an equity interest or subscription to the increase in the registered capital of non-foreign-invested enterprises, (ii) the establishment of foreign-invested enterprises to purchase and operate the assets of non-foreign-invested enterprises, or (iii) the purchase of the assets of non-foreign-invested enterprises and the use of such assets to establish foreign-invested enterprises to operate such assets, in each case, by foreign investors shall be subject to the Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors. Particularly, application shall be made for examination and approval of the acquisition of any company in China affiliating to a domestic company, enterprise or natural person, which is made in the name of an oversea company established or controlled by such domestic company, enterprise or natural person.

PRC Drug Regulation

The Drug Administration Law of the PRC promulgated by the Standing Committee of the NPC on September 20, 1984 and effective from July 1, 1985 and amended on February 28, 2001, December 28, 2013, April 24, 2015 and August 26, 2019, respectively, and the Implementing Measures of the Drug Administration Law promulgated by the State Council on August 4, 2002 and effective from September 15, 2002 and amended on February 6, 2016 and March 2, 2019, respectively, have jointly established the legal framework for the administration of pharmaceutical products in China, including the research, development and manufacturing of new drugs. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products, which regulates and provides for a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. The Implementing Measures of the Drug Administration Law, on the other hand, provides detailed implementation regulations for the Drug Administration Law.

The newly amended Drug Administration Law, which became effective on December 1, 2019, brought a series of changes to the drug supervision and administration system, including but not limited to the clarification of the drug marketing authorization holder system, pursuant to which the marketing authorization holder shall assume responsibilities for non-clinical studies, clinical trials, manufacturing and marketing, post-marketing studies, monitoring, reporting and handling of adverse reactions of the drug. The amendment also stipulates that the State supports the innovation of drugs with clinical value and specific or special effects on human diseases, encourages the development of drugs with new therapeutic mechanisms and have multi-targeted, systematic regulatory and intervention functions on human body and promotes the technological advancement of drugs.

We are required to follow the above-mentioned regulations in respect of our non-clinical research, clinical trials and production of new drugs.

Regulatory Authorities and Recent Government Reorganization

Pharmaceutical products and medical devices and equipment in China are monitored and supervised on a national scale by the NMPA (formerly known as the China Food and Drug Administration, or the "CFDA"), while the local provincial medical products administrative authorities are responsible for the supervision and administration of drugs within their respective administrative regions. Pursuant to the Decision of the First Session of the Thirteenth National People's Congress on the State Council Institutional Reform Proposal made by the NPC on March 17, 2018, the NMPA is no longer an independent agency and its duties shall be performed by the newly established State Administration for Market Regulation, into which the various agencies responsible for, among other areas, consumer protection, advertising, anticorruption, pricing, fair competition and intellectual property, have been merged.

The NMPA is still the chief drug regulatory agency and implements the same laws, regulations, rules, and guidelines as the CFDA, and the NMPA regulates almost all of the key stages of the life cycle of pharmaceutical products, including non-clinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e., post-marketing safety reporting obligations). The Center for Drug Evaluation (the "CDE"), which remains under the NMPA, conducts the technical evaluation of each drug and biologic application for safety and effectiveness.

Formed on March 2018, the National Health Commission (the "NHC") (formerly known as the Ministry of Health ("MOH") and the National Health and Family Planning Commission ("NHFPC")) is China's chief healthcare regulator. It is primarily responsible for overseeing the operation of medical institutions, which also serve as clinical trial sites, and regulating the licensure of hospitals and medical personnel. The NHC plays a significant role in drug reimbursement. Furthermore, the NHC and its local counterparts at or below provincial-level local governments also oversee and organize public medical institutions' centralized bidding and procurement process for pharmaceutical products, which is the chief means through which public hospitals and their internal pharmacies acquire drugs.

Also, as part of its 2018 reorganization, the PRC government formed a new State Medical Insurance Bureau (the "SMIB"), which focuses on regulating reimbursement under the state-sponsored insurance plans.

Non-Clinical Research

On August 4, 2003, the NMPA promulgated the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory, which was revised on July 27, 2017, to improve the quality of non-clinical research, and began to conduct the Good Laboratories Practice. Pursuant to the Circular on Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory issued by the NMPA on April 16, 2007, the NMPA is responsible for the certification of non-clinical research institutions nationwide and local provincial medical products administrative authorities is in charge of the daily supervision of non-clinical research institution. The NMPA decides whether an institution is qualified for undertaking pharmaceutical non-clinical research by evaluating such institution's organizational administration, its research personnel, its equipment and facilities, and its operation and management of non-clinical pharmaceutical projects. A Good Laboratory Practice Certification will be issued by the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA's website.

Pursuant to the Regulations for the Administration of Affairs Concerning Experimental Animals promulgated by the State Science and Technology Commission on November 14, 1988 and amended on January 8, 2011, July 18, 2013 and March 1, 2017, respectively, by the State Council, the Administrative Measures on Good Practice of Experimental Animals jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) promulgated by the State Science and Technology Commission and other regulatory authorities on December 5, 2001, a Certificate for Use of Laboratory Animals is required for performing experimentation on animals. Applicants must satisfy the following conditions:

- Laboratory animals must be qualified and sourced from institutions that have Certificates for Production of Laboratory Animals;
- The environment and facilities for the animals' living and propagating must meet national requirements;
- The animals' feed and water must meet national requirements;
- The animals' feeding and experimentation must be conducted by professionals, specialized and skilled workers, or other trained personnel;
- The management systems must be effective and efficient; and
- The applicable entity must follow other requirements as stipulated by Chinese laws and regulations.

Pre-clinical and Clinical Development

The NMPA requires supporting pre-clinical data for the registration applications for imported and domestic drugs. Pre-clinical work, including pharmacology and toxicology studies, must satisfy the requirements of the Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory. No approval is required from the NMPA to conduct pre-clinical studies.

Clinical Trials and Registration of New Drugs

Categories—

Pursuant to the Administrative Measures for Drug Registration promulgated by the NMPA on July 10, 2007 and effective from October 1, 2007, which provides the standards and requirements for clinical trials and drug registration applications, drug registration applications are divided into three different types, namely, New Drug Application, Generic Drug Application, and Imported Drug Application. Drugs are categorized based on their working mechanism, including chemical medicine, biological product or traditional Chinese or natural medicine. On January 22, 2020, the SAMR promulgated the new Administrative Measures for Drug Registration (the "New Measures for Registration"), which will become effective from July 1, 2020. According to the New Measures for Registration, drug registration applications are divided into three different types, namely, traditional Chinese medicine, chemical medicine, and biological products, and each type is further divdied into several sub-types. The category and corresponding application requirements will be promulgated by the NMPA based on a drug's working mechanism, degree of innovation, and the need of review management. As provided in the New Administrative Measures for Registration, the Drug Administration Law and Implementing Measures of the Drug Administration Law, upon completion of non-clinical research, clinical trials shall be conducted for the application of new drug registration.

Clinical Trial Approval—

All clinical trials conducted in China for new drug development must be approved and conducted at pharmaceutical clinical trial institution which shall be under filing administration. For imported drugs, proof of foreign approval is required prior to the trial, unless the drug has never been approved anywhere in the world. In addition to a standalone trial in China, imported drug applicants may establish a site in China as part of an international multi-center trial (the "IMCT") at the outset of the global trial. Domestically manufactured drugs are not subject to foreign approval requirements, and by contrast to prior practice, the NMPA has recently decided to also permit such drugs to be tested and developed through an IMCT.

In addition, the NMPA has adopted a notification system for clinical trials of new drugs. Pursuant to the newly amended Drug Administration Law and the New Measures for Registration, effective from July 1, 2020, clinical trials may be commenced as long as the applicant has not received any objections from the CDE within 60 business days of application filing after acceptance of the application, and such applaction will be deemed as approved. Bioequivalence test may only be conducted after the completion of record-filing on the website of the CDE. All clinical trials that have been approved but not initiated within three years since the execution of the Informed Consent Forms will become invalid. As provided in the New Measures for Registration, a new application of clinical trial must be submitted if an applicant of an approved clinical trial decides to add new indications or drug combinations into the trial.

Drug Clinical Trial Registration

Pursuant to the Administrative Measures for Drug Registration, upon obtaining the clinical trial approval and before commencing a clinical trial, the applicant shall file a registration with the NMPA containing various details of the clinical trial, including the clinical study protocol, the name of the principal researcher of the leading institution, names of participating institutions and researchers, an approval letter from the ethics committee, and a sample of the Informed Consent Form, with a copy sent to the competent provincial administration departments where the trial institutions will be located. On September 6, 2013, the NMPA released the Announcement on Drug Clinical Trial Information Platform, providing that for all clinical trials approved by the NMPA and conducted in China, instead of the aforementioned registration filed with the NMPA, clinical trial registration shall be completed and trial information shall be published through the Drug Clinical Trial Information Platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and shall complete registration of certain follow-up information before the first subject's enrollment in the trial. If approval of the foregoing pre-registration and registration is not obtained within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically expire.

Pursuant to the New Measures for Registration, effective from July 1, 2020, during the period of clinical trial, the applicant must continuously update the registration information and the trial results after completion of each clinical trial on the Drug Clinical Trial Information Platform. Applicants are responsible for the authenticity of the registration information.

Human Genetic Resources Approval—

On June 10, 1998, the Ministry of Science and Technology and the MOH jointly established the rules for protecting and utilizing human genetic resources in China. 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, Exporting Human Genetic Resources, or Taking Such Resources out of the PRC, which provides that foreign-invested sponsors that sample and collect human genetic resources in clinical trials shall be required to file with the China Human Genetic Resources Management Office through its online system. On October 26, 2017, the Ministry of Science and Technology issued the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources, which simplified the approval for sampling and collecting human genetic resources for the purpose of commercializing a drug in the PRC.

On June 10, 2019, the State Council of PRC issued the National Regulations on the Management of Human Genetic Resources, which formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to this new rule, a new notification system (as opposed to the advance approval approach originally in place) is put in place for clinical trials using China's human genetic resources at clinical institutions without involving the export of human genetic resources outside of China.

Trial Exemptions and Acceptance of Foreign Data—

The NMPA may reduce its requirements for clinical trials and data, depending on the drug and the existing data. The NMPA has granted waivers for all or part of trials and has stated that it will accept data generated abroad (even if not as part of a global study), including early phase data, that meets its requirements. On July 6, 2018, the NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (the "Guidance Principles") as one of the implementing rules for the Innovation Opinion. According to the Guidance Principles, the data of foreign clinical trials must meet the authenticity, completeness, accuracy and traceability requirements, and such data must be obtained in consistency with the relevant requirements under the Good Clinical Trial Practice (GCP) of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (the "ICH"). Clinical trial sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

The NMPA now officially permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of China to be approved in China on a conditional basis without pre-approval clinical trials being conducted in China. Specifically, in 2018, the NMPA issued the Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs, permitting drugs that have been approved within the last ten years in the United States, the European Union or Japan and that prevent or treat orphan diseases or prevent or treat serious life-threatening illnesses for which there is either no effective therapy in China or for which the foreign-approved drug would have clear clinical advantages. Applicants will be required to establish a risk mitigation plan and may be required to complete trials in China after the drug has been marketed. The CDE has developed a list of qualifying drugs that meet the foregoing criteria.

Clinical Trial Process and Good Clinical Practices—

Typically, drug clinical trials in China have four phases. Phase 1 refers to the initial clinical pharmacology and human safety evaluation studies. Phase 2 refers to the preliminary evaluation of a drug candidate's therapeutic efficacy and safety for target indication(s) in patients. Phase 3 (often the pivotal study) refers to clinical trials that further verify the drug candidate's therapeutic efficacy and safety on patients with target indication(s) and ultimately provide sufficient evidence for the review of a drug registration application. Phase 4 refers to a new drug's post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose, etc.

On August 6, 2003, the NMPA promulgated the Administration of Quality of Drug Clinical Practice (the "GCP") to improve the quality of clinical trials. Pursuant to the newly amended Drug Administrative Law, and the Regulations on the Administration of Drug Clinical Trial Institution jointly promulgated by NMPA and NHC on November 29, 2019 and effective from December 1, 2019, drug clinical trial institutions shall be under filing administration. Clinical trial institutions that only conduct analysis of biological samples related to clinical trials of drugs do not need to be filed. Pursuant to the Circular on Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory, a Good Laboratory Practice Certification will be issued by the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA's website. Pursuant to the Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices and Equipment, the accreditation of the institutions for drug clinical trials shall be subject to record-filing administration. The conduct of clinical trials must adhere to the Good Laboratory Practice, and the protocols must be approved by the ethics committees of each study site.

Reform of Evaluation and Approval System for Drugs

On August 9, 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment, which establishes the reform framework of the evaluation and approval system for drugs, medical devices and equipment, indicating the enhancement of the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

On November 11, 2015, the NMPA issued the Circular Concerning Several Policies on Drug Registration Review and Approval, which further clarifies the measures and policies with regard to the simplification and acceleration of the approval process for drugs.

According to the Decision of the NMPA on Adjusting the Approval Procedures under the Administrative Approval Items for Certain Drugs made on March 17, 2017 and effective from May 1, 2017, the approval for a clinical trial application can be directly issued by the CDE under the NMPA on behalf of the NMPA.

On October 8, 2017, the General Office of the State Council promulgated the Innovation Opinions, which further promotes the structural adjustment to and technical innovations of drugs, medical devices and equipment.

On December 21, 2017, the NMPA promulgated the Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovations, replacing the Opinions on Priority Review and Approval for Resolving Drug Registration Applications Backlog promulgated on February 24, 2016, which provides for fast track clinical trial approval or drug registration pathway to innovative drugs.

On May 23, 2018, the NMPA and the NHC jointly issued the Circular on Issues Concerning Optimizing Drug Registration Review and Approval, which further simplifies and accelerates the clinical trial approval process.

On January 22, 2020, the SAMR promulgated the New Measures for Registration, effective from July 1, 2020, which deploys several mechanisms to simplify and accelerate the drug registration process, including the Priority Review Procedure and the Special Review Procedure.

Special Examination and Fast Track Approval for Innovative Drugs under Current Reform Frame

Pursuant to the Provisions on the Administration of Special Examination and Approval of Registration of New Drugs promulgated by the NMPA on January 7, 2009, the NMPA conducts special examination and approval for new drug registration applications when, among others, (1) the effective constituent of a drug extracted from plants, animals, minerals, etc., as well as the preparations thereof, have never been marketed in China, or 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 anywhere in the world; (3) the new drugs are for treating AIDS, malignant tumors and rare diseases, etc., and have obvious advantages in clinical treatment; or (4) the new drugs are for treating diseases with no effective methods of treatment. The Provisions on the Administration of Special Examination and Approval of Registration of New Drugs provides 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.

The Circular Concerning Several Policies on Drug Registration Review and Approval issued on November 11, 2015 further clarifies the above-mentioned policy, potentially simplifying and accelerating the approval process of clinical trials: (x) 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 (y) a fast track drug registration or clinical trial approval pathway for the following applications: (i) registration of innovative new drugs treating AIDS, malignant tumors, serious infectious diseases and rare diseases; (ii) registration of pediatric drugs; (iii) registration of drugs treating specific or prevalent diseases in elders; (iv) registration of drugs listed in national major science and technology projects or national key research and development plan; (v) registration of innovative drugs using advanced technology, using innovative treatment methods, or having distinctive clinical benefits; (vi) registration of foreign innovative drugs to be manufactured locally in China; (vii) concurrent applications for new drug clinical trials which are already approved in the United States or the European Union or concurrent drug registration applications for drugs which have applied to the competent drug approval authorities for marketing authorization and passed such authorities' onsite inspections in the United States or European Union and are manufactured using the same production line in China; and (viii) clinical trial approval 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.

The Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovations promulgated on December 21, 2017 provides that a fast track clinical trial approval or drug registration pathway will be available to both innovative drugs with distinctive clinical benefits, which have not been sold within or outside China, and drugs using advanced technology, innovative treatment methods or having distinctive treatment advantages.

The Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment promulgated on August 9, 2015 provides that the composition of the examiner team of the CDE shall be strengthened by, among other actions, (1) recruiting professional evaluation talent from the public, (2) engaging relevant experts to participate in technological examination and evaluation, and (3) establishing a system of chief professional positions. Additionally, the Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovations emphasizes the improvement of the examination and evaluation system, which requires the establishment of a new drug examination and evaluation team comprising professionals specialized in clinical medicine, pharmaceutical sciences, pharmacology, toxicology and statistics. As a result, since 2015, the NMPA and the CDE have started a large-scale expansion of examiners, which could greatly accelerate the new drug approval process in China.

Pursuant to the New Measures for Registration, effective from July 1, 2020, at the stage of clinical trial application, depending on the characteristics of the drug and the cooresponding conditions, applicants may apply for adoption of the Breakthrough Drug Procedure or the Conditioned Approval Procedure. Such procedures may be applied for eligible drugs, including drugs for fatal diseases without any effective treatment and breakthrough drugs, and extra policy support, including communication with the CDE at the critical stage of clinical trials and suggestions from the CDE may be given to applicants in such special procedures.

Manufacturing and Distribution

According to the Drug Administration Law, all facilities that manufacture drugs in China must receive a drug manufacturing license from the local drug regulatory authority. Each drug manufacturing license issued to a pharmaceutical manufacturing enterprise is effective for a period of five years. Any enterprise holding a drug manufacturing license is subject to review by the relevant regulatory authorities on an annual basis. A separate certification of compliance with Good Manufacturing Practice (the "GMP") is also required.

Similarly, to conduct sales, importation, shipping and storage (collectively, the "distribution activities"), a company must obtain a Drug Distribution License from the local drug regulatory authority, subject to renewal every five years. A separate certification of compliance with the NMPA's drug good supply practice (the "GSP"), is also required.

China has implemented a "Two-Invoice System" to control the distribution of prescription drugs. The "Two-Invoice System" generally requires that no more than two invoices be issued throughout the distribution chain: one from the manufacturer to a distributor and another from the distributor to the end-user hospital. This excludes the sale of products invoiced from the manufacturer to its wholly-owned or controlled distributors, or for imported drugs, to its exclusive distributor, or from a distributor to its wholly-owned or controlled subsidiary (or between its wholly-owned or controlled subsidiaries). However, the system still significantly limits the options for companies to use multiple distributors to reach a larger geographic area in China. Compliance with the Two-Invoice System is a prerequisite for pharmaceutical companies to participate in the procurement processes of public hospitals, which currently provide most of China's healthcare services. Manufacturers and distributors that fail to implement the Two-Invoice System may lose their qualifications to participate in the bidding process. Non-compliant manufacturers may also be blacklisted from engaging in drug sales to public hospitals in a locality.

The Two-Invoice System was first implemented in 11 provinces involved in pilot comprehensive medical reforms, and the program has been expanded to nearly all provinces, each with its own individual rules for the program.

New Drug Application

Pursuant to the Administrative Measures for Drug Registration, when Phases 1, 2 and 3 clinical trials have been completed, the applicant may apply to the NMPA for approval of a new drug application. The NMPA shall then determine whether to approve the application according to the comprehensive evaluation opinion provided by the CDE of the NMPA.

Pursuant to the New Measures for Registration, effective from July 1, 2020, at the stage of new drug application, depending on the characteristics of the drug and the cooresponding conditions, applicants may apply for adoption of special procedures, including the Priority Review Procedure and the Special Review Procedure. Such procedures may be applied for innovative drugs for severe infectious diseases or rare diseases, breakthrough drugs and other eligible drugs stipulated in the New Measures for Registration. Extra policy support, including less review period, may be given to appicants in such special procedures.

International Multi-center Clinical Trials Regulations

On January 30, 2015, the NMPA promulgated the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial), effective as of March 1, 2015, to provide guidance on the regulation of the application, implementation and administration of international multi-center clinical trials in China. Pursuant to the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial), international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for its application to the NMPA for approval of a new drug application, such international multi-center clinical trials shall satisfy, in addition to the requirements set forth in the Drug Administration Law and its implementation measures, the Administrative Measures for Drug Registration and other relevant laws and regulations, the following requirements:

- The applicant shall first conduct an overall evaluation on the global clinical trial data and further make trend analysis of the Asian and Chinese clinical trial data. In the analysis of Chinese clinical trial data, the applicant shall consider the representativeness of the research subjects, i.e., the participating patients;
- The applicant shall analyze whether the amount of Chinese research subjects is sufficient to assess and adjudicate the safety and effectiveness of the drug under clinical trial, and satisfy the statistical and relevant legal requirements; and
- The onshore and offshore international multi-center clinical trial research centers shall be subject to on-site inspections by competent PRC governmental agencies.

International multi-center clinical trials shall follow international prevailing GCP principles and ethics requirements. Applications shall ensure the truthfulness, reliability and trustworthiness of clinical trials results; the researchers shall have the qualification and capability to perform relevant clinical trials; and an ethics committee shall continuously review the trials and protect the subjects' interests, benefits and safety. Before the performance of the international multi-center clinical trial, applicants shall obtain clinical trial approvals or complete filings pursuant to requirements under the local regulations where clinical trials are conducted, and register and disclose the information of all major researchers and clinical trial organizations on the NMPA drug clinical trial information platform.

Pursuant to the Opinions on Deepening the Reform of the Evaluation and Approval System and Inspiring Innovation of Drugs and Medical Devices and Equipment, clinical trial data obtained from foreign centers may be used to apply for registration in China as long as such data meet the relevant requirements for the registration of drugs and medical devices in China. When using international multi-center clinical trial data to support new drug applications in China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with ICH-CTD (International Conference on Harmonization-Common Technical Document) content and format requirements; subgroup research results summary and comparative analysis shall also be conducted concurrently.

Marketing Authorization Holder System

Pursuant to the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment promulgated on August 9, 2015, the State Council published the policy for carrying out a pilot plan for the drug marketing authorization holder mechanism.

Pursuant to the newly amended Drug Administrative Law, under the drug marketing authorization holder mechanism, an enterprise obtained drug registration certificate and a research and development institution are eligible to be a pharmaceutical marketing authorization holder and the drug marketing authorization holder shall be responsible for nonclinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the Drug Administrative Law. The pharmaceutical marketing authorization holder may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and may engage pharmaceutical distribution enterprises with drug distribution license for the distribution activities. Upon the approval of the medical products administrative department under the State Council, a drug marketing authorization holder may transfer the drug marketing license and the transferee shall have the capability of quality management, risk prevention and control, and liability compensation to ensure the safety, effectiveness and quality controllability of drugs, and fulfill the obligations of the drug marketing license holder.

Administrative Observation Periods for New Drugs

According to the Implementing Measures of the Drug Administration Law, the NMPA may, for the purposes of protecting public health, set an administrative observation period of not more than five years for a new drug produced by a drug manufacturer. During the administrative observation period, no approval shall be given to any other manufacturer to produce or import the said drug.

Non-Inferiority Standard

In China, a drug may receive regulatory approval without showing superiority in its primary endpoint. Rather, a drug may be approved for use if it shows non-inferiority in its primary endpoint and superiority in one of its secondary endpoints.

Packaging of Pharmaceutical Products

Pursuant to the Administration of Quality of Drug Clinical Practice, the applicant shall be responsible for proper packaging and labeling of drugs for clinical trials, and in double-blinded clinical trials, the test drug shall be consistent with the control drug or placebo in appearance, odor, packaging, labeling, and certain other features. According to the Measures for the Administration of Pharmaceutical Packaging promulgated on February 12, 1988 and effective from September 1, 1988, pharmaceutical packaging must comply with national and professional standards. If there is no national or professional standard available, an applicant may formulate and implement its own standards after obtaining the approval of the provincial administration or bureau of standards. The applicant must reapply if it needs to change its own packaging standards. Drugs that have not been developed and approved for packaging standards must not be sold or marketed in the PRC (except for drugs for the military).

National List of Essential Drugs

On August 18, 2009, the MOH and eight other ministries and commissions in the PRC issued the Provisional Measures on the Administration of the National List of Essential Drugs which was revised on February 13, 2015 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 List of Essential Drugs. The MOH promulgated the National List of Essential Drugs on March 13, 2013 and on September 30, 2018. According to these regulations, basic healthcare institutions funded by the government shall store up and use drugs listed in the National List of Essential Drugs. The drugs listed in the National List of Essential Drugs shall be purchased by centralized tender process and shall be subject to the price control by the National Development and Reform Commission (the "NDRC"). Remedial drugs in the National List of Essential Drugs are all listed in the NRDL and the purchase price of such drugs is entitled to reimbursement.

Government Price Controls

The Chinese government has abolished the 15-year-old government-led pricing system for drugs. On May 4, 2015, the NDRC and six other ministries and commissions in the PRC issued the Opinion on Promoting Drug Pricing Reform, which lifted the government-prescribed maximum retail price for most drugs, except for narcotic drugs and Class I psychotropic drugs. The government regulates drug prices mainly by establishing a consolidated procurement mechanism, restructuring medical insurance reimbursement standards and strengthening the regulation of medical and pricing practices as discussed below.

Centralized Procurement and Tenders

Under the current regulations, public medical institutions owned by the government or owned by State-owned or controlled enterprises are required to purchase pharmaceutical products through centralized online procurement processes. There are exceptions for drugs on the National List of Essential Drugs, which have their own procurement rules, and for certain drugs subject to the central government's special control, such as toxic, radioactive and narcotic drugs and traditional Chinese medicines.

The centralized procurement process takes the form of public tenders operated by provincial or municipal-level government agencies. The centralized tender process is typically conducted once every year. The bids are assessed by a committee randomly selected from a database of experts. The committee members assess the bids based on a number of factors, including, but not limited to, bid price, product quality, clinical effectiveness, product safety, level of technology, qualifications and reputation of the manufacturer, after-sale services and innovation.

The State Council approved state-run centralized medicine procurement and 11 pilot cities for the program in a circular issued on January 17, 2019. It is an effort to deepen reform of the medical and health sector and optimize the pricing system of drugs. According to the circular, in the 11 pilot cities drugs will be selected from generic brands for centralized medicine procurement. The selected drugs must pass the consistency evaluation on quality and effectiveness. The policy is aimed at lowering drug costs for patients, reducing transaction costs for enterprises, regulating drug use of institutions, and improving the centralized medicine procurement and pricing system. The centralized procurement is open to all approved enterprises that can produce drugs on the procurement list in China. Clinical effects, adverse reactions, and batch stability of the drugs will be considered, and their consistency will be the main criteria for evaluation, while production capacity and stability of the supplier will also be considered.

Commercial Insurance

On October 25, 2016, the State Council issued the Plan for Healthy China 2030. According to the Plan, the country will establish a multi-level medical security system built around basic medical insurance, with other forms of insurance supplementing the basic medical insurance, including serious illness insurance for urban and rural residents, commercial health insurance and medical assistance. Furthermore, the Plan encourages enterprises and individuals to participate in commercial health insurance and various forms of supplementary insurance. The evolving medical insurance system makes innovative drugs more affordable and universally available to the Chinese population, which renders greater opportunities to drug manufacturers that focus on the research and development of innovative drugs, such as high-cost cancer therapeutics.

Healthcare System Reform

The PRC government recently promulgated several healthcare reform policies and regulations to reform the healthcare system. On March 17, 2009, the State Council issued the Guidelines on Strengthening the Reform of Healthcare System. On December 27, 2016, the State Council issued the Notice on the Issuance of the 13th Five-year Plan on Strengthening the Reform of Healthcare System. On May 23, 2019, the General Office of the State Council issued the Notice on the Main Tasks of Strengthening the Reform of Healthcare System in 2019, which specified the key legislative work of the national medical and health system and the key tasks to promote its implementation. Twenty-one specific tasks have been proposed to address the difficulty and high cost of getting medical services and to strengthen hospital management.

Chronic Diseases Prevention and Treatment

Pursuant to the Guiding Opinion of the General Office of the State Council on Promoting the Construction of the Hierarchical Healthcare System issued by the General Office of the State Council on September 8, 2015 and the Notice on Promoting Pilot Work for Hierarchical Healthcare System jointly promulgated by the NHFPC and the State Administration of Traditional Chinese Medicine on August 19, 2016, the hierarchical healthcare system is expected to be gradually improved, and the framework for division and coordination among medical and health institutions shall be substantially established by 2017, and a diagnosis and treatment model featuring objectives, such as initial diagnosis of common diseases and frequent diseases at primary hospitals and separate treatment of acute and chronic diseases, are expected to be gradually established. According to the Guiding Opinion of the General Office of the State Council on Promoting the Construction of the Hierarchical Healthcare System, several chronic diseases, including hypertension, diabetes, cancer and cardiovascular and cerebrovascular diseases, are pilot diseases under the hierarchical healthcare system. Primary healthcare institutions, rehabilitation hospitals and nursing institutions may provide treatment, rehabilitation and nursing services for patients with chronic diseases, patients in stable conditions, elderly patients, and advanced cancer patients who have clear diagnosis and stable disease conditions.

On January 22, 2017, the General Office of the State Council issued the Notice on the Medium and Long-Term Plan for Chronic Disease Prevention and Treatment in China (2017-2025), which sets up the objectives of the management of diabetes patients, targeting the involvement of 35 million diabetic patients by 2020 and 40 million by 2025 in chronic disease management. The Notice on the Medium and Long-Term Plan for Chronic Disease Prevention and Treatment in China (2017-2025) reaffirms that the hierarchical healthcare system of chronic diseases such as diabetes shall be promoted and encourages the initial diagnosis of common diseases and frequent diseases at primary hospitals. In addition, social participation in regional medical services, health management and chronic disease prevention services, as well as investments in the field of chronic disease prevention by social capital, are encouraged.

Intellectual Property Rights

China became a member of the World Trade Organization and a party to the Agreement on Trade-Related Aspects of Intellectual Property Rights on December 11, 2001. China has also entered into several international conventions on intellectual property rights, including, but not limited to, the Paris Convention for the Protection of Industrial Property, the Madrid Agreement Concerning the International Registration of Marks, and the Patent Cooperation Treaty.

Patents

Pursuant to the PRC Patent Law promulgated by the Standing Committee of the NPC on March 12, 1984 and amended on September 4, 1992, August 25, 2000 and December 27, 2008, respectively, and effective from October 1, 2009, and the Implementation Rules of the Patent Law of the PRC promulgated by the State Council on June 15, 2001 and amended on December 28, 2002 and January 9, 2010, respectively, patents in China fall into three categories: invention, utility model and design. An invention patent is granted to a new technical solution proposed in respect of a product or method or an improvement of a product or method. A utility model is granted to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product. A design patent is granted to the new design of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility models and designs are effective for ten years from the date of application. The PRC Patent Law adopts the principle of “first-to-file” system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who files the application first.

Existing patents can become narrowed, invalid or unenforceable due to a variety of grounds, including lack of novelty, creativity, and deficiencies in patent application. In China, a patent must have novelty, creativity and practical applicability. Under the PRC Patent Law, novelty means that before a patent application is filed, no identical invention or utility model has been publicly disclosed in any publication in China or overseas or has been publicly used or made known to the public by any other means, whether in or outside of China, nor has any other person filed with the patent authority an application that describes an identical invention or utility model and is recorded in patent application documents or patent documents published after the filing date. Creativity means that, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress. Practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the State Intellectual Property Office (the “SIPO”). Normally, the SIPO publishes an application for an invention patent within 18 months after the filing date, which may be shortened at the request of applicant. The applicant must apply to the SIPO for a substantive examination within three years from the date of application.

Article 20 of the PRC Patent Law provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the SIPO for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the relevant invention. This added requirement of confidential examination by the SIPO has raised concerns by foreign companies who conduct research and development activities in China or outsource research and development activities to service providers in China.

Patent Enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offenses such as forgery of patents may be subject to criminal penalties.

When a dispute arises out of infringement of the patent owner’s patent right, Chinese law requires that the parties first attempt to settle the dispute through mutual consultation. However, if the dispute cannot be settled through mutual consultation, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A Chinese court may issue a preliminary injunction upon the patent owner’s or an interested party’s request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement, and if the loss suffered by the patent holder arising from the infringement cannot be determined, the damages for infringement shall be calculated as the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the above-mentioned calculation standards. The damage calculation methods shall be applied in the aforementioned order. Generally, the patent owner has the burden of proving that the patent is being infringed. However, if the owner of an invention patent for manufacturing process of a new product alleges infringement of its patent, the alleged infringer has the burden of proof.

Medical Patent Compulsory License

According to the PRC Patent Law, for the purpose of public health, the SIPO may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which the PRC has acceded.

Trade Secrets

Pursuant to the PRC Anti-Unfair Competition Law promulgated by the Standing Committee of the NPC on September 2, 1993 and amended on November 4, 2017 and April 23, 2019, respectively, 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, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; (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; or (4) instigating, inducing or assisting others to disclose, use or permit others to use the trade secrets, in violation of any contractual agreements or any requirement of the legal owners or holders to keep such trade secret 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 terminate any illegal activities and impose fines on the infringing parties.

Trademarks

Pursuant to the Trademark Law of the PRC promulgated by the Standing Committee of the NPC on August 23, 1982 and amended on February 22, 1993, October 27, 2001 and August 30, 2013, respectively, and effective from May 1, 2014, which has been amended on April 23, 2019 and became effective from November 1, 2019, the period of validity for a registered trademark is ten years, commencing from the date of registration. The registrant shall go through the formalities for renewal within twelve months prior to the expiry date of the trademark if continued use is intended. Where the registrant fails to do so, a grace period of six months may be granted. The validity period for each renewal of registration is ten years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be cancelled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to the law.

Domain Names

Domain names are protected under the Measures on Administration of Domain Names for the Chinese Internet promulgated by the Ministry of Industry and Information Technology, on November 5, 2004 and effective from December 20, 2004, which was replaced by the Administrative Measures on the Internet Domain Names issued by the Ministry of Industry and Information Technology on August 24, 2017 and effective from November 1, 2017, and the Implementing Rules on Registration of Domain Names issued by China Internet Network Information Center on May 28, 2012, which became effective on May 29, 2012. The Ministry of Industry and Information Technology is the main regulatory body responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

Product Liability

The Product Quality Law of the PRC promulgated by the Standing Committee of the NPC on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and December 29, 2018, respectively, is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them, and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable for compensating for any bodily injuries or property damages, other than the defective product itself, resulting from the defects in the product, unless the manufacturer is able to prove that: (1) the product has never been distributed; (2) the defects causing injuries or damages did not exist at the time when the product was distributed; or (3) the science and technology at the time when the product was distributed was at a level incapable of detecting the defects. A seller shall be liable for compensating for any bodily injuries or property damages of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate either the manufacturer or the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

Pursuant to the General Principles of the Civil Law of the PRC promulgated by the NPC on April 12, 1986 and amended on August 27, 2009, both manufacturers and sellers shall be held liable where the defective products result in property damages or bodily injuries to others. Pursuant to the Tort Liability Law of the PRC promulgated by the Standing Committee of the NPC on December 26, 2009 and effective from July 1, 2010, manufacturers shall assume tort liabilities where the defects in products cause damages to others. Sellers shall assume tort liabilities where the defects in products that have caused damages to others are attributable to the sellers. The aggrieved party may claim for compensation from the manufacturer or the seller of the defected product that has caused damage.

Regulation of Commercial Bribery

Pharmaceutical companies involved in a criminal investigation or administrative proceedings related to bribery are listed in the Adverse Records of Commercial Briberies by their respective provincial health and family planning administrative department. Pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry which became effective on March 1, 2014, provincial health and family planning administrative departments formulate the implementing measures for establishment of Adverse Records of Commercial Briberies. Where a pharmaceutical company or its agent is listed in the Adverse Records of Commercial Briberies on one occasion, it will be prohibited from participating in the procurement bidding process or selling its products to public medical institutions located in the local provincial-level region for two years from the publication of the adverse records. The evaluation points of such pharmaceutical company or agent in respect of the procurement bidding process and procurement by public medical institutions must be credited by public medical institutions in the other provincial-level regions for two years from the publication of the adverse records. Where a pharmaceutical company or its agent is listed in the Adverse Records of Commercial Briberies on two or more occasions within five years, it will be prohibited from participating in the procurement bidding process or selling its products to all public medical institutions in the PRC for two years from the publication of these adverse records.

Regulations Relating to Employee Stock Incentive Plan

In February 2012, the SAFE promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies (the “Stock Option Rules”), which replaced the Application Procedures of Foreign Exchange Administration for Domestic Individuals Participating in Employee Stock Ownership Plans or Stock Option Plans of Overseas Publicly Listed Companies issued by the SAFE on March 28, 2007. In accordance with the Stock Option Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with the SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. In addition, the SAT has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax (the “IIT”). The PRC subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

Regulations Relating to Foreign Exchange and the Dividend Distribution

Foreign Exchange Control

The State Council promulgated the PRC Regulation for the Foreign Exchange on January 29, 1996, which was amended on January 14, 1997 and August 5, 2008, respectively. On June 20, 1996, the People's Bank of China promulgated the Regulation on the Administration of the Foreign Exchange Settlement, Sales and Payment, which came into effect on July 1, 1996. Pursuant to the above-mentioned regulations, foreign exchanges required for distribution of profits and payment of dividends may be purchased from designated foreign exchange banks in the PRC upon presentation of a board resolution authorizing the distribution of profits or payment of dividends. The Regulation on the Administration of the Foreign Exchange Settlement, Sales and Payment removed the previous restrictions on convertibility of foreign exchange in respect of current account items, including the distribution of dividends, interest and royalty payments, trade and service-related foreign exchange transactions, while foreign exchange transactions in respect of capital account items, such as direct investment, loan, securities investment and repatriation of investment, remain subject to the approval of the SAFE.

On November 19, 2012, the SAFE issued the Operating Rules for Foreign Exchange Issues with Regard to Direct Investment under Capital Account as an appendix to the Circular of the SAFE on Further Improving and Adjusting the Foreign Exchange Policies on Direct Investment, which was issued on November 19, 2012 and amended on May 4, 2015. According to the Circular of the SAFE on Further Improving and Adjusting the Foreign Exchange Policies on Direct Investment, (i) the opening of and payment into foreign exchange accounts under direct investment accounts are no longer subject to approval by the SAFE; (ii) reinvestment with the legal income of foreign investors in China is no longer subject to approval by the SAFE; (iii) the procedures for capital verification and confirmation that foreign-funded enterprises need to go through are simplified; (iv) the purchase and external payment of foreign exchange under direct investment accounts are no longer subject to approval by the SAFE; (v) domestic transfer of foreign exchange under direct investment accounts is no longer subject to approval by the SAFE; and (vi) the administration over the conversion of foreign exchange capital of foreign-funded enterprises is improved. On February 13, 2015, the SAFE issued the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment, which came into effect on June 1, 2015, providing that the banks, instead of the SAFE, can directly handle the foreign exchange registration and approval under foreign direct investment, while the SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the banks.

On May 11, 2013, the SAFE promulgated the Provisions on the Administration of Foreign Exchange in Foreign Direct Investments by Foreign Investors, which became effective on May 13, 2013, and relevant supporting documents that regulate and clarify the administration over foreign exchange administration in foreign direct investments.

On March 30, 2015, the SAFE released the Circular on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, which came into effect on June 1, 2015 and superseded the Notice on the Relevant Operating Issues Concerning the Improvement of the Administration of Payment and Settlement of Foreign Currency Capital of Foreign-funded Enterprises issued by the SAFE on August 29, 2008. The Circular on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises has made certain adjustments to some regulatory requirements on the settlement of foreign exchange capital of foreign-invested enterprises, and some foreign exchange restrictions provided in the Notice on the Relevant Operating Issues Concerning the Improvement of the Administration of Payment and Settlement of Foreign Currency Capital of Foreign-funded Enterprises. On June 9, 2016, the SAFE issued the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects. Under the Circular on the Reform and Standardization of the Management Policy of the Settlement of Capital Projects and the Circular on the Reform of the Management Method for the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, the settlement of foreign exchange by foreign-invested enterprises shall be governed by the policy of foreign exchange settlement on a discretionary basis. However, the aforementioned circulars also reiterate that the settlement of foreign exchange shall only be used for its own operation purposes within the business scope of the foreign-invested enterprises and following the principles of authenticity. Considering that these circulars are relatively new, it is unclear how they will be implemented, and there exist great uncertainties with respect to their interpretation and implementation by the authorities.

The SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles on July 4, 2014, which requires PRC residents to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity for the purpose of overseas investment and financing, with such PRC residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests as a "special purpose vehicle" as defined therein. The aforesaid circular further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. Failure to comply with the SAFE registration requirements under the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles could result in liabilities under PRC law for evasion of foreign exchange controls. The Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment, provides that local banks, instead of the SAFE, can directly handle the initial foreign exchange registration and amendment registration under the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles.

Dividend Distribution

Pursuant to the PRC Company Law, the Wholly Foreign-Owned Enterprise Law of the PRC and the Detailed Implementing Rules for the Wholly Foreign-Owned Enterprise Law of the People's Republic China, foreign-invested enterprises in the PRC may pay dividends only out of their accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a foreign-invested enterprise is required to set aside at least 10% of its accumulated profits each year to fund certain reserve funds, until the accumulative amount of such fund reaches 50% of its registered capital. These wholly foreign-owned companies may also allocate a portion of their after-tax profits based on PRC accounting standards to employee welfare and bonus funds. Amounts allocated to these reserve funds and employee welfare and bonus funds reduce the amount distributable as cash dividends. Upon approval of the competent governmental authorities, foreign investors may utilize RMB dividends to invest or re-invest in enterprises established in China.

On January 26, 2017, the SAFE issued the Notice on Improving the Check of Authenticity and Compliance to Further Promote Foreign Exchange Control, which stipulates several capital control measures with respect to outbound remittance of profits from domestic entities to offshore entities, including the following: (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities shall provide detailed explanations of the sources of capital and the utilization arrangements and board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound investment.

Regulations Relating to Labor

Labor Law and Labor Contract Law

Pursuant to the PRC Labor Law promulgated by the Standing Committee of the NPC on July 5, 1994 and effective from January 1, 1995 and amended on August 27, 2009 and December 29, 2018, respectively, the PRC Labor Contract Law promulgated by the Standing Committee of the NPC on June 29, 2007 and effective from January 1, 2008 and amended on December 28, 2012 and effective from July 1, 2013, and the Implementing Regulations of the Employment Contracts Law of the PRC promulgated by the State Council on September 18, 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. Wages cannot be lower than the local minimum wage. The employer must establish a system for labor safety and sanitation, strictly abide by the state rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitary conditions and necessary protection materials in compliance with the state rules and standards, and carry out regular health examinations for employees engaged in work involving occupational hazards.

Social Insurance and Housing Provident Funds

Under applicable PRC laws, including the Social Insurance Law of the PRC which became effective on July 1, 2011 and was amended on December 19, 2018, the Interim Regulations on the Collection and Payment of Social Security Funds promulgated by the State Council on January 22, 1999 and amended on March 24, 2019, and the Regulations on the Administration of Housing Provident Funds promulgated by the State Council on April 3, 1999 and amended on March 24, 2002 and March 24, 2019, respectively, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance, maternity insurance and housing provident funds. These payments are made to local administrative authorities, and any employer who fails to contribute may be fined and ordered to pay the deficit amount within a stipulated time limit.

Regulations Relating to Enterprise Income Tax

Pursuant to the Enterprise Income Tax Law of the PRC effective as of January 1, 2008 and as amended on February 24, 2017 and December 29, 2018, respectively, the income tax rate for both domestic and foreign-invested enterprises is 25% with certain exceptions. To clarify certain provisions in the Enterprise Income Tax Law, the State Council promulgated the Implementation Rules of the Enterprise Income Tax Law on December 6, 2007, which was amended and became effective on April 23, 2019. Under the Enterprise Income Tax Law and the Implementation Rules of the Enterprise Income Tax Law, enterprises are classified as either “resident enterprises” or “non-resident enterprises.” Besides enterprises established within the PRC, enterprises established outside of China whose “de facto management bodies” are located in China are considered “resident enterprises” and subject to the uniform 25% enterprise income tax rate for their global income. In addition, the Enterprise Income Tax Law provides that a non-resident enterprise refers to an entity established under foreign law whose “de facto management bodies” are not within the PRC, but has an establishment or place of business in the PRC, or does not have an establishment or place of business in the PRC but has income sourced within the PRC.

The Implementation Rules of the Enterprise Income Tax Law provide that since January 1, 2008, an income tax rate of 10% shall normally be applicable to dividends declared to non-PRC resident enterprise investors that do not have an establishment or place of business in the PRC, or have such establishment or place of business but the relevant income is not effectively connected with the establishment or place of business, to the extent such dividends are derived from sources within the PRC. The income tax on the dividends may be reduced pursuant to a tax treaty between China and the jurisdictions in which the non-PRC shareholders reside.

Other PRC National- and Provincial-Level Laws and Regulations

We are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations control the confidentiality of patients’ medical information and the circumstances under which patient medical information may be released for inclusion in our databases, or released by us to third parties. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future.

We also comply with numerous additional national and provincial laws relating to matters such as safe working conditions, manufacturing practices, environmental protection and fire hazard control. We believe that we are currently in compliance with these laws and regulations; however, we may be required to incur significant costs to comply with these laws and regulations in the future. Unanticipated changes in existing regulatory requirements or adoption of new requirements could therefore have a material adverse effect on our business, results of operations and financial condition.

U.S. Regulation

Government Regulation and Product Approval in the United States

The FDA and other regulatory authorities in the United States at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biological products. Along with third-party contractors, we will be required to navigate the various pre-clinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our drug candidates. The processes for obtaining regulatory approvals in the United States and in foreign jurisdictions, along with subsequent compliance with applicable laws and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Government policies may change and additional government regulations may be enacted that could prevent or delay further development or regulatory approval of any of our drug candidates, or anticipated manufacturing processes, disease indications, or labeling. We cannot predict the likelihood, nature or extent of government regulation that might arise from future legislative or administrative action.

Review and Approval for Licensing Biologics in the United States

In the United States, the FDA regulates our current drug candidates as biological products, or biologics, under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), the Public Health Service Act and associated implementing regulations. Biologics, like other drugs, are used for the treatment, prevention or cure of disease in humans. In contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biologics are generally derived from living material (human, animal, or microorganism) and are complex in structure, and thus are usually not fully characterized. Biologics include immunomedicines for cancer and other diseases.

Biologics are also subject to other federal, state and local statutes and regulations. The failure to comply with applicable statutory and regulatory requirements at any time during the product development process, approval process or after approval may subject a sponsor or applicant to administrative or judicial enforcement actions. These actions could include the suspension or termination of clinical trials by the FDA, the FDA's refusal to approve pending applications or supplemental applications, withdrawal of an approval, "Warning Letters" (official messages from the FDA to a manufacturer or other organization that it has violated some rule in a federally regulated activity) or "Untitled Letters" (initial correspondences from the FDA with a regulated industry that cite violations that do not meet the threshold of regulatory significance for a Warning Letter and request correction of the violation), product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA, the Department of Justice (the "DOJ"), or other governmental entities.

An applicant seeking approval to market and distribute a biologic in the United States typically must undertake the following:

- *completion of non-clinical laboratory tests and animal studies performed in accordance with the FDA's good laboratory practice (the "GLP"), regulations;*
- *submission to the FDA of an application for an Investigational New Drug ("IND"), which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;*
- *manufacture, labeling and distribution of an investigational drug in compliance with current good manufacturing practice (the "cGMP");*
- *approval by an independent institutional review board (the "IRB"), or ethics committee at each clinical site before each clinical trial may be initiated;*

- *performance of adequate and well-controlled human clinical trials in accordance with the FDA's current Good Clinical Practices requirements (the "cGCP"), to establish the safety, purity and potency of the proposed biological drug candidate for its intended purpose;*
- *preparation of and submission to the FDA of a biologics license application ("BLA"), after completion of all pivotal clinical trials requesting marketing approval for one or more proposed indications;*
- *satisfactory completion of an FDA Advisory Committee review, where appropriate or if applicable, as may be requested by the FDA to assist with its review;*
- *satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the proposed product, or components thereof, are produced to assess compliance with cGMP and data integrity requirements to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, safety, quality, purity and potency;*
- *satisfactory completion of FDA audits of selected clinical investigation sites to assure compliance with cGCP requirements and the integrity of the clinical data;*
- *payment of user fees under the Prescription Drug User Fee Act (the "PDUFA"), for the relevant year;*
- *obtaining FDA review and approval of the BLA to permit commercial marketing of the licensed biologic for particular indications for use in the United States; and*
- *compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (the "REMS"), and the potential requirement to conduct post-approval studies.*

The testing and approval process requires substantial time, effort and financial resources and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all.

From time to time, legislation is drafted, introduced and passed in the Congress of the United States that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our drug candidates. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

Pre-clinical and Clinical Development in the United States

Before a BLA applicant can begin testing the potential asset in human subjects, the applicant must first conduct pre-clinical studies. Pre-clinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as in vitro and animal studies to assess the potential safety and activity of the biologic for initial testing in humans and to establish a rationale for therapeutic use. Pre-clinical studies are subject to federal regulations and requirements, including GLP regulations. The results of an applicant's pre-clinical studies are submitted to the FDA as part of an IND.

An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. An IND is an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial. Such authorization must be secured prior to interstate shipment. In support of a request for an IND, applicants must submit a range of information, including pre-clinical data, manufacturing information and a detailed protocol for each clinical trial. Any subsequent protocol amendments must be submitted to the FDA as part of the IND.

Human clinical trials may not begin until an IND is effective. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises safety concerns or questions about the proposed clinical trial within the 30-day time period. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

The FDA may also place a clinical hold or partial clinical hold on such trial following commencement of a clinical trial under an IND. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after the imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor with a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCP regulations, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with cGCP regulations in order to use the study as support for an IND or application for marketing approval, including review and approval by an independent ethics committee and informed consent from subjects.

Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives.

Some trials also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board (the “DSMB”). DSMBs provide authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial and may halt the clinical trial if a DSMB determines that there is an unacceptable safety risk for subjects or based on other grounds, such as no demonstration of efficacy. Other grounds for suspension or termination may be made based on evolving business objectives and/or competitive climate. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

Clinical Trials

For purposes of BLA approval, clinical trials are typically conducted in the following sequential phases that may overlap or be combined:

- Phase 1: The investigational product is initially introduced into a small number of healthy human subjects or patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans and the side effects associated with increasing doses. These trials may also yield early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.
- Phase 2: The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: The investigational product is administered to an expanded patient population generally at multiple geographically dispersed clinical trial sites to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety. These clinical trials are intended to generate sufficient data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval by the FDA.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product, referred to as Phase 4 trials. Such post-approval trials, when applicable, are conducted following initial approval, typically to develop additional data and information relating to the biological characteristics of the product and treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: suspected serious and unexpected adverse reactions; findings from epidemiological studies, pooled analysis of multiple studies, animal or in vitro testing, or other clinical studies, whether or not conducted under an IND, and whether or not conducted by the sponsor, that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the rate of a serious suspected adverse reaction over such rate listed in the protocol or investigator brochure, which is a comprehensive document summarizing the body of information about an investigational product obtained during clinical and non-clinical trials.

Each of Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with cGCP and the integrity of the clinical data submitted.

During clinical development, the sponsor often refines the indication and endpoints on which the BLA will be based. For endpoints based on patient-reported outcomes (the "PROs"), and observer-reported outcomes (the "OROs"), the process typically is an iterative one. The FDA has issued guidance on the framework it uses to evaluate PRO instruments. Although the agency may offer advice on optimizing PRO and ORO instruments during the clinical development process, the FDA usually reserves final judgment until it reviews the BLA.

Concurrent with clinical trials, companies often complete additional animal studies, and develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required clinical testing in accordance with all applicable regulatory requirements, an applicant may submit a BLA requesting licensing to market the biologic for one or more indications in the United States. The BLA must include the results of product development, non-clinical studies and clinical trials; detailed information on the product's chemistry, manufacture and controls; and proposed labeling. Under the Prescription Drug User Fee Amendments, a BLA submission is subject to an application user fee, unless a waiver or exemption applies.

The FDA will initially review the BLA for completeness before accepting it for filing. Under the FDA's procedures, the agency has 60 days from its receipt of a BLA to determine whether the application will be accepted for filing and substantive review. If the agency determines that the application does not meet this initial threshold standard, the FDA may refuse to file the application and request additional information, in which case the application must be resubmitted with the requested information and review of the application delayed.

With certain exceptions, BLAs must include a pediatric assessment, generally based on clinical trial data, of the safety and effectiveness of the biologic in relevant pediatric populations. Under certain circumstances, the FDA may waive or defer the requirement for a pediatric assessment, either at the sponsor's request or by the agency's initiative.

After the BLA is accepted for filing, the FDA reviews the BLA to determine, among other things, whether a product is safe, pure and potent and if the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued identity, strength, quality, safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP and are adequate to assure consistent production of the product within required specifications. In addition, the FDA expects that all data be reliable and accurate, and requires sponsors to implement meaningful and effective strategies to manage data integrity risks. Data integrity is an important component of the sponsor's responsibility to ensure the safety, efficacy and quality of its product or products.

The FDA will typically inspect one or more clinical sites to assure compliance with cGCP regulations before approving a BLA. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

FDA performance goals generally provide for action on a BLA within ten months of filing, which (as discussed above) typically occurs within 60 days of submission, but that deadline is extended in certain circumstances. Furthermore, the review process is often significantly extended by FDA requests for additional information or clarification.

The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee consists of a panel that includes clinicians and other experts who will review, evaluate and provide a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and usually has followed such recommendations.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its components will be produced, the FDA may issue an approval letter or a Complete Response Letter (the "CRL"). An approval letter authorizes commercial marketing of the biologic with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. If and when the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the BLA, the FDA will issue an approval letter. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional data, information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, and may require additional testing or information and/or require post-marketing studies and clinical trials. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

During the approval process, the FDA will determine whether a REMS is necessary to assure the safe use of the biologic. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes that a REMS is needed, the BLA sponsor must submit a proposed REMS and the FDA will not approve the BLA without a REMS that the agency has determined is acceptable.

In addition, under the Pediatric Research Equity Act of 2003 (the "PREA"), as amended and reauthorized, certain applications or supplements must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

If the FDA approves a product, it may limit the approved indications for use for the product, or require that contraindications, warnings or precautions be included in the product labeling. The FDA may also require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs.

The FDA may also require testing and surveillance programs to monitor the product after commercialization. For biologics, such testing may include official lot release, which requires the manufacturer to perform certain tests on each lot of the product before it is released for distribution. The manufacturer then typically must submit samples of each lot of product to the FDA, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products itself, before releasing the lots for distribution by the manufacturer.

After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are often subject to further testing requirements and FDA review and approval, depending on the nature of the post-approval change. The FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, reporting of certain deviations and adverse experiences, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their third-party contractors are required to register their establishments with the FDA and certain state agencies. These establishments are subject to routine and periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and data integrity requirements, which impose certain procedural and documentation requirements to assure quality of manufacturing and product. The FDA has increasingly observed cGMP violations involving data integrity during site inspections and investigating compliance with data integrity requirements is a significant focus of its oversight. Requirements with respect to data integrity include, among other things, controls to ensure data are complete and secure; activities documented at the time of performance; audit trail functionality; authorized access and limitations; validated computer systems; and review of records for accuracy, completeness and compliance with established standards.

Post-approval changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP, data integrity, pharmacovigilance (i.e., post-marketing safety reporting obligations) and other aspects of regulatory compliance.

The FDA may withdraw a product approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-approval studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS. Other potential consequences include:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, Warning Letters, Untitled Letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products that it believes present safety problems by issuing an Import Alert;
- permanent injunctions and consent decrees, including the imposition of civil or criminal penalties; or
- voluntary product recall.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA's regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the Internet and social media. Promotional claims relating to a product's safety or effectiveness are prohibited before the drug is approved. After approval, a product generally may not be promoted for uses that are not approved by the FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-promotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ or the Office of the Inspector General of the Department of Health and Human Services, as well as other federal and state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that companies enter into consent decrees and permanent injunctions under which specified promotional conduct is changed or curtailed.

The distribution of prescription drugs and biologics are subject to the Drug Supply Chain Security Act (the "DSCSA"), which requires manufacturers and other stakeholders to comply with product identification, tracing, verification, detection and response, notification and licensing requirements. In addition, the Prescription Drug Marketing Act (the "PDMA"), and its implementing regulations, and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove prescription drug and biological products that may be counterfeit, stolen, contaminated, or otherwise harmful from the market.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product's testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The United States Patent and Trademark Office (the "USPTO"), in consultation with the FDA, reviews and approves the application for patent term restoration.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which a BLA has not been submitted.

Expedited Development and Review Programs

The FDA is required to facilitate the development and expedite the review of pharmaceutical products that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical need for the condition. Under the fast track program, the sponsor of a new drug candidate may request the FDA to designate the product for a specific indication as a fast track product concurrent with or after the filing of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days after receipt of the sponsor's request.

In addition to other benefits, such as the ability to have more frequent interactions with the FDA, the agency may initiate review of sections of a fast track product's BLA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's PDUFA review period for a fast track application does not begin until the last section of the BLA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the agency believes that the designation is no longer supported by data emerging in the clinical trial process.

Healthcare Regulation

Pharmaceutical Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. Third-party payors establish the coverage and reimbursement policies for pharmaceutical products, and the marketability of any products for which we may receive regulatory approval for commercial sale depends on those payors' coverage policies and reimbursement rates. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include one or more of our drug candidates, if approved. Third-party payors, together with regulators and others, are increasingly challenging the prices charged for pharmaceutical products and health services, in addition to their cost-effectiveness, safety and efficacy.

In addition, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement rates can vary significantly from payor to payor.

Moreover, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our drug candidates will be considered cost-effective by third-party payors. This process could delay the market acceptance of any drug candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our business may be subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business, particularly once third-party reimbursement becomes available for one or more of our products. The healthcare fraud and abuse laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under the Medicare and Medicaid programs, or other federal healthcare programs;
- The federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, or FCA, which prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government;
- The federal Health Insurance Portability and Accountability Act of 1996 (the "HIPAA"), which, among other things, prohibits executing a scheme to defraud any healthcare benefit program, including private third-party payors, and prohibits (i) knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation and (ii) making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (the "HITECH"), and their respective implementing regulations, which impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, including health plans, healthcare clearinghouses and certain healthcare providers, and their business associates, individuals or entities that perform certain services on behalf of a covered entity that involve the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;
- The federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services (the "CMS"), information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in a company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and
- U.S. state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require drug manufacturers to report information on the pricing of certain drugs; state laws and local ordinances that require identification or licensing of sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Even then, governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If governmental authorities find that our operations violate any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our operations and business. In addition, the approval and commercialization of any drug candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. The extent to which future legislation or regulations, if any, relating to health care fraud and abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

Healthcare Reform

In the United States there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system to contain costs, improve quality and expand access to care. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives that have significantly affected the pharmaceutical industry. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), was passed in March 2010, substantially changing the way healthcare is financed by both governmental and private insurers and significantly impacting the U.S. pharmaceutical industry. Among other things, the ACA subjects biologics to potential competition by lower-cost biosimilars; addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; establishes annual fees and taxes on manufacturers of certain branded prescription drugs; and creates a new Medicare Part D coverage gap discount program in which, as a condition of coverage of its products under Medicare Part D, manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump Administration to repeal or replace certain aspects of the ACA and to alter the implementation of the ACA and related laws. For example, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (the "Tax Act"), includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year commonly referred to as the "individual mandate." On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018 (the "BBA"), among other things, amends the ACA, effective January 1, 2019, to reduce the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, in July 2018, the CMS issued a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Additional legislative changes or regulatory changes related to the ACA remain possible. In December 2018, a United States District Court Judge for the Northern District of Texas ruled that the entire ACA is unconstitutional because the tax penalty associated with the "individual mandate" was repealed by Congress as part of the Tax Act. This ruling is under appeal and stayed pending appeal. While the United States District Court Judge for the Northern District of Texas, as well as the Trump Administration and the CMS, have stated that the ruling will have no effect while this appeal is pending, it is unclear how this decision, subsequent appeals and other efforts to invalidate the ACA, regulations promulgated under the ACA or portions thereof, will impact the ACA and its implementation.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing; reduce the cost of prescription drugs under Medicare; review the relationship between pricing and manufacturer patient programs; and reform government program reimbursement methodologies for drugs. For example, the Trump Administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. On January 31, 2019, Office of the Inspector General of the Department of Health and Human Services proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will remove safe harbor protection from rebates paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these, and other proposed measures may require additional authorization to become effective, Congress and the Trump Administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

Moreover, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Manufacturing and Supply

Our manufacturing strategy for our drug candidates consists of two progressive steps, involving (i) using contract development and manufacturing organizations ("CDMOs") and (ii) establishing our own capabilities and infrastructure, including a manufacturing facility. We believe that development of our own manufacturing facility will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes and help us achieve better long-term margins.

We currently outsource the manufacturing of clinical trial material for our internally developed, IND enabling projects to leading CDMOs in China such as WuXi Biologics, and the manufacturing of clinical trial material for clinical stage projects which were in-licensed from our global partners to reputable global CDMOs, which have established track records for both clinical trial material supply and commercial material supply. We have assembled a seasoned internal team with deep experience in this area to drive and monitor this process. For contingency planning purposes, we have also established relationships with other CDMOs. We expect to continue our outsourcing relationships with contract manufacturers to meet the ongoing needs for the development of our drug candidates. We have framework agreements with these external service providers, under which they provide services to us on a project-by-project basis. We also monitor the manufacturing activities of clinical trial material at CDMO to ensure the compliance with local and international cGMP and applicable regulations. Currently, our contract manufacturers obtain raw materials and supplies for the manufacturing activities from multiple suppliers who we believe have sufficient capacity to meet our demands. We typically order materials and services on a purchase order basis. We also enter into long-term capacity or minimum supply arrangements with them.

We believe it is advantageous that we own and control our GMP manufacturing process in order to ensure quality and secure production slots for clinical trial materials and commercial supplies. We plan to commence the construction of our own state-of-the-art biologics manufacturing facility in China in 2020. At this manufacturing facility, we plan to produce drug substance and drug product for clinical and, in the future, commercial use. We expect this facility to include a pilot GMP manufacturing plant with two 2,000-liter single-use bioreactors, and upon completion of the construction, a commercial scale manufacturing plant with eight more 2,000-liter single-use bioreactors with filling and finishing lines.

Manufacturing is subject to extensive regulations governing quality management systems, manufacturing processes and controls, personnel training, and operating procedures. The CDMOs will be required to operate under cGMP conditions. These cGMP conditions are regulatory requirements for the production of pharmaceuticals for human use.

R&D Governance

We have established robust governance regime for all stages of our research and development activities, through our internal discovery, CMC, pre-clinical and clinical development programs, and through product acquisition and in-licensing strategies. The research and development governance regime has enabled our senior management to continuously oversee and monitor our company's research and development activities for complying with applicable laws, regulations, rules, guidelines and internal policies.

We have established various governance and decision-making committees, composed of senior representatives from the respective functional units to review, discuss and determine, for instance, whether a drug candidate molecule is qualified to move forward into the next stage or not, what data package is considered appropriate and compliant to be submitted to regulatory agencies and how clinical safety of our investigational drugs will be monitored and reported. These committees make decisions over the critical "checkpoints" of our research and development activities and include our (i) Science Committee, (ii) IND Scientific Advisory Committee, (iii) R&D Project/Program/Portfolio Governance, (iv) Medical Safety Council, (v) Safety Management Team, and (vi) Quality Committees.

Science Committee for Early Stage Research of Drug Candidates

Our Science Committee is composed of selected functional heads and members of the leadership, including Dr. Taylor B. Guo, Dr. Zheru Zhang, Dr. Joan Huaqiong Shen, Dr. Jane Meng, Yuan Meng, Dr. Weimin Tang, Dr. Chao Zhang and Dr. Zhengyi Wang, chaired by Dr. Taylor B. Guo. The Science Committee will collaborate with the management team to enhance our company's research practices and assist management in evaluating scientific aspects of potential in-licensing opportunities, collaborations and new technologies that may bolster our pipeline and research and development capabilities. The Science Committee's responsibilities include:

- approving the target review package submitted by our discovery group;
- providing governance on the quality and integrity of drug candidates, before entering into CMC process development;
- examining the experimental data and scientific evidence supporting the drug candidate;
- reviewing and making recommendations on our company's resource allocation in further development; and
- setting the direction for scientific and technical review of potential in-licensing opportunities.

Furthermore, our Corporate Compliance Function led by Mr. Thomas Song has taken a number of steps to review the integrity and reliability of the experimental data submitted with the selected drug candidate. The design, operation and monitoring of this data integrity program is integral to our quality control and assurance system, and is independent with respect to our research and development unit and Science Committee, to ensure the compliance with the principles of scientific data integrity, including controls over changes to, and deletions of source of data.

IND Scientific Advisory Committee for Drug Candidates Entering into Clinical Development Stage

Our IND Scientific Advisory Committee is composed of Dr. Joan Huaqiong Shen, Dr. Zheru Zhang, Dr. Jane Meng and Rebecca Zhang. The IND Scientific Advisory Committee is accountable for our IND application strategy and the data quality of our IND registration dossier before submission to the FDA, the NMPA and other comparable authorities. Our IND Scientific Advisory Committee advises the project team on policy matters and provides overall direction of new drug studies, and to that extent serves as a standing modality committee.

R&D Project/Program/Portfolio Governance ("IP3 Governance")

Our IP3 Governance is composed of Dr. Joan Huaqiong Shen, Dr. Zheru Zhang and Dr. Chao Zhang, with Dr. Joan Huaqiong Shen serving as the chair. Our IP3 Governance is a decision-making body that assesses and approves research and development portfolio strategy and execution proposals from a multi-discipline perspective, with an integrated approach incorporating scientific, clinical and commercial considerations. Our IP3 Governance aims to ensure that the project, program and/or portfolio-related decisions are logical, robust and repeatable and that our investments in research and development activities is aligned with our vision and strategy. The IP3 Governance responsibilities include:

- reviewing and determining the in-licensing and out-licensing strategic plan;
- performing reviews on critical research and development stage gates, including clinical asset selection, GLP pharmacology and toxicology studies, FIH studies, clinical development and regulatory submission; and
- reviewing product development strategy and monitoring project timeline and costs.

Medical Safety Council ("MSC")

Our MSC is composed of selected research and development functional heads and Subject Matter Experts, including Yuan Meng, Dr. Joan Huaqiong Shen, Michelle Yang, Rebecca Zhang, Dr. Taylor B. Guo, Dr. Jane Meng, Dr. Claire Xu and Zhengsong Zhang, chaired by Yuan Meng, Head of Medical Office. Our MSC is the highest medical safety governance body engaged in setting standards for protecting the medical safety of patients and users of our products, and providing strategic direction in product vigilance and patient or user safety. The MSC's responsibilities include:

- establishing standards and policies, and identifying best practices related to medical safety;
- providing oversight of all medical safety relevant activities, and overseeing the implementation of our company's medical safety standard, as well as the outcomes of the periodic audits;
- addressing safety information that could result in a significant change in the benefit-risk profile of our products; and
- reviewing and approving FIH studies and any other issues with respect to the safety of human exposure during early development stage.

Safety Management Teams ("SMT") for Product-Related Safety System

Our SMT is composed of representatives from each research and development function, including Yuan Meng, program lead, clinical physician (on program level), representatives of regulatory affairs (on program level), representatives of project management (on project level), external business partner (if applicable) and representatives of medical affairs (if applicable), chaired by Yuan Meng. The SMT is a product-based, cross-functional collaborative team responsible for the review and evaluation of medical safety data arising from any source throughout the product lifecycle. Our SMT performs assessments to identify changes in safety profiles or potential safety signals. Based on these safety evaluations, the SMT will determine the appropriate safety-related actions to be taken with respect to the product based on its benefit-risk profile for subjects in clinical trials and for patients treated with the marketed product.

Our SMT works closely with and escalates safety issues, as appropriate, to the MSC to fulfill our medical safety obligations. Our SMT is responsible for reviewing available safety information from multiple sources on a regular basis and make final decisions on safety in a timely manner with appropriate cross-functional input.

Quality Committees

We have formed two Quality Committees, namely, I-Mab Biopharma Quality Management Review and R&D Quality Council.

I-Mab Biopharma Quality Management Review ("I-Mab QMR") is composed of Dr. Joan Huaqiong Shen, Dr. Zheru Zhang, Yuan Meng, Thomas Song and Rebecca Zhang, co-chaired by R&D Quality Assurance officer Yuan Meng and CMC Quality Assurance officer Jack Qin. I-Mab QMR is a company-level cross-functional senior leadership meeting to provide management oversight of our company's Quality Management System ("QMS") and the compliance status of our company's regulated activities with applicable laws, regulations, policies and procedures, focusing on R&D and CMC GXP activities. To ensure our Corporate Quality Plan is set, key QMS elements are established and maintained, quality requirements are met, and trends, changes and risks are identified and addressed proactively.

R&D Quality Council is composed of representatives from each research and development function, including Dr. Joan Huaqiong Shen, Niri Wu, Yuan Meng, Michelle Yang, Dr. Claire Xu, Dr. Jane Meng, Rebecca Zhang and heads of therapeutic areas (in China and the United States), chaired by Dr. Joan Huaqiong Shen. R&D Quality Council is a governance body that oversees the performance of the QMS and serves as the final decision-making body for critical quality issues that affect subject and patient safety, data integrity and compliance with global and local regulatory authorities. The QMS encompasses the structure, responsibilities and procedures that enable the organization to identify, measure, control and enhance core regulated processes and activities.

Code of Conduct

We have adopted a Code of Conduct that is applicable to many aspects of our business operation, such as business ethics, responsible research and development activities, IP and data protection, workplace ethics and other corporate governance topics, as well as implementing high ethical standards that are mandatory for our employees. In addition, we have adopted an employee handbook which describes the compliance management system implemented at I-Mab to ensure compliance with applicable legal and regulatory requirements.

Quality Control and Assurance

In addition to the research and development governance regime described above, we have established an independent quality control and assurance system and devote significant attention to quality control for the designing, manufacturing and testing of our drug candidates. Our Assurance Board is composed of Dr. Joan Huaqiong Shen, Dr. Zheru Zhang and Thomas Song. Our senior management is firmly committed to delivering our quality performance, actively involved in allocating sufficient resources to quality management system and setting quality governance mechanism.

For pre-clinical and clinical trials, the overall quality management outlines the implementation of our business policies and procedures in order to consistently comply with the regulatory requirements, including Good Laboratory Practices, or GLP; Good Clinical Practices, or GCP; Good Pharmacovigilance Practice, or GVP and other applicable regulatory requirements in the performance of the trials. This includes:

- predefined policies and procedures to manage pre-clinical and clinical studies;

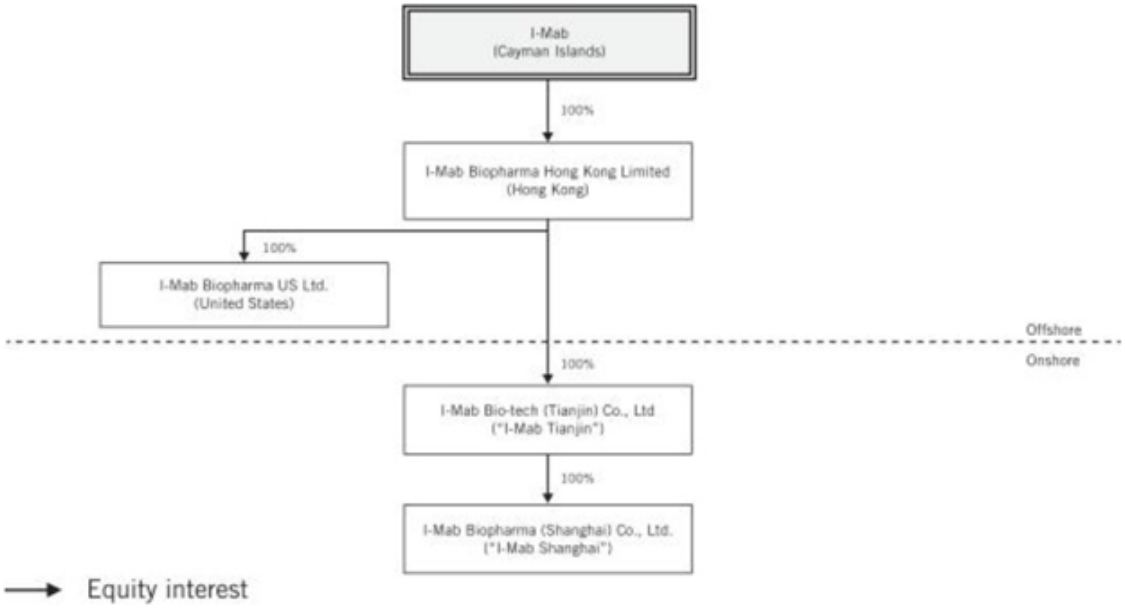
- dedicated resources and personnel with well delineated roles and responsibilities;
- quality risk management across the product lifecycle;
- continuous quality management system improvement;
- non-conformance management via quality issue management process;
- development and execution of quality audit program; and
- regulatory inspection readiness.

For CMC, we have established a quality management system to oversee the process development and API and drug production at the CDMOs. This system takes a holistic approach bringing senior management, quality assurance team and company policies together to create an efficient and agile quality culture. Our CMC quality commitment includes, but not limited to:

- ensure that the product manufacturing, releasing, packaging, storage, and shipment meets all specifications and the requirements of the FDA and/or NMPA's quality system regulations, cGMP or other applicable laws and regulations;
- review of process deviations and changes, root cause analysis, impact assessment, corrective and preventative actions, and validation;
- ensure the consistency of key quality practices with our CDMOs;
- proactive quality system review based on audits, process data analysis, equipment condition, and periodic review of internal and external sources of data; and
- assessment of regulatory guidance and ensure readiness for regulatory inspections.

C. Organizational Structure

The following chart illustrates our company's organizational structure, including our principal subsidiaries, as of March 31, 2018:



D. Property, Plant and Equipment

Our headquarter is located in Shanghai, China, where we lease and occupy approximately 2,866 square meters as office space and laboratories. We currently lease approximately 435 square meters of office space in Beijing, approximately 54 square meters of office space in Tianjin, approximately 49 square meters of office space in Chengdu, approximately 292 square meters of office space and laboratories in Hong Kong, and approximately 441 square meters of office space and laboratories in Maryland. The terms of these leases range from one year to five years.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes included elsewhere in this annual report on Form 20-F. This discussion may contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Item 3. Key Information—D. Risk Factors" or in other parts of this annual report on Form 20-F.

A. Operating Results

Overview

We are a clinical stage biopharmaceutical company committed to the discovery, development and commercialization of novel or highly differentiated biologics to treat diseases with significant unmet medical needs, particularly cancers and autoimmune disorders. To date, we have developed an innovative pipeline of more than 10 clinical and preclinical stage assets through our internal research and development efforts and in-licensing arrangements with global pharmaceutical and biotech companies.

Our research and development capabilities encompass discovery, translational medicine, biologics CMC development, pre-clinical development and clinical development with footprints in Shanghai, Beijing and the United States. We are now at a critical juncture to transition from a clinical stage biotech company into a fully integrated end-to-end global biopharmaceutical company in the next few years.

Since the commencement of our operation in 2014, we have devoted most of our efforts and financial resources to organize and staff our operations, business planning, raise capital, establish our intellectual property portfolio and conduct pre-clinical and clinical trials of our drug candidates.

We have not generated any revenue from product sales, and as a result, we have never been profitable and have incurred net losses since the commencement of our operations. In 2017, 2018 and 2019, our net losses were RMB298.2 million, RMB402.8 million and RMB1,452.0 million (US$208.6 million), respectively. We do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize a drug candidate, and we cannot assure you that we will ever generate significant revenue or profits.

Key Factors Affecting Our Results of Operations

Our results of operations, financial condition, and the year-to-year comparability of our financial results have been, and are expected to continue to be, principally affected by the below factors:

Cost and Expenses Structure

Our results of operations are significantly affected by our cost structure, which primarily consists of research and development expenses and administrative expenses.

Research and development activities are central to our business model. We believe our ability to successfully develop drug candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high-quality drug candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Since our inception, we have focused our resources on our research and development activities, including conducting pre-clinical studies and clinical trials, and activities related to regulatory filings for our drug candidates. Our research and development expenses primarily include the following:

- costs related to development of our pipeline assets under all stages including discovery, pre-clinical testing or clinical trials;
- patent license fees and other fees under the licensing, collaboration and development agreements with respect to our in-licensed drug candidates; and
- employee salaries and related benefit costs, including share-based compensation expenses, for research and development personnel and key management.

At this time, we are unable to predict when, if ever, we will be able to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. This is due to the numerous risks and uncertainties associated with developing such drug candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing the drug candidates, if and when approved, whether alone or in collaboration with others;

- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drug candidates;
- continued acceptable safety profiles of the products following approval; and
- retention of key research and development personnel.

Any change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs, timing and viability associated with the development of that drug candidate. We expect research and development costs to continue to increase for the foreseeable future as we expand our operations and our development programs progress, including as we continue to support and advance the clinical trials of our drug candidates.

Our administrative expenses consist primarily of employee salaries and related benefit costs. Other administrative expenses include professional fees for consulting and auditing as well as other direct and allocated expenses for rental expenses for our facilities, travel costs and other supplies used in administrative activities. We expect our administrative expenses to increase in the future to support our pipeline assets and research and development efforts, and the commercialization of our drug candidates once approval is obtained. We also anticipate that our administrative expenses will increase as we operate as a public company.

Revenue from Out-Licensing Agreements

We continue to seek out-licensing opportunities for our de-prioritized assets to streamline our pipeline. In 2017, 2018 and 2019, our revenue consisted primarily of payments from granting licenses to use and otherwise exploit certain of our intellectual properties linked to our de-prioritized assets. See “Item 4. Information on the Company—B. Business Overview—Licensing and Collaboration Arrangements” for more information on the existing out-licensing arrangements. In addition, after validating clinical safety and preliminary efficacy of a drug candidate in our Global Portfolio in clinical trials in the United States, we may elect to out-license the global rights (excluding Greater China) of such drug candidate, while retaining the Greater China rights for further development and commercialization. But we may also choose to retain these rights for the United States or other countries or regions as we may deem fit. Before the commercialization of one or more of our drug candidates, we expect that the majority of our revenue will continue to be generated from out-licensing our intellectual properties.

Funding for Our Operations

During the periods presented, we funded our operations primarily from financing through the issuance and sale of preferred shares and convertible promissory notes in private placement transactions. Going forward, in the event of successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with revenue generated from sales of our commercialized drug products. However, with the continuing expansion of our business and our product pipeline, we may require further funding through public or private offerings, debt financing, collaboration, and licensing arrangements or other sources. Any fluctuation in our ability to fund our operations will impact our cash flow plan and our results of operations.

Our Ability to Commercialize Our Drug Candidates

Our business and results of operations depend on our ability to commercialize our drug candidates, once and if those candidates are approved for marketing by the respective health authority. Currently, our pipeline consists of more than ten drug candidates ranging in development status from pre-clinical to late-stage clinical programs. Although we currently do not have any product approved for commercial sale and have not generated any revenue from product sales, we expect to generate revenue from sales of a drug candidate after we complete the clinical development, obtain regulatory approval, and successfully commercialize such drug candidate. Our late-stage investigational drugs at or potentially near pivotal trials are TJ202, TJ101, TJ301 and enoblituzumab. See “Item 4. Information on the Company—B. Business Overview—Our Drug Pipeline” for more information on the development status of our various drug candidates.

The Effect of Our Acquisition of I-Mab Tianjin

We acquired a controlling interest in I-Mab Tianjin on July 15, 2017 and the remaining interest in I-Mab Tianjin in May 2018. Since our acquisition of the controlling interest in I-Mab Tianjin on July 15, 2017, I-Mab Tianjin has been consolidated into our results of operations. Shortly after we acquired the controlling interest in I-Mab Tianjin, we integrated the operations of I-Mab Tianjin into our operations.

I-Mab Tianjin did not generate any external revenue from July 15, 2017 to December 31, 2019. In connection with our acquisition of I-Mab Tianjin, we identified RMB148.8 million of intangible assets and RMB162.6 million of goodwill of I-Mab Tianjin. Goodwill is not amortized, but impairment of goodwill assessment is performed on an least an annual basis on December 31 or whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. No impairment was identified as of December 31, 2017, 2018 and 2019. Impairment charges could substantially affect our results of operations in the periods of such charges. In addition, impairment charges would negatively impact our financial ratios and could limit our ability to obtain financing in the future. See “Item 3. Key Information—D. Risk Factors—Risks Related to Our Industry, Business and Operations—Change in business prospects of acquisitions may result in impairment to our goodwill, which could negatively affect our reported results of operations.”

Impact of the COVID-19 Outbreak

Since the end of December 2019, a novel strain of coronavirus has surfaced in the city of Wuhan, China. The virus causes the outbreak of pneumonia-like illness named COVID-19 (the “COVID-19 outbreak”), which has been rapidly spreading through and outside of Wuhan. Several cities in China and the United States have been under a lockdown and/or have imposed travel restrictions in an effort to curb the spread of the highly infectious COVID-19. We believe the COVID-19 outbreak has not significantly impacted our ability to carry out our obligations under existing contracts or disrupted any supply chains that we rely upon. Our operations in China are in conjunction with hospitals located in regions that were relatively less affected by COVID-19. However, as research hospitals and government agencies focus clinical resources on the pandemic, we believe there could be some delays in regulatory interactions and inspections, and patient recruitment and participation. Similarly, the worsening situation of COVID-19 in the United States may cause some delays in the on-going clinical trials in the United States. On the other hand, our clinical trials in both the U.S. and China involve many clinical sites and hospitals located in many different regions.

While the extent to which the COVID-19 outbreak will affect our operations cannot be predicted at this stage, we have not experienced and do not expect significant financial damage or impact to our long-term commercial prospect from the COVID-19 outbreak. At the present time, the COVID-19 situation has improved in China, and we will continue to execute on its regulatory and clinical development goals in China and the United Staets. We cannot guarantee you, however, that the COVID-19 outbreak will not further escalate or have a material adverse effect on our results of operations.

We have employed various measures to mitigate the impact of the COVID-19 outbreak on our ongoing clinical trials, including supplying enrolled patients with study medication at the early stage of the outbreak, continuing patient enrollment through remote access, and engaging frequent communications with our principal investigators to identify and address any issues that may arise. Although we experienced minor delays in data entry for some of our trials at the beginning of the COVID-19 outbreak due to difficulties in scheduling routine site visits, the situation has improved as short-duration site visits were adopted. We expect this situation to continue to improve with the containment of the COVID-19 outbreak and do not expect it to have any material long-term impact on the data quality of our clinical studies or our overall clinical development plans.

To minimize the impact of the COVID-19 outbreak, we have also implemented company-wide self-protection policies for employees to either working remotely or onsite with protective masks and sanitization. We currently do not anticipate any material deviation from our commercialization plans, as such plans are based upon FDA and NMPA approval timeline and nothing has come to our attention at this stage that the FDA or the NMPA review process is experiencing delays. We have also begun to consider digital promotion activities to explore online marketing as an avenue to facilitate anticipated product launch to ensure we are on schedule for our current commercialization plans.

Key Components of Results of Operations

Revenues

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales for the foreseeable future before the successful commercialization of one or more of our drug candidates.

We generated substantially all of our revenues for the years ended December 31, 2017, 2018 and 2019 from granting licenses to use and otherwise exploit certain of our intellectual properties in connection with our de-prioritized assets.

Research and Development Expenses

Research and development expenses primarily consist of: (i) payroll and other related expenses of research and development personnel, (ii) fees associated with the exclusive development rights of our in-licensed drug candidates, (iii) fees for services provided by contract research organizations, investigators and clinical trial sites that conduct our clinical studies, and (iv) expenses relating to the development of our drug candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses.

Our current research and development activities primarily relate to the clinical development of the following investigational drugs:

- TJ202, a potential highly differentiated CD38 antibody for multiple myeloma and autoimmune diseases, if approved;
- TJ107, the first long-acting recombinant human IL-7 with the potential for cancer treatment-related lymphopenia and cancer immunotherapy, if approved;
- TJ101, a potential highly differentiated long-acting growth hormone for growth hormone deficiency, if approved;
- TJ301, a potential highly differentiated IL-6 blocker for ulcerative colitis and other autoimmune diseases, if approved;
- Enoblituzumab, the most advanced clinical stage humanized B7-H3 antibody as a potential immuno-oncology treatment, if approved;
- TJC4, a potential highly differentiated CD47 monoclonal antibody with unique RBC-sparing differentiation, if approved;
- TJD5, a potential highly differentiated CD73 antibody for immuno-oncology, if approved; and
- TJM2, a GM-CSF monoclonal antibody for rheumatoid arthritis and CAR-T-related therapies, if approved.

We incurred research and development expenses of RMB267.1 million, RMB426.0 million and RMB840.4 million (US$120.7 million) for the years ended December 31, 2017, 2018 and 2019, respectively, representing 91.3%, 86.5% and 56.2% of our total research and development and administrative expenses for the corresponding periods. We expect our research and development expenses to continue to increase for the foreseeable future, as we continue to expand our operations and to advance our pipeline and our drug candidates toward later stages.

Administrative Expenses

Administrative expenses primarily consist of salaries and related benefit costs, including share-based compensation, for employees engaged in managerial and administrative positions or involved in general corporate functions, professional fees for consulting and auditing as well as other direct and allocated expenses for rental expenses for our facilities, travel costs and other supplies used in administrative activities. For the years ended December 31, 2017, 2018 and 2019, our administrative expenses amounted to RMB25.4 million, RMB66.4 million and RMB654.6 million (US$94.0 million), respectively.

Interest Expense

Interest expense consist primarily of interest expenses on our (i) short-term bank borrowings and (ii) convertible promissory notes issued to certain investors.

Interest Income

Interest income consists primarily of interest income derived from our term deposit and restricted cash pledged as collateral for a working capital loan.

Other Income (Expenses), Net

Other income consists primarily of income from other financial assets.

Other expenses consist primarily of the net loss resulting from the conversion of a portion of our convertible promissory notes and loss on the termination agreement with Everest.

Fair Value Change of Warrants

Fair value change of warrants consists primarily of the non-cash items incurred in connection with changes in the fair value of our warrant liabilities that we issued to certain investors.

Taxation

Cayman Islands

I-Mab, our holding entity, is incorporated in the Cayman Islands. The Cayman Islands currently has no income, corporation or capital gains tax and no estate duty, inheritance tax or gift tax. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

Hong Kong

I-Mab Biopharma Hong Kong Limited is incorporated in Hong Kong. Companies registered in Hong Kong are subject to Hong Kong profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with the relevant Hong Kong tax laws. The applicable tax rate is 16.5% in Hong Kong. For the years ended December 31, 2017, 2018 and 2019, I-Mab Biopharma Hong Kong Limited did not make any provisions for Hong Kong profit tax as there were no assessable profits derived from or earnings in Hong Kong for any of the periods presented. Under the Hong Kong tax law, I-Mab Biopharma Hong Kong Limited is exempted from income tax on its foreign-derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

Australia

I-Mab Biopharma Australia Pty Ltd is incorporated in Australia. Companies registered in Australia are subject to Australia profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with the relevant Australia tax laws. The applicable tax rate in Australia is 30%. I-Mab Biopharma Australia Pty Ltd has no taxable income for all periods presented, therefore, no provision for income taxes is required.

United States

I-Mab Biopharma US Ltd. is incorporated in Maryland and is subject to U.S. federal corporate income tax at a rate of 21%. It is also subject to state income tax in Maryland at a rate of 8.25%. I-Mab Biopharma US Ltd. has no taxable income for all periods presented and therefore no provision for income taxes is required.

China

On March 16, 2007, the National People's Congress of PRC enacted a new Corporate Income Tax Law ("new CIT law"), under which Foreign Investment Enterprises ("FIEs") and domestic companies would be subject to corporate income tax at a uniform rate of 25%. The new CIT law became effective on January 1, 2008. Under the new CIT law, preferential tax treatments will continue to be granted to entities which conduct businesses in certain encouraged sectors and to entities otherwise classified as "High and New Technology Enterprises."

I-Mab Shanghai has been qualified as a "High and New Technology Enterprise" and enjoys a preferential income tax rate of 15% from 2018 to 2020. Our company's other PRC subsidiaries are subject to the statutory income tax rate of 25%. No provision for income taxes has been accrued because all of our PRC subsidiaries are in cumulative loss positions for all the periods presented.

A valuation allowance is provided to reduce the amount of deferred tax assets if it is considered more likely than not that some portion or all of the deferred tax assets will not be realized in the foreseeable future. In making such determination, we evaluate a variety of positive and negative factors including our operating history, accumulated deficit, the existence of taxable temporary differences and reversal periods.

We have incurred net accumulated operating losses for income tax purposes since our inception. We believe that it is more likely than not that these net accumulated operating losses will not be utilized in the future. Therefore, we have provided full valuation allowances for the deferred tax assets as of December 31, 2017, 2018 and 2019.

We evaluate each uncertain tax position (including the potential application of interest and penalties) based on the technical merits, and measure the unrecognized benefits associated with the tax positions. As of December 31, 2017, 2018 and 2019, we did not have any significant unrecognized uncertain tax positions.

Results of Operations

The following table sets forth a summary of our consolidated results of operations for the periods indicated. This information should be read together with our consolidated financial statements and related notes included elsewhere in this annual report. The operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	For the Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$
	(in thousands, except for per share data)			
Summary Consolidated Statements of Comprehensive Loss Data:				
Revenues				
Licensing and collaboration revenue	11,556	53,781	30,000	4,309
Expenses				
Research and development expenses (1)	(267,075)	(426,028)	(840,415)	(120,331)
Administrative expenses (1)	(25,436)	(66,391)	(654,553)	(94,021)
Loss from operations	(280,955)	(438,638)	(1,464,968)	(210,430)
Interest income	858	4,597	30,570	4,391
Interest expense	(5,643)	(11,695)	(2,991)	(430)
Other income (expenses), net	1,527	(16,780)	(20,205)	(2,902)
Fair value change of warrants	(14,027)	61,405	5,644	811
Loss before income tax expense	(298,240)	(401,111)	(1,451,950)	(208,560)
Income tax expense	—	(1,722)	—	—
Net loss attributable to I-Mab	(298,240)	(402,833)	(1,451,950)	(208,560)

Deemed dividend to Series C-1 preferred shareholders extinguishment of Series C-1 Preferred Shares	—	—	(5,283)	(759)
Deemed dividend to Series B-1, B-2 and C preferred shareholders at modification of Series B-1, B-2 and C Preferred Shares	—	—	(27,768)	(3,989)
Net loss attributable to ordinary shareholders	(298,240)	(402,833)	(1,485,001)	(213,308)
Other comprehensive income				
Foreign currency translation adjustments, net of nil tax	5,918	53,689	10,747	1,544
Total comprehensive loss attributable to I-Mab	**(292,322)**	**(349,144)**	**(1,441,203)**	**(207,016)**
Net loss attributable to ordinary shareholders	**(298,240)**	**(402,833)**	**(1,485,001)**	**(213,308)**
Weighted-average number of ordinary shares used in calculating net loss per shares				
Basic and diluted	5,742,669	6,529,092	7,381,230	7,381,230
Net loss per share attributable to ordinary shareholders				
Basic	(51.93)	(61.70)	(201.19)	(28.90)
Diluted	(51.93)	(61.70)	(201.19)	(28.90)

Notes:

(1) Share-based compensation expenses were allocated as follows:

	FOR THE YEAR ENDED DECEMBER 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$
	(in thousands)			
Research and development expenses	2,112	1,056	470	68
Administrative expenses	4,927	2,464	514,733	73,936
Total	**7,039**	**3,520**	515,203	74,004

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Revenues

Our revenues generated from licensing and collaboration decreased by 44.2% from RMB53.8 million for the year ended December 31, 2018 to RMB30.0 million (US$4.3 million) for the year ended December 31, 2019. Our revenues generated for the year ended December 31, 2018 consisted of both HDYM's milestone payment and ABL Bio's upfront payment to us pursuant to our out-licensing arrangements with them, respectively. Our revenues generated for the year ended December 31, 2019 solely consisted of CSPC entity's upfront and milestone payments to us pursuant to our out-licensing arrangement with CSPC entity.

Research and Development Expenses

The following table sets forth a breakdown of the major components of our research and development expenses in absolute amounts and as a percentage of our total research and development expenses for the periods indicated:

	For the Year Ended December 31,				
	2018		2019		
	RMB	%	RMB	US$	%
	(in thousands, except percentages)				
CRO service fees	212,278	49.8	521,920	74,969	62.1
In-licensed patent right fees	108,794	25.5	166,844	23,966	19.9
Employment benefit expenses	56,630	13.3	106,313	15,271	12.7
Material costs for drug candidates	19,652	4.6	6,117	879	0.7
Other expenses	28,674	6.8	39,221	5,633	4.6
Total	426,028	100.0	840,415	120,718	100.0

Our research and development expenses increased by 97.3% from RMB426.0 million for the year ended December 31, 2018 to RMB840.4 million (US$120.7 million) for the year ended December 31, 2019, primarily attributable to (i) an increase in the CRO service fees from RMB212.3 million for the year ended December 31, 2018 to RMB521.9 million (US$75.0 million) for the year ended December 31, 2019, as we initiated a few more research and development programs and advanced some of our existing investigational drugs into more advanced clinical development stages; (ii) an increase in in-licensed patent right fees from RMB108.8 million for the year ended December 31, 2018 to RMB166.8 million (US$24.0 million) for the year ended December 31, 2019, mainly due to upfront fees paid to MacroGenics; and (iii) an increase in employee benefit expenses of employees involved in research and development from RMB56.6 million for the year ended December 31, 2018 to RMB106.3 million (US$15.3 million) for the year ended December 31, 2019, due to an increase in the headcount.

In 2019, 87.3% and 12.7% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. In 2018, 72.3% and 27.7% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. In 2019, TJ202 represented approximately 41.4% of our external research and development expenses, which primarily included licensing fees and payments to CROs and CMOs. In 2018, TJ107 and TJ202 represented approximately 25.0% and 9.9% of our external research and development expenses, which primarily included licensing fees and payments to CROs and CMOs. No other programs represented a significant amount of research and development expenses in 2019 and 2018. Though we manage our external research and development expenses by program, we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any time.

Administrative Expenses

Our administrative expenses increased from RMB66.4 million for the year ended December 31, 2018 to RMB654.6 million (US$94.0 million) for the year ended December 31, 2019, primarily attributable to (i) RMB365.3 million (US$52.5 million) in connection with stock options granted to a director of our company under the 2018 Plan which were immediately vested, (ii) RMB148.3 million (US$21.3 million) in connection with repurchase of share awards held by a director of our company, (iii) the increase in employee benefit expenses by RMB7.9 million (US$1.1 million) due to headcount increase, and (iv) the increase in third-party professional expenses by RMB41.4 million (US$5.9 million).

Interest Income

We recorded RMB4.6 million of interest income for the year ended December 31, 2018 and RMB30.6 million (US$4.4 million) of interest income for the year ended December 31, 2019. The change was primarily attributable to the interest income derived from bank deposits.

Interest Expense

We recorded RMB11.7 million of interest expense for the year ended December 31, 2018 and RMB3.0 million (US$0.4 million) of interest expense for the year ended December 31, 2019. The change was primarily attributable to the interest expense related to our convertible promissory notes, which were converted in June and July 2018.

Other Income (Expenses), Net

We recorded RMB16.8 million of other expenses for the year ended December 31, 2018 and RMB20.2 million (US$2.9 million) of other income for the year ended December 31, 2019. The change was primarily attributable to the conversion of our convertible promissory notes and onshore convertible loans and loss on the termination agreement with Everest in 2019.

Fair Value Change of Warrants

We recorded a gain from change in the fair value of warrant liability of RMB61.4 million for the year ended December 31, 2018 and RMB5.6 million (US$0.8 million) for the year ended December 31, 2019. The change was primarily attributable to the change in fair value of warrants due to the increase in the valuation of our company.

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

Revenues

Our revenues generated from licensing and collaboration increased by 365.4% from RMB11.6 million for the year ended December 31, 2017 to RMB53.8 million for the year ended December 31, 2018. Our revenues generated for the year ended December 31, 2017 consisted solely of HDYM's milestone payment to us pursuant to our out-licensing arrangement with it. Our revenues generated for the year ended December 31, 2018 consisted of both HDYM's milestone payment and ABL Bio's upfront payment to us pursuant to our out-licensing arrangements with them, respectively.

Research and Development Expenses

The following table sets forth a breakdown of the major components of our research and development expenses in absolute amounts and as a percentage of our total research and development expenses for the periods indicated:

	For the Year Ended December 31,			
	2017		2018	
	RMB	%	RMB	%
	(in thousands, except percentages)			
CRO service fees	83,047	31.1	212,278	49.8
In-licensed patent right fees	134,846	50.5	108,794	25.5
Employment benefit expenses	26,799	10.0	56,630	13.3
Material costs for drug candidates	10,393	3.9	19,652	4.6
Other expenses	11,990	4.5	28,674	6.8
Total	267,075	100.0	426,028	100.0

Our research and development expenses increased by 59.5% from RMB267.1 million for the year ended December 31, 2017 to RMB426.0 million for the year ended December 31, 2018, primarily attributable to (i) an increase in the CRO service fees from RMB83.0 million in 2017 to RMB212.3 million in 2018, as we initiated a few more research and development programs and advanced some of our existing investigational drugs into more advanced clinical development stages; and (ii) an increase in employee benefit expenses of employees involved in research and development from RMB26.8 million in 2017 to RMB56.6 million in 2018, due to an increase in the headcount.

In 2018, 72.3% and 27.7% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. In 2017, 77.5% and 22.5% of our total research and development expenses were attributable to clinical programs and pre-clinical programs, respectively. In 2018, TJ107 and TJ202 represented approximately 25.0% and 9.9% of our external research and development expenses, which primarily included licensing fees and payments to CROs and CMOs. In 2017, TJ202 represented approximately 59.1% of our external research and development expenses, which primarily included licensing fees and payments to CROs and CMOs. No other programs represented a significant amount of research and development expenses in 2018 and 2017. Though we manage our external research and development expenses by program we do not allocate our internal research and development expenses by program because our employees and internal resources may be engaged in projects for multiple programs at any time.

Administrative Expenses

Our administrative expenses increased from RMB25.4 million for the year ended December 31, 2017 to RMB66.4 million for the year ended December 31, 2018, primarily attributable to (i) the increase in employee benefit expenses due to headcount increase, and (ii) the increase in third-party professional expenses.

Interest Income

We recorded RMB0.9 million of interest income for the year ended December 31, 2017 and RMB4.6 million of interest income for the year ended December 31, 2018. The change was primarily attributable to the interest income derived from our bank deposits.

Interest Expense

We recorded RMB5.6 million of interest expense for the year ended December 31, 2017 and RMB11.7 million of interest expense for the year ended December 31, 2018. The change was primarily attributable to (i) the interest expense accrued on the one-year bank borrowing facilities we entered into in the third quarter of 2017 and 2018, respectively; and (ii) the interest expense related to our convertible promissory notes, which were converted in June and July 2018.

Other Income (Expenses), Net

We recorded RMB1.5 million of other income for the year ended December 31, 2017 and RMB16.8 million of other expenses for the year ended December 31, 2018. The change was primarily attributable to the net loss resulting from the conversion of a portion of our convertible promissory notes, partially offset by an increase in the income from the other financial assets.

Fair Value Change of Warrants

We recorded a loss from change in the fair value of warrant liability of RMB14.0 million for the year ended December 31, 2017, and a gain from change in the fair value of warrant liability of RMB61.4 million for the year ended December 31, 2018. The change was primarily attributable to (i) the change in fair value of warrants due to the increase in the valuation of our company, and (ii) the modification in 2018 that added certain forfeiture conditions to the warrants, which increased the possibility of forfeiture of the warrants and therefore resulted in a reduction in our warrant liabilities.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities and other intangible assets as well as subsequent fair value measurements. Additionally, estimates are used in determining items such as useful lives of property, equipment and software, impairment of contract assets and other receivables, leases, tax valuation allowances and revenues from licensing and collaboration arrangements. We base the estimates on historical experience, known trends and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimates.

Revenue Recognition

We adopted Accounting Standard Codification (“ASC”) 606, Revenue from Contracts with Customers (Topic 606) (“ASC 606”) for all periods presented. Consistent with the criteria of Topic 606, we recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to receive in exchange for those goods or services.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of ASC 606 at contract inception, we audit the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Collaboration Revenue

At contract inception, we analyze its collaboration arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine if the collaboration is deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For the collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently.

Our collaborative arrangements may contain more than one unit of account, or performance obligation, including grants of licenses to intellectual property rights, agreement to provide research and development services and other deliverables. The collaborative arrangements do not include a right of return for any deliverable. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. In developing the stand-alone selling price for a performance obligation, we consider competitor pricing for a similar or identical product, market awareness of and perception of the product, expected product life and current market trends. In general, the consideration allocated to each performance obligation is recognized when the respective obligation is satisfied either by delivering a good or providing a service, limited to the consideration that is not constrained.

When the timing of the delivery of product is different from the timing of payments made by the customers, we recognizes either a contract asset (performance precedes the contractual due date) or a contract liability (customer payment precedes performance). Our contractual payment terms are typically due in no more than 30 days from invoicing. In limited situations, certain customer contractual payment terms require us to bill in arrears; thus, we satisfy some or all of our performance obligations before we are contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. For example, certain of the contractual arrangements do not permit us to bill until the completion of the production of the samples. In other limited situations, certain customer contractual payment terms allow us to bill in advance; thus, we receive customer cash payment before satisfying some or all of its performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities.

Licenses of Intellectual Property

Upfront non-refundable payments for licensing our intellectual property are evaluated to determine if the license is distinct from the other performance obligations identified in the arrangement. For licenses determined to be distinct, we recognize revenues from non-refundable, up-front fees allocated to the license at a point in time, when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

Research and Development Services

The portion of the transaction price allocated to research and development services performance obligations is deferred and recognized as collaboration revenue over time as delivery or performance of such services occurs.

Milestone Payments

At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and to the extent that a significant reversal of cumulative revenue would not occur in future periods, estimates the amount to be included in the transaction price using the most likely amount method. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achieving such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Research and Development Expenses

Elements of research and development expenses primarily include: (1) payroll and other related expenses of personnel engaged in research and development activities, (2) in-licensed patent rights fee of exclusive development rights of drugs granted to us, (3) expenses related to pre-clinical testing of our technologies under development and clinical trials such as payments to contract research organizations ("CRO"), investigators and clinical trial sites that conduct our clinical studies, (4) expenses to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, and (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to our research and development services and have no alternative future uses.

We have acquired rights to develop and commercialize producdt candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a "business" as defined under U.S. GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval would be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. The conditions enabling capitalization of development expenses as an asset have not yet been met and, therefore, all development expenditures are recognized in profit or loss when incurred.

Share-Based Compensation

We grant restricted shares and stock options to eligible employees and account for share-based compensation in accordance with ASC 718, *Compensation — Stock Compensation.*

Employees' share-based compensation awards are measured at the grant date fair value of the awards and recognized as expenses (i) immediately at the grant date if no vesting conditions are required; (ii) for share-based awards granted with only service conditions, using the graded vesting method net of estimated forfeitures over the vesting period; or (iii) for share-based awards granted with service conditions and the occurrence of an initial public offering as performance condition cumulative share-based compensation expenses for the options that have satisfied the service condition should be recorded upon the completion of the initial public offering using the graded vesting method.

A change in any of the terms or conditions of share-based awards is accounted for as a modification of the awards. We calculate incremental compensation expense of a modification as the excess of the fair value of the modified awards over the fair value of the original awards immediately before its terms are modified at the modification date. For vested awards, we recognize incremental compensation cost in the period when the modification occurs. For awards not being fully vested, we recognize the sum of the incremental compensation expense and the remaining unrecognized compensation expense for the original awards over the remaining requisite service period after modification.

Share-based compensation in relation to the restricted shares is measured based on the fair market value of our ordinary shares at the grant date of the award. Prior to the listing, estimation of the fair value of our ordinary shares involves significant assumptions that might not be observable in the market, and a number of complex and subjective variables, including discount rate, and subjective judgments regarding our projected financial and operating results, its unique business risks, the liquidity of its ordinary shares and its operating history and prospects at the time the grants are made. Share-based compensation in relation to the share options is estimated using the Binominal Option Pricing Model. The determination of the fair value of share options is affected by the share price of our ordinary shares as well as the assumptions regarding a number of complex and subjective variables, including the expected share price volatility, risk-free interest rate, exercise multiple and expected dividend yield. The fair value of these awards was determined with the assistance from an independent valuation firm.

Restricted ordinary shares

During the year ended December 31, 2016, we issued 4,019,554 ordinary shares to Mr. Zang Jingwu Zhang, Ms. Qian Lili, Mr. Wang Zhengyi and Mr. Fang Lei (collectively the "Founders"), including the 369,301 shares which represented the equity interests of Third Venture held by the Founders, and we recorded share-based compensation expense of RMB18.7 million for issuance and grant of 3,650,253 ordinary shares to the Founders in June 2016.

In October 2016, the Founders entered into an arrangement with our other investors, and the 87,441 ordinary shares issued to the Founders in June 2016 were cancelled, and out of the remaining 3,932,113 ordinary shares held by the Founders, 70% became restricted and subject to service vesting conditions, that shall vest 20%, 20% and 30% over the next three years, respectively. By October 2019, all the restricted shares were vested.

Deferred share-based compensation was measured for the restricted shares using the estimated fair value of our ordinary shares of US$0.77 at the date of imposition of the restriction in October 2016, and was amortized to the consolidated statements of comprehensive loss by using graded vesting method over the vesting term of 3 years. The following table summarizes our Founders' restricted shares activities for the years ended December 31, 2017, 2018 and 2019:

	NUMBERS OF SHARES	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE
Outstanding at December 31, 2016	2,752,479	0.77
Vested	(786,423)	
Outstanding at December 31, 2017	1,966,056	0.77
Vested	(786,423)	
Outstanding at December 31, 2018	1,179,633	0.77
Vested	(1,179,633)	
Outstanding at December 31, 2019	—	—

The amounts of shared-based compensation expense in relation to the restricted ordinary shares recognized in the years ended December 31, 2017, 2018 and 2019 was RMB7,039 thousand, RMB3,520 thousand and RMB1,566 thousand, respectively.

Shared-based compensation expenses relating to restricted shares were included in:

	YEAR ENDED DECEMBER 31,			
	2017	2018	2019	
	RMB'000	RMB'000	RMB'000	US$'000
Research and development expenses	2,112	1,056	470	68
Administrative expenses	4,927	2,464	1,096	157
	7,039	3,520	1,566	225

Second Amended and Restated 2017 Employee Stock Option Plan (the "2017 Plan")

In October 2017, we adopted the 2017 Plan (as last amended and restated on December 25, 2019). Under the 2017 Plan, a maximum aggregate number of 13,376,865 shares that may be issued pursuant to all awards granted were approved. Stock options granted to an employee under the 2017 Plan will be exercisable upon the completion of a listing and the employee renders service to us in accordance with a stipulated service schedule starting from the employee's date of employment. Employees are generally subject to a three-year service schedule, under which an employee earns an entitlement to vest in 50% of the option grants on the second anniversary of the grant date, a vesting of the remaining fifty percent 50% on the third anniversary of the applicable grant date. The stock options under the 2017 Plan, to the extent then vested, shall become exercisable only upon the earlier of (i) a listing, and (ii) occurrence of a change in control.

On December 25, 2019, the 2017 Plan was approved by our shareholders and board of directors, pursuant to which, in connection with our initial public offiering, the maximum aggregate number of shares that may be granted pursuant to all awards under the 2017 Plan shall be adjusted in accordance with a formula pre-approved by the shareholders. In connection with above amendments to the 2017 Plan, each of our founders, namely, Zheru Zhang, Lili Qian, Zhengyi Wang and Lei Fang, is willing to irrevocably surrender by him or her, for no consideration, of a portion of the unvested options granted to him or her, which, if vested, would entitle him or her to acquire up to 130,000 ordinary shares of our company, par value US$0.0001 per share, at an exercise price of US$1.0, respectively, under the 2017 Plan (in respect of each individual, the "Founder's Surrendered Options"). On December 25, 2019, our board of directors approved that our company accepts all Founder's Surrendered Options from each of the founders, namely, Zheru Zhang, Lili Qian, Zhengyi Wang and Lei Fang, for no consideration, with effect immediately prior to the completion of the initial public offering and such surrendered options be cancelled with effect immediately prior to the completion of the initial public offering.

Prior to our completion of a listing, all stock options granted to an employee shall be forfeited at the time the employee terminates his employment with us. After we complete a listing, vested options not exercised by an employee shall be exercised until later of: (i) 90 days after the date when the options become exercisable, or (ii) 30 days after the date of cessation of employment or directorship, or such longer period as the board of directors may otherwise determine.

We granted 11,051,230, 1,470,000 and 640,000 stock options to employees, all with an exercise price of US$1, for the years ended December 31, 2017, 2018 and 2019, respectively. No options are exercisable as of December 31, 2017, 2018 and 2019.

The following table sets forth the stock options activities for the periods presented:

	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE US$	WEIGHTED AVERAGE REMAINING CONTRACTUAL TERM	AGGREGATE INTRINSIC VALUE US$'000
Outstanding as of December 31, 2016	—	—	—	—
Granted	11,051,230	1.00	—	—
Other addition (note)	710,366	0.06	—	—
Outstanding as of December 31, 2017	11,761,596	0.94	9.50	24,890
Granted	1,470,000	1.00	—	—
Forfeited	(226,000)	1.00	—	—
Outstanding as of December 31, 2018	13,005,596	0.95	8.61	70,129
Granted	640,000	1.00	—	—
Forfeited	(397,500)	1.00	—	—
Repurchased	(3,435,215)	1.00	—	—
Outstanding as of December 31, 2019	9,812,881	0.93	7.76	47,671
Exercisable as of December 31, 2019	—	—	—	—

Note: Other addition represented the modified share options that originally granted to two senior management employees in October 2016 (see "— other share-based compensation").

Stock options granted to the employees were measured at fair value on the dates of grant using the Binomial Option Pricing Model with the following assumptions:

	YEAR ENDED DECEMBER 31,		
	2017	2018	2019
Expected volatility	62.34%	61.32%-62.13%	54.64%
Risk-free interest rate (per annum)	2.32%	2.81%-3.06%	2.15%
Exercise multiple	2.80	2.80	2.80
Expected dividend yield	—	—	—
Contractual term (in years)	10	10	10

The expected volatility was estimated based on the historical volatility of comparable peer public companies with a time horizon close to the expected term of our options. The risk-free interest rate was estimated based on the yield to maturity of U.S. treasury bonds denominated in US$ for a term consistent with the expected term of our options in effect at the option valuation date. The expected exercise multiple was estimated as the average ratio of the stock price to the exercise price when employees would decide to voluntarily exercise their vested options. As we did not have sufficient information of past employee exercise history, it was estimated by referencing to a widely-accepted academic research publication. Expected dividend yield is zero as we have never declared or paid any cash dividends on its shares, and we do not anticipate any dividend payments in the foreseeable future. Expected term is the contract life of the option.

There were 640,000 stock options granted to employees under the 2017 Plan for the year ended December 31, 2019. Since the exercisability is dependent upon our initial public listing, and it is not probable that this performance condition can be achieved until our initial public listing is effective, no share-based compensation expense relating to the 2017 Plan was recorded for the years ended December 31, 2017, 2018 and 2019. We will recognize compensation expenses relating to options vested cumulatively upon the completion of the company's listing.

Second Amended and Restated 2018 Employee Stock Option Plan (the "2018 Plan")

On February 22, 2019, our company adopted the 2018 Plan (as last amended and restated on December 25, 2019). Under the 2018 Plan, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards is 14,005,745, and if we successfully list on an internationally recognized securities exchange for a qualified public offering by December 31, 2019, the maximum aggregate number of ordinary shares which may be issued shall be 15,452,620. On December 25, 2019, the 2018 Plan was approved by the shareholders and board of directors of our company, pursuant to which, in connection with offering, the maximum aggregate number of shares that may be granted pursuant to all awards under the 2018 Plan may be adjusted in accordance with a formula pre-approved by our shareholders. In connection with above amendments to the 2018 Plan, the director of our company, Dr. Jingwu Zhang Zang is willing to irrevocably surrender by him, for no consideration, of the right to acquire a certain amount of ordinary shares of our company, par value US$0.0001 per share, at an exercise price of US$1.0 pursuant to the options granted to him under the 2018 Plan (the "Dr. Zang's Surrendered Options"). On December 25, 2019, the board of directors of our company approved that our company accepts the irrevocable surrender of Dr. Zang's Surrendered Options for no consideration, with effect immediately prior to the completion of the initial public offering and such surrendered options be cancelled with effect immediately prior to the completion of the initial public offering. See "Item 6. Directors, Senior Management and Employees—Compensation of Directors and Executive Officers—Share Incentive Plans—Second Amended and Restated 2018 Employee Stock Option Plan."

Stock options granted to an employee under the 2018 Plan will be generally exercisable when our company completes a listing and the employee renders service to our company in accordance with a stipulated service schedule starting from the employee's date of employment. Employees are generally subject to a two-year vesting schedule consisting of a cliff vesting of 50% of the stock options on the first anniversary of the applicable vesting commencement date and a vesting of the remaining 50% on the second anniversary of the applicable vesting commencement date. If a listing occurs at any time prior to any stock option granted under the 2018 Plan becoming fully vested, to the extent such stock option has been granted and is outstanding, any such stock option shall vest in full with immediate effect upon the listing. Except as otherwise approved by the Board of Directors, any vested portion of the stock options shall become exercisable upon the earlier of six months after a listing or the occurrence of a change in control; provided, however, that in each case, no stock option of an employee shall become exercisable until the third anniversary of such employee's employment commencement date.

Pursuant to the board of director's approval of the 2018 Plan on February 22, 2019, the 10,893,028 stock options granted to a director of our company under the 2018 Plan were fully vested and exercisable upon the adoption of 2018 Plan. Out of these 10,893,028 stock options, 454,940 stock options were repurchased by our company (see Note 17 (d) to our consolidated financial statements for further details).

The amounts of shared-based compensation expense in relation to the aforementioned grant of stock options to a director of our company (except for those repurchased by our company as described in note 17 (d) to our consolidated financial statements) recognized in the year ended December 31, 2019 was RMB365,329, which were allocated to our administrative expenses.

The following table sets forth the stock options activities under the 2018 Plan for the year ended December 31, 2019:

	NUMBER OF SHARES	WEIGHTED AVERAGE EXERCISE PRICE US$	WEIGHTED AVERAGE REMAINING CONTRACTUAL TERM	AGGREGATE INTRINSIC VALUE US$
Outstanding as of January 1, 2019	—	—	—	—
Granted	13,991,528	1.00	—	—
Repurchased (Note 17 (d))	(454,940)	1.00	—	—
Outstanding as of December 31, 2019	13,536,588	1.00	8.86	64,840
Exercisable as of December 31, 2019	10,438,088	1.00	9.15	49,998

Stock options granted to certain directors and employees of our company were measured at fair value on the dates of grant using the Binomial Option Pricing Model with the following assumptions:

	YEAR ENDED DECEMBER 31, 2019
Expected volatility	54.64-56.31%
Risk-free interest rate (per annum)	2.15%-2.75%
Exercise multiple	2.80
Expected dividend yield	—
Contractual term (in years)	10

The expected volatility was estimated based on the historical volatility of comparable peer public companies with a time horizon close to the expected term of our company's options. The risk-free interest rate was estimated based on the yield to maturity of U.S. treasury bonds denominated in US$ for a term consistent with the expected term of our company's options in effect at the option valuation date. The expected exercise multiple was estimated as the average ratio of the stock price to the exercise price when employees would decide to voluntarily exercise their vested options. As our company did not have sufficient information of past employee exercise history, it was estimated by referencing to a widely-accepted academic research publication. Expected dividend yield is zero as our company has never declared or paid any cash dividends on its shares, and our company does not anticipate any dividend payments in the foreseeable future. Expected term is the contract life of the option.

Except for the aforementioned grant of stock options to a director of our company under the 2018 Plan, since the exercisability is dependent upon the listing, and it is not probable that this performance condition can be achieved until a listing, no share-based compensation expense related to the 2018 Plan was recorded for the year ended December 31, 2019. We will recognize compensation expenses relating to options vested cumulatively upon the completion of our listing.

Repurchase of share awards held by a director

On February 22, 2019, the amendment and restated 2017 equity incentive plan was approved by the Board of Directors of our company, pursuant to which only the 3,435,215 stock options held by a director of our company under the 2017 equity incentive plan became fully vested and exercisable on February 22, 2019. As a result of the performance condition being waived, the shares held by a director of our company were accounted for as a Type III modification where a condition that our company expects will not be satisfied is changed to a condition that our company expects will be satisfied.

Additionally, on the same day, our company repurchased such 3,435,215 stock options under the amendment and restated 2017 equity incentive plan that was held by a director of our company along with 454,940 of his stock options under the 2018 equity incentive plan for which the share awards also became fully vested and exercisable, at a total consideration of US$21,902 (equivalent to approximately RMB148,308) at an average share price of US$5.63 per share.

For the year ended December 31, 2019, our company recorded the total payment of US$21,902 (equivalent to approximately RMB148,308) as share-based compensation costs (included in administrative expenses) in the consolidated statement of comprehensive loss. There was no impact to the overall stockholder's equity balance as the amended shares vested immediately and were repurchased.

2019 Share Incentive Plan (the "2019 Plan")

On October 29, 2019, we adopted the 2019 Plan, which will become effective immediately prior to the completion of our initial public offering. Under the 2019 Plan, the maximum aggregate number of ordinary shares available for issuance shall initially be 100,000.

Other share-based compensation

In October 2017, in connection with the adoption of the 2017 Plan, we amended the stock option agreement with the two aforementioned employees, under which the stock options would become exercisable only upon the earlier of (i) a listing, and (ii) occurrence of a change in control that defined in the stock option agreements. As the modification of terms and conditions of share-based compensation were not beneficial to its employees, no further accounting impact was resulting from it.

Establishment of Biomaster Trust

Biomaster Trust was established under the trust deed, dated October 23, 2019, between us and TMF Trust (HK) Limited, or TMF Trust, as the trustee of the Biomaster Trust. Through the Biomaster Trust, our company's ordinary shares and other rights and interests under awards granted pursuant to the 2017 Plan and the 2018 Plan may be provided to certain recipients of equity awards. Upon satisfaction of the vesting conditions, TMF Trust will exercise the equity awards and transfer the relevant ordinary shares and other rights and interests under the equity awards to the relevant grant recipients with the consent of the advisory committee of Biomaster Trust. TMF Trust shall not exercise the voting rights attached to such ordinary shares unless otherwise directed by the advisory committee, whose members shall be appointed by our company. Our company has the power to direct the relevant activities of Biomaster Trust and has the ability to use its power over Biomaster Trust to affect its exposure to returns. Therefore, the assets and liabilities of Biomaster Trust are included in our consolidated statements of financial position.

Fair Value of Ordinary Shares—

We are required to estimate the fair value of the ordinary shares on grant dates of share-based compensation awards/share option to our employees and the issuance of financial instruments to investors. Therefore, our board of directors has estimated the fair value of our ordinary shares on various dates, with inputs from management, considering the third-party valuations. The valuations of our ordinary shares were performed using methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants Audit and Accounting Practice Aid Series: Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the AICPA Practice Guide.

In addition, our board of directors considered various objective and subjective factors, along with inputs from management and the independent third-party valuation firm, to determine the fair value of our ordinary shares, including: external market conditions affecting the biopharmaceutical industry, trends within the biopharmaceutical industry, the prices at which we sold convertible preferred shares, the superior rights and preference of the convertible preferred shares or other senior securities relative to our ordinary shares at the time of each grant and the likelihood of achieving a liquidity event such as an initial public offering. The option-pricing method was used to allocate the enterprise's value to preferred shares or other senior securities and ordinary shares, taking into account the guidance prescribed by the AICPA Practice Guide. This method treats ordinary shares and convertible preferred shares or other senior securities as call options on the enterprise's value, with exercise prices based on their respective payoffs upon a liquidity event.

In determining the enterprise's value, we applied the market approach/backsolve method based on pricing from recent transactions in our own securities. The basis for application of this method is our transactions in equity securities with unrelated parties or among unrelated parties themselves. No evidence is observed to indicate these transactions are not arm's-length transactions.

Our board of directors determined the fair value of our share options and the restricted shares as of the dates of grant, taking into consideration the various objective and subjective factors described above, including the conclusion of valuation of our ordinary shares as of dates close to the grant dates of our share options and the restricted shares. We computed the per share estimated fair value for share options based on the binomial option pricing model and the per share estimated fair value for restricted shares based on per share estimated fair value of ordinary shares as of the date of grant.

Once public trading market of the ADSs has been established in connection with the completion of our initial public offering, it is no longer necessary for our board of directors to estimate the fair value of our ordinary shares in connection with our accounting for granted share options and restricted shares.

Fair Value Measurements—

Our financial assets and liabilities primarily comprise of cash and cash equivalents, restricted cash, short-term investments, other financial assets, contract assets, other receivables, short-term borrowings, accruals and other payables and warrant liabilities. As of December 31, 2017, 2018 and 2019, except for short-term investments, other financial assets and warrants liabilities, the carrying values of these financial assets and liabilities approximated their fair values because of their generally short maturities. We report short-term investments, other financial assets and warrant liabilities at fair value at each balance sheet date and changes in fair value are reflected in the consolidated statements of comprehensive loss.

We measure our financial assets and liabilities using inputs from the following three levels of the fair value hierarchy. The three levels are as follows:

Level 1 inputs are unadjusted quoted prices in active markets for identical assets that the management has the ability to access at the measurement date.

Level 2 inputs include quoted prices for similar assets in active markets, quoted prices for identical or similar assets in markets that are not active, inputs other than quoted prices that are observable for the asset (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 includes unobservable inputs that reflect the management's assumptions about the assumptions that market participants would use in pricing the asset. The management develops these inputs based on the best information available, including the own data.

We measured our short-term investments, other financial assets and warrant liabilities at fair value on a recurring basis. As our short-term investments, other financial assets and warrant liabilities are not traded in an active market with readily observable prices, we use significant unobservable inputs to measure the fair value of short-term investments, other financial assets and warrant liabilities. These instruments are categorized in the Level 3 valuation hierarchy based on the significance of unobservable factors in the overall fair value measurement.

Recent Accounting Pronouncements

A list of recently issued accounting pronouncements that are relevant to us is included in note 2 "Principal Accounting Policies—2.26 Recent Accounting Pronouncements" of our consolidated financial statements included elsewhere in this annual report.

B. Liquidity and Capital Resources

Cash Flows and Working Capital

Since inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our losses have resulted from funding our research and development programs and administrative costs associated with our operations. We incurred net losses of RMB298.2 million, RMB402.8 million and RMB1,452.0 million (US$208.6 million) for the years ended December 31, 2017, 2018 and 2019, respectively. Our primary use of cash is to fund our research and development activities. We used RMB252.2 million, RMB280.7 million and RMB868.0 million (US$124.7 million) in cash for our operating activities for the years ended December 31, 2017, 2018 and 2019, respectively. Historically, we have financed our operations principally through proceeds from the issuance and sale of preferred shares and convertible promissory notes in private placement transactions. As of December 31 2019, we had cash, cash equivalents and restricted cash of RMB1,193.3 million (US$171.4 million). Our cash, cash equivalents and restricted cash consist primarily of cash in bank and on hand.

The following table sets forth the movements of our cash flows for the periods presented:

	Years Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$
	(in thousands)			
Summary Consolidated Statements of Cash Flow Data:				
Net cash used in operating activities	(252,157)	(280,705)	(867,982)	(124,678)
Net cash (used in) generated from investing activities	(157,665)	9,500	212,462	30,518
Net cash generated from financing activities	758,585	1,479,669	152,709	21,936
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(132)	59,754	15,163	2,178
Net increase (decrease) in cash, cash equivalents and restricted cash	348,631	1,268,218	(487,648)	(70,046)
Cash, cash equivalents and restricted cash, beginning of the year	64,082	412,713	1,680,931	241,451
Cash, cash equivalents and restricted cash, end of the year	412,713	1,680,931	1,193,283	171,405

We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future drug candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our drug candidates and begin to commercialize any approved products. We also expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our drug candidates, we expect to incur significant commercialization expenses for product sales, marketing and manufacturing. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations.

Based on our current operating plan, we believe that our current cash and cash equivalents will be sufficient to meet our current and anticipated working capital requirements and capital expenditures for at least the next 12 months. In that time, we expect that our expenses will increase substantially as we fund new and ongoing research and development activities and working capital needs. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

We may decide to enhance our liquidity position or increase our cash reserve for future operations and investments through additional financing. The issuance and sale of additional equity would result in further dilution to our shareholders and ADS holders, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as an ADS holder. The incurrence of indebtedness would result in increased fixed obligations and could result in operating covenants that would restrict our operations, which could potentially dilute your interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or drug candidates that we would otherwise prefer to develop and market ourselves.

As of December 31, 2019, 10.8% of our cash and cash equivalents were denominated in RMB and held in China. We may make additional capital contributions to our PRC subsidiaries, establish new PRC subsidiaries and make capital contributions to these new PRC subsidiaries, make loans to our PRC subsidiaries, or acquire offshore entities with business operations in China in offshore transactions. However, most of these uses are subject to PRC regulations and approvals. See “Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—PRC regulation of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay or prevent us from making loans to our PRC subsidiaries or making additional capital contributions to our wholly foreigned-owned subsidiaries in China, which could materially and adversely affect our liquidity and our ability to fund and expand our business” and “Use of Proceeds” for more information on the related PRC rules and regulations on the use of proceeds. In addition, the COVID-19 outbreaks may materially and adversely affect our ability to raise additional capital in future and our liquidity. See “Item 3. Key Information—3.D. Risk Factors—Risks Related to Our Business and Our Industry—Our business and results of operations could be adversely affected by public health crisis (including the COVID-19 global pandemic) and natural catastrophes or other disasters outside of our control in the locations in which we, our suppliers, CROs, CMOs and other contractors operate.”

We expect that the majority of our future revenues will be denominated in RMB. Under existing PRC foreign exchange regulations, payments of current account items, including profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior SAFE approval as long as certain routine procedural requirements are fulfilled. Therefore, our PRC subsidiaries are allowed to pay dividends in foreign currencies to us without prior SAFE approval by following certain routine procedural requirements. However, approval from or registration with competent government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. The PRC government may at its discretion restrict access to foreign currencies for current account transactions in the future.

Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 was RMB868.0 million (US$124.7 million). Our net loss was RMB1,452.0 million (US$208.6 million) for the same period. The difference between our net loss and our net cash used in operating activities was primarily attributable to certain non-cash expenses, including share-based compensation of RMB366.9 million (US$52.7 million) and loss on the termination agreement with Everest of RMB23.0 million (US$3.3 million), and changes in certain working capital items, including an increase in the research and development funding of RMB53.1 million (US$7.6 million), an increase in the accruals and other payables of RMB188.4 million (US$27.1 million), partially offset by an decrease in advance from customers of RMB14.2 million (US$2.0 million) and an decrease in repayments and other receivables of RMB48.8 million (US$7.0 million). The change in share-based compensation was attributable to the grant of stock options to a director of our company under the 2018 Plan.

Net cash used in operating activities for the year ended December 31, 2018 was RMB280.7 million. Our net loss was RMB402.8 million for the same period. The difference between our net loss and our net cash used in operating activities was primarily attributable to certain non-cash expenses or gains, including fair value gains of warrants of RMB61.4 million, and changes in certain working capital items, including (i) an increase in the research and development funding of RMB178.7 million and (ii) an increase in accruals and other payables of RMB55.6 million, partially offset by an increase in prepayments and other receivables of RMB76.3 million. The accruals and other payables principally consist of accrued external research and development activities related expenses and staff salaries and welfare payables. The change in fair value of warrant liabilities was attributable to the exercise of part of the warrants issued in 2017 and the modification in 2018 that added certain forfeiture conditions to the warrants. Prepayments and other receivables primarily consist of our prepayment to CRO partners and value-added tax recoverable.

Net cash used in operating activities for the year ended December 31, 2017 was RMB252.2 million. Our net loss was RMB298.2 million. The difference between our net loss and our net cash used in operating activities was primarily attributable to certain non-cash expenses or gains, including the fair value loss of warrant liabilities of RMB14.0 million, and changes in certain working capital items, including (i) an increase in contract liabilities of RMB15.8 million and (ii) a decrease in prepayments and other receivables of RMB8.8 million.

Investing Activities

Net cash generated from investing activities for the year ended December 31, 2019 was RMB212.5 million (US$30.5 million). The net cash increase was primarily attributable to RMB256.0 million (US$36.8 million) of the cash received from disposal of other financial assets and RMB134.0 million (US$ 19.2 million) of purchase of short-term investments, partially offset by RMB102.0 million (US$14.7 million) of proceeds from disposal of short-term investments.

Net cash generated from investing activities for the year ended December 31, 2018 was RMB9.5 million. The net cash increase was primarily attributable to RMB40.0 million of the cash received from disposal of other financial assets, partially offset by RMB30.0 million of the cash used in other financial assets.

Net cash used in investing activities for the year ended December 31, 2017 was RMB157.7 million. The net cash decrease was primarily attributable to RMB369.0 million of investments in other financial assets, partially offset by RMB133.0 million of proceeds from disposal of other financial assets and RMB93.3 million of cash acquired from acquisition of I-Mab Tianjin.

Financing Activities

Net cash generated from financing activities for the year ended December 31, 2019 was RMB152.7 million (US$21.9 million), primarily attributable to the proceeds from issurance of convertible preferred shares, net of issurance cost of RMB183.5 million (US$26.4 million) and the repayment of bank borrowings of RMB80.0 million (US$11.5 million), partially offset by the proceeds of bank borrowings of RMB50.0 million (US$7.2 million).

Net cash generated from financing activities in the year ended December 31, 2018 was RMB1,479.7 million , primarily attributable to (i) proceeds from issuance of RMB1,306.6 million convertible preferred shares and (ii) receipt of RMB132.3 million resulting from the exercise of warrants by investors.

Net cash generated from financing activities in the year ended December 31, 2017 was RMB758.6 million, primarily attributable to proceeds of our issuance of RMB346.5 million convertible preferred shares, RMB161.2 million redeemable non-controlling interest and RMB99.0 million proceeds from bank borrowings.

Capital Expenditures

Our capital expenditures were incurred for purposes of purchasing property, equipment and software. Our capital expenditures were RMB20.3 million, RMB14.4 million and RMB12.2 million (US$1.8 million) in the years ended December 31, 2017, 2018 and 2019, respectively.

Borrowings

As of December 31, 2019, our total borrowings were RMB50.0 million (US$7.2 million), consisting of a loan of RMB50,000 from China Merchant Bank Co., Ltd.

Holding Company Structure

We are a holding company with no material operations of its own. We currently conduct our operations primarily through our PRC subsidiaries. As a result, our ability to pay dividends depends upon dividends paid by our PRC subsidiaries. If our existing PRC subsidiaries or any newly formed ones incur debt on their own behalf in the future, the instruments governing their debt may restrict their ability to pay dividends to us. In addition, our wholly foreign-owned subsidiaries in China are permitted to pay dividends to us only out of its retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. Under PRC law, each of our subsidiaries and their subsidiaries in China is required to set aside at least 10% of its after-tax profits each year, if any, to fund certain statutory reserve funds until such reserve funds reach 50% of their registered capital. In addition, our wholly foreign-owned subsidiaries in China may allocate a portion of their after-tax profits based on PRC accounting standards to enterprise expansion funds and staff bonus and welfare funds at their discretion, and their subsidiaries may allocate a portion of their after-tax profits based on PRC accounting standards to a surplus fund at their discretion. The statutory reserve funds and the discretionary funds are not distributable as cash dividends. Remittance of dividends by a wholly foreign-owned company out of China is subject to examination by the banks designated by SAFE. Our PRC subsidiaries have not paid dividends and will not be able to pay dividends until they generate accumulated profits and meet the requirements for statutory reserve funds.

C. Research and Development, Patents and Licenses, Etc.

See “Item 4. Information on the Company—B. Business Overview— Intellectual Property” and “—R&D Governance.”

D. Trend Information

Other than as disclosed elsewhere in this annual report, we are not aware of any trends, uncertainties, demands, commitments or events since January 1, 2019 that are reasonably likely to have a material adverse effect on our net revenues, income, profitability, liquidity or capital resources, or that caused the disclosed financial information to be not necessarily indicative of future operating results or financial conditions.

E. Off-balance Sheet Arrangements

We have not entered into any financial guarantees or other commitments to guarantee the payment obligations of any third parties. In addition, we have not entered into any derivative contracts that are indexed to our shares and classified as shareholder's equity or that are not reflected in our consolidated financial statements. Furthermore, we do not have any retained or contingent interest in assets transferred to an unconsolidated entity that serves as credit, liquidity or market risk support to such entity. We do not have any variable interest in any unconsolidated entity that provides financing, liquidity, market risk or credit support to us or engages in leasing, hedging or product development services with us.

F. Tabular Disclosure of Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2019:

	TOTAL		LESS THAN 1 YEAR		1-3 YEARS		3-5 YEARS		MORE THAN 5 YEARS	
(in thousands)	RMB	US$	RMB	US$	RMB	US$	RMB	US$	RMB	US$
Operating lease commitments	15,437	2,217	7,634	1,095	7,502	1,078	120	18	181	26

Our operating lease commitments relate to leases for our office premises pursuant to non-cancellable operating lease agreements. Other than as shown above, we did not have any significant capital and other commitments, long-term obligations or guarantees as of December 31, 2019.

G. Safe Harbor

See "Forward-Looking Statements" on page 1 of this annual report.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth information regarding our directors and executive officers as of the date of this annual report.

DIRECTORS AND EXECUTIVE OFFICERS	AGE	POSITION/TITLE
Jingwu Zhang Zang, M.D., Ph.D.	64	Founder, Honorary Chairman and Director
Joan Huaqiong Shen, M.D., Ph.D.	58	Director and Chief Executive Officer
Zheru Zhang, Ph.D.	57	Director and President
Jielun Zhu	44	Director and Chief Financial Officer
Wei Fu	38	Director
Mengjiao Jiang	39	Director
Jie Yu	45	Director
Bing Yuan	51	Director
Chun Kwok Alan Au	47	Independent Director
Conor Chia-hung Yang	57	Independent Director
Pamela M. Klein	58	Independent Director
Lili Qian, Ph.D.	38	Vice President of Operations
Weimin Tang, Ph.D.	54	Executive Vice President of Global Business Development
Yunhan Lin, Ph.D.	42	Vice President of Corporate Development
Neil Warma	57	General Manager of I-Mab US

Jingwu Zhang Zang , M.D., Ph.D., is our founder, honorary chairman and director. Dr. Zang served as our chief executive officer from our inception to October 2019. Prior to founding our company, Dr. Zang served as the chief scientific officer and president of Simcere Pharmaceutical Group and Bioscikin Co., Ltd. from September 2013 to April 2016. Dr. Zang held senior management positions at GlaxoSmithKline (GSK), as the global senior vice president and head of GSK's Research and Development in China from April 2007 to June 2013. The academic career of Dr. Zang started in Dr. Willems Institute and University of Limburg in Belgium. Dr. Zang became a professor at Baylor College of Medicine in Houston and later joined the Chinese Academy of Sciences as the founding director of the Institute of Health Sciences and as a co-director of Institute Pasteur Shanghai, an independent non-profit life science institute to address public health problems in China, where he served as its director from October 2004 to September 2006. Dr. Zang also served as a director of Shanghai Institute of Immunology from June 2002 to April 2007. Dr. Zang received his M.D. from Shanghai Second Medical University (now part of Shanghai Jiaotong University) in 1984, and his Ph.D. in neuroimmunology from the University of Brussels in 1990. Dr. Zang conducted his post-doctoral work at Harvard Medical School in 1992, and obtained his U.S. medical license from the Texas Medical Board through a clinical residency at Baylor College of Medicine in Houston.

Joan Huaqiong Shen , M.D., Ph.D., has served as our head of discovery and clinical development since September 2017, as our director since July 2019 and as our chief executive officer since October 2019. Prior to joining our company, Dr. Shen served as the vice president and development head of Janssen Pharmaceutical Companies of Johnson & Johnson from September 2015 to September 2017. Dr. Shen was the chief medical officer and vice president in Jiangsu Hengrui Medicine, Co., Ltd. (SHA: 600276) from May 2013 to August 2015. Dr. Shen served as the head of the China clinical department and a senior director at Pfizer (China) Research and Development Co., Ltd. from August 2011 to May 2013. Prior to that, Dr. Shen worked as a senior medical director at Pfizer Inc. (NYSE: PFE) from November 2009 to August 2011. From August 2005 to November 2009, Dr. Shen was the medical director at Wyeth Research, a leading pharmaceutical company. Dr. Shen worked as a clinical research physician at Eli Lilly and Company (NYSE: LLY) from September 2003 to August 2005. Dr. Shen served as an adjunctive assistant professor in the department of psychiatry of the Indiana University School of Medicine from October 2003 to October 2005. She has also been a guest professor of Beijing University Clinical Research Institute since March 2018. Dr. Shen completed three fellowships in the Indiana University School of Medicine, one in endocrinology from August 1996 to July 1998, one in psychopharmacology and one in clinical pharmacology, both from January 2002 to September 2003. Dr. Shen obtained her U.S. medical license from the Indiana University School of Medicine through a clinical residency. Dr. Shen received her M.D. from Southeast University Medical College in 1983, master's degree in anatomy from West China University of Medical Sciences, currently Sichuan University School of Medicine in 1989, and her Ph.D. in anatomy/neuroscience from the Indiana University School of Medicine in 1996.

Zheru Zhang , Ph.D., has served as our director and president since September 2017. Prior to joining our company, Dr. Zhang served as the president at Tasgen Bio-tech (Tianjin) Co., Ltd. from November 2015 to April 2017, as the chief executive officer at Shanghai JMT-Bio Co., Ltd. from October 2012 to October 2015, as a vice president, research and development at Celltrion Inc. from March 2008 to October 2012, as a group leader for the development of analytics and drug products at Johnson & Johnson (NYSE: JNJ) from January 2006 to March 2008, and as a research investigator at Bristol-Myers Squibb Company from May 2000 to January 2006, focusing on bioanalytical development and protein therapeutics development, respectively. Dr. Zhang received his master's degree in chemistry from Suzhou University in 1991, and his Ph.D. in chemistry from University of Alberta in Canada in 2000.

Jielun Zhu has served as our chief financial officer since August 2018 and as our director since July 2019. Prior to joining our company, Mr. Zhu held positions as a managing director and the head of healthcare investment banking, Asia, at Jefferies Hong Kong Limited from December 2015 to July 2018, advising biotechnology and healthcare clients globally on initial public offerings, mergers and acquisitions and other strategic transactions. From August 2008 to December 2015, Mr. Zhu worked at the Deutsche Bank Group in its Hong Kong branch, with his last position being a director in the corporate finance division. He worked as an investment banker at UBS Investment Bank in Hong Kong from July 2007 to July 2008. Mr. Zhu received his bachelor's degree of arts with honors in mathematics-economics from Wesleyan University in May 2000 and master's degree in business administration from the Harvard Business School with Distinction in June 2007. Mr. Zhu was awarded the Chartered Financial Analyst (CFA) charter by the CFA Institute in January 2012.

Wei Fu has served as our director since June 2018. Mr. Fu was appointed by the C-Bridge entities pursuant to our shareholders agreement dated July 6, 2018. Mr. Fu has served as the chief executive officer and a managing partner of C-Bridge Capital Investment Management, Ltd. since April 2014. Mr. Fu currently also serves on the board of several private companies. From August 2011 to December 2013, Mr. Fu served as the general manager of the investment department at Far East Horizon International, a financial services organization. Mr. Fu served as a partner and the head of the Beijing office of Themes Investment Management Ltd, a private equity firm specializing in healthcare and environmental businesses, from July 2010 to July 2011. From March 2008 to April 2010, Mr. Fu worked as an associate director of the private equity department at Standard Chartered Business Consulting (Beijing) Co., Ltd, where he was mainly responsible for private equity investment in relation to infrastructure projects. Mr. Fu received his bachelor's degree in electrical engineering and business administration from Nanyang Technological University in Singapore in February 2005.

Mengjiao Jiang has served as our director since September 2017. Ms. Jiang was appointed by the C-Bridge entities pursuant to our shareholders agreement dated July 6, 2018. Ms. Jiang is a managing director of C-Bridge Capital Investment Management, Ltd., a healthcare-dedicated private equity firm, and has served as a partner and a managing director since January 2014. Ms. Jiang currently also serves on the board of several private companies. Ms. Jiang served as a director at International Far East Horizon International, a financial services organization, from March 2012 to December 2013. Prior to that, Ms. Jiang served at ARC China Inc. as a managing director from May 2008 to June 2011. Ms. Jiang received her bachelor's degree in economics with a political science double major from Wellesley College in Massachusetts in May 2003.

Jie Yu has served as our director since July 2019. Mr. Yu was appointed by the Tasly entities pursuant to our shareholders agreement dated July 6, 2018. Mr. Yu has served as the secretary of the board at Tasly Pharmaceutical Group Co., Ltd. since November 2016. Prior to that, Mr. Yu was a director of brand management office at China Minsheng Investment Co., Ltd., an international private capital investment group, from March 2015 to October 2016. Mr. Yu worked as the head of the brand management department and the head of Chinese media affairs department at Huawei Technologies Co., Ltd. from April 2001 to March 2015. Mr. Yu received his bachelor's degree in management from Harbin Normal University in 1998 and master's degree in management from Northeast Forestry University in 2001.

Bing Yuan has served as our director since April 2020. Mr. Yuan is a managing director of Hony Capital and a member of Hony Capital's executive committee, responsible for its equity investment operations. Mr. Yuan joined Hony Capital in April 2009 and has served as a managing director of the private equity department since January 2010. Prior to joining Hony Capital, Mr. Yuan served as a managing director of the direct investment department of Morgan Stanley Asia Limited from 2008 to 2009. Before that, Mr. Yuan served as a managing director of the investment banking division of Morgan Stanley Asia Limited from April 2004 to June 2008. Prior to that, Mr. Yuan served as a vice president with Credit Suisse First Boston in Hong Kong and New York from August 1998 to March 2004, focusing on corporate finance and merger & acquisitions transactions in the technology, media and telecom industry. During his investment banking time, Mr. Yuan assisted numerous prominent Chinese state-owned enterprises and private sector companies in completing their initial public offerings, corporate finance and merger & acquisition transactions. Mr. Yuan also worked as a financial analyst in project finance with Fieldstone Private Equity LLP in New York from 1993 to 1995. Mr. Yuan received his bachelor's degree in English from Nanjing University in July 1990 and received his master's degree in international relations in June 1993 and his Juris Doctor degree in June 1998 from Yale University.

Mr. Chun Kwok Alan Au has served as our director since January 2020. Mr. Au is the founder of GT Healthcare Group, a private equity platform focusing on cross border healthcare investments, and has served as the managing partner of GT Healthcare Group since September 2015. Mr. Au has served as a director of Cellular BioMedicine Group (Nasdaq: CBMG), a clinical-stage biopharmaceutical firm engaged in the development of immunotherapies for cancer and stem cell therapies for degenerative diseases, since November 2014. Mr. Au also has served as a panel member for the Entrepreneur Support Scheme (ESS Program) of the Innovation and Technology Fund of the Hong Kong SAR Government since 2014. Mr. Au was an advisor to Simcere Pharmaceutical Group, a leading pharmaceutical company in China (previously listed on NYSE: SCR, privatized in December 2013, when Mr. Au served as chairman of the special committee on the board of directors). Mr. Au was also a member of the board of China Nepstar Chain Drugstore Ltd. (NYSE: NPD, privatized in September 2016) from March 2013 to August 2016. Mr. Au served as the head of the Asia Healthcare Investment Banking of Deutsche Bank Group, advising healthcare IPOs and M&A in the region from April 2011 to December 2012. Prior to that, Mr. Au served as the executive director at JAFCO Asia Investment Group, responsible for healthcare investments in China from 2008 to 2010. Mr. Au worked at Morningside Group as a director in charge of healthcare investments in Asia from 2000 to 2005. Mr. Au received his bachelor's degree in psychology from Chinese University of Hong Kong in 1995 and his master's degree in management from Columbia Business School in New York in 2007. Mr. Au is a certified public accountant (CPA) in the U.S. and a chartered financial analyst (CFA). He is an associate member of the Hong Kong Institute of Financial Analysts and member of the American Institute of Certified Public Accountants.

Mr. Conor Chia-hung Yang has served as our director since January 2020. Mr. Yang is a co-founder of Black Fish Group Limited and has served as the president of Black Fish Group Limited since November 2017. Prior to that, Mr. Yang was the chief financial officer of Tuniu Corporation (Nasdaq: TOUR) from January 2013 to November 2017, the chief financial officer of E-Commerce China Dangdang Inc. from March 2010 to July 2012 and the chief financial officer of AirMedia Group Inc., currently known as AirNet Technology Inc., (Nasdaq: ANTE) from March 2007 to March 2010. Mr. Yang was the chief executive officer of Rock Mobile Corporation from 2004 to February 2007. From 1999 to 2004, Mr. Yang served as the chief financial officer of the Asia Pacific region for CellStar Asia Corporation. Mr. Yang was an executive director of Goldman Sachs (Asia) L.L.C. from 1997 to 1999. Prior to that, Mr. Yang was a vice president of Lehman Brothers Asia Limited from 1994 to 1996 and an associate at Morgan Stanley Asia Limited from 1992 to 1994. Mr. Yang currently serves as an independent director and chairman of the audit committee of each of China Online Education Group (NYSE: COE) and Ehang Holdings Limited (Nasdaq: EH). Mr. Yang received a master's degree of business administration from University of California, Los Angeles in 1992.

Dr. Pamela M. Klein has served as our director since January 2020. Dr. Klein currently serves a director of Spring Bank Pharmaceuticals, Inc. (Nasdaq: SBPH) since July 2019, a director of argenx SE (Nasdaq: ARGX) since April 2016 and a director of Patrys Limited (ASX: PAB) since October 2019. In addition, Dr. Klein has served as the president at PMK BioResearch since 2008, offering consultancy in Oncology Drug Development to Biotech, Pharma and the Investment Community. Previously, Dr. Klein served as Chief Medical Officer for successful biotech start-ups and prior to that, Vice President, Genentech, Development. Dr. Klein received her bachelor's degree in cell and molecular biology from California State University in 1985 and an M.D. from Stritch School of Medicine, Loyola University Chicago in 1992 followed by an internal medicine residency at Cedars Sinai, Los Angeles. Dr. Klein spent seven years at the National Cancer Institute of the NIH in Bethesda, Maryland in medical oncology.

Lili Qian , Ph.D., has served as the vice president of operations since June 2016 and our director from September 2017 to July 2019. Dr. Qian worked at Bioscikin Biopharma Technology Co., Ltd. from January 2016 to May 2016, serving as the secretary to the board of directors and president office manager. Prior to that, Dr. Qian held various positions at Simcere Pharmaceutical Group as the president assistant and a project management manager from October 2013 to December 2015, and as a business development manager from July 2013 to October 2013. She was the project leader of the national key laboratory of protein and plant genetic engineering at Peking University from September 2007 to June 2013. Dr. Qian received her bachelor's degree in biochemistry from University of British Columbia in 2005 and her Ph.D. in biochemistry and molecular biology from Peking University in 2013.

Weiming Tang , Ph.D., has served as our executive vice president of global business development since April 2018. Prior to joining our company, Dr. Tang served as an executive director and a business director at Hengrui Therapeutics, Inc. from July 2015 to April 2018. Dr. Tang served as the vice president and a business director at Crown Bioscience Inc., a pre-clinical contract research organization, from July 2011 to July 2015. Prior to that, Dr. Tang served as the vice president and a business director at ShanghaiBio Corporation Shanghai Biotechnology Cooperation, a biotech company based in Shanghai, from October 2010 to July 2011. Dr. Tang received his bachelor's degree in plant pathology from Zhejiang University in 1986, master's degree in microbiology from Chinese Academy of Sciences in 1989, and Ph.D. in biochemistry from Rutgers University, New Jersey in 1997.

Yunhan Lin , Ph.D., has served as our vice president of corporate development since September 2017. Prior to joining our company, Dr. Lin served as the head of business development at Mycenax Biotech Inc., a Taiwan-based public pharmaceutical company, from January 2016 to September 2017. Prior to that, Dr. Lin served as the head of business development at SynCore Biotechnology Co., Ltd, a Taiwan-based public biopharmaceutical company, from February 2012 to December 2015. Dr. Lin worked as a science project deputy manager at Sinphar Pharmaceutical Co, Ltd., a Taiwan-based pharmaceutical company, from September 2001 to January 2012. Dr. Lin received his bachelor's degree in applied chemistry from Providence University, Taiwan in 2000, master's degree in chemistry from Fu Jen Catholic University, Taiwan in 2003, and Ph.D. in chemistry from Tamkang University, Taiwan in 2008.

Neil Warma has served as the general manager of I-Mab US since September 2019. Mr. Warma is currently an advisor to several companies and serves on the board of directors of several biotechnology companies and BioHouston, a non-profit tax-exempt 501(c)(3) corporation founded by Houston area academic/research institutions. Prior to joining our company, Mr. Warma served as the president and chief executive officer of Opexa Therapeutics, currently Acer Therapeutics Inc. (Nasdaq: OPXA), from June 2008 to September 2017, and as its director from September 2008 to September 2017. At Opexa Therapeutics, he also served as acting chief financial officer from March 2016 to September 2017, and previously served in such role from March 2009 to August 2012. From July 2004 to September 2007, Mr. Warma served as president and chief executive officer of Viron Therapeutics Inc., a privately-held clinical stage biopharmaceutical company. Mr. Warma co-founded MedExact USA, Inc., an Internet company providing clinical information and services to physicians and pharmaceutical companies in 2000 and served as president until 2003. From 1992 to 2000, Mr. Warma held senior positions of increasing responsibility at Novartis Pharmaceuticals (previously Ciba-Geigy Ltd.) at its corporate headquarters in Basel, Switzerland. While at Novartis, Mr. Warma served as the Head of International Pharma Policy & Advocacy and in senior management within global marketing where he worked on the international launch of a gastrointestinal product. Mr. Warma obtained an honors degree specializing in neuroscience from the University of Toronto in 1984 and an International M.B.A. from the Schulich School of Management at York University in Toronto in 1992.

Our Scientific Advisory Board

The members of our scientific advisory board provide scientific, portfolio and project strategy advice to us, including the evaluation of research and development strategies. The members of our scientific advisory board receive cash compensation for their services.

Howard Weiner , M.D., has served on our scientific advisory board since July 2019. Dr. Weiner is the Robert L. Kroc Professor of Neurology at the Harvard Medical School, Director of the Partners Multiple Sclerosis ("MS") Center and Co-Director of Center for Neurologic Diseases at Brigham & Women's Hospital in Boston. The Partners MS Center is the first integrated MS Center that combines clinical care, MRI imaging and immune monitoring to the MS patient as part of the 2000 patient CLIMB cohort study. Dr. Weiner has pioneered immunotherapy in MS and has investigated immune mechanisms in nervous system diseases including MS, Alzheimer's disease, amyotrophic lateral sclerosis, stroke and brain tumors. Dr. Weiner has also pioneered the investigation of the mucosal immune system for the treatment of autoimmune and other diseases and the use of anti-CD3 to induce regulatory T cells for the treatment of these diseases.

Eric K. Rowinsky , M.D., has served on our scientific advisory board since June 2019. Dr. Rowinsky is an independent consultant and/or board member of various public and private companies and not-for-profit efforts. Since 2017, Dr. Rowinsky has served as an advisor to C-Bridge Capital and the U.S. Chief Medical Officer for Everest Medicines, Inc. Since 2015, Dr. Rowinsky has served as an Executive Director and President at Rgenix Inc. and as the Chief Scientific Officer of Clearpath Development Co. From 2005 to 2015, Dr. Rowinsky held various positions with various biotechnology companies. At ImClone Systems (now a wholly-owned subsidiary of Eli Lilly), Dr. Rowinsky and his team developed and registered cetuximab (Erbitux) and ramucirumab in five indications and two other monoclonal antibodies in North America and elsewhere. Dr. Rowinsky has been an Adjunct Professor of Medicine at New York University School of Medicine since 2005. From 1987 to 2005, Dr. Rowinsky held various academic and research positions with various universities and research institutions including the Institute for Drug Development of the Cancer Therapy and Research Center in San Antonio, where he held the SBC Endowed Chair for Early Drug Development, and the Johns Hopkins University School of Medicine. Dr. Rowinsky received his B.A. degree from New York University and his M.D. from the Vanderbilt University School of Medicine and completed fellowship training at the Johns Hopkins University School of Medicine. Dr. Rowinsky received the career development award of the American Cancer Society and the 6th Annual Emil J. Freireich Award. He has also served on the Board of Scientific Counselors of the NCI. Dr. Rowinsky is the Editor-in-Chief of Investigational New Drugs, an Editorial Board Member of Cancer Research and several other oncology journals.

Patricia LoRusso , D.O., M.A., Ph.D., has served on our scientific advisory board since July 2019. Dr. LoRusso is currently a professor of medicine and a clinical scholar in medical oncology and Associate Director of Innovative Medicine at Yale Cancer Center in New Haven, Connecticut, USA, where she is also Director of Early Therapeutics Disease-Aligned Team. Dr. LoRusso's expertise is in testing new treatments on patient volunteers with advanced-stage cancer. She heads the early clinical trials program at Yale Cancer Center. She has served as the co-leader of the Stand Up To Cancer/Melanoma Research Alliance–funded Melanoma Dream Team, a Komen Promise grant co-Principal Investigator, and has been a Principal Investigator of the National Cancer Institute Phase 1/early phase clinical trials program grant in excess of 20 years. She is currently primary investigator or co-investigator of numerous clinical trials. Prior to joining Yale in August 2014, Dr. LoRusso served in numerous leadership roles at Wayne State University's Barbara Karmanos Cancer Institute for more than 25 years, most recently as director of the Phase 1 Clinical Trials Program and of the Eisenberg Center for Experimental Therapeutics. Dr. LoRusso also worked as a director in Karmanos Cancer Institute, a cancer research and provider network, from 1997 to 2014. Dr. LoRusso received her B.A. degree of science in religion/religious studies and biology, her master's degree at Yale University, her D.O. and Ph.D. from Michigan State University, and completed fellowship training at Wayne State University. Dr. LuRosso served as co-chair of the National Cancer Institute Cancer Therapy Evaluation Program (NCI CTEP) Investigational Drug Steering Committee, a prior parent member of the NCI's Quick Trials Clinical Subcommittee, and has served as either an ad hoc or an appointed member on multiple study sections and has reviewed for Komen Promise grants, numerous SPORE and P01 study sections, and translational research grants. She has served on the education and scientific committees of the American Society of Clinical Oncology, the Scientific Committee of the American Association for Cancer Research as well as a Vice-Chair for the 2019 AACR annual meeting. She is a member of the NCI Board of Scientific Council and has served on the Board of Directors for the American Association for Cancer Research.

Yi-Long Wu , M.D., FACS, has served on our scientific advisory board since August 2019. Yi-Long Wu is a tenured professor of Guangdong General Hospital, Guangdong Academy of Medical Sciences and Guangdong Lung Cancer Institute. He is the former President of Chinese Society of Clinical Oncology (CSCO), the Chief of the WUJIEPING Oncology Medical Foundation, the vice-director of the Precision Medicine of the Chinese Medical Doctor Association, the President of Chinese Thoracic Oncology Group (C-TONG), the President of International Chinese Society of Thoracic Surgery (ICSTS), a Fellow of the American College of Surgeons, a Member of Board of Directors of the International Association Study of Lung Cancer (IASLC), the Chairman of European Society for Medical Oncology (ESMO) in China, the Chairman of Federation of Asia Clinical Oncology (FACO), a past Member of the International Affairs Committee of American Society of Clinical Oncology (ASCO), and a former Member of staging committee of the IASLC. He graduated from Sun Yat-sen University of Medical Sciences in 1982 and completed his thoracic surgery training in Germany in 1989. His main research interests are the multidisciplinary synthetic therapy on lung cancer in translation medicine and evidence-based medicine in oncology. He is leading the Chinese lung cancer research field and has been the Principal Investigator or Co-PI of more than 120 international or national multicenter clinical trials. He has contributed 20 books on cancer and has published more than 300 articles in peer-reviewed journals including *J Clin Oncol*, *Lancet Oncol*, *New Engl J Med*, *Cancer Cell and J Thorac Oncol* . He also serves on the editorial boards of *Cancer Letters*, *Annals of Surgical Oncology*, *Lung Cancer Management*, *International Journal of Biological Marker and General Thoracic and Cardiovascular Surgery* . He is Editor-in-Chief of *Journal of Evidence-based Medicine*, *Journal of Thoracic Oncology (Chinese Edition), and The Oncologist (Chinese Edition)* etc.

Timothy Yap , M.D., Ph.D., has served on our scientific advisory board since August 2019. Dr. Yap is a medical oncologist and physician-scientist based at the University of Texas MD Anderson Cancer Center. He is an Associate Professor in the Department for Investigational Cancer Therapeutics (Phase I Program), and the Department of Thoracic/Head and Neck Medical Oncology. Dr. Yap is the Medical Director of the Institute for Applied Cancer Science, a drug discovery biopharmaceutical unit where drug discovery and clinical translation are seamlessly integrated. He is also the Associate Director of Translational Research in the Institute for Personalized Cancer Therapy, which is an integrated research and clinical trials program aimed at implementing personalized cancer therapy and improving patient outcomes. Prior to his current position, Dr. Yap was a Consultant Medical Oncologist at The Royal Marsden Hospital in London, UK and National Institute for Health Research BRC Clinician Scientist at The Institute of Cancer Research, London, UK. Dr. Yap gained his BSc degree with First Class Honors in Immunology and Infectious Diseases at Imperial College London, UK, and was awarded the Huggett Memorial Prize. His BSc laboratory research involved an immunogenetics study under the supervision of Professor Charles Bangham. He subsequently went on to attain his Medical degree from Imperial College London, UK, before completing general medical training in Oxford. Dr. Yap's main research focuses on the first-in-human and combinatorial development of molecularly targeted agents and immunotherapies, and their acceleration through clinical studies using novel predictive and pharmacodynamic biomarkers. Dr. Yap leads immuno-oncology clinical and associated translational studies, including novel agents targeting PD-1/PD-L1, ICOS, IDO, LAG3, TIM3, STING, TGFbeta, adenosine A2A receptor and fucosylation. He was previously the UK Chief Investigator for the CheckMate 331 Phase III trial in relapsed small cell lung cancer and the KEYNOTE-158 Phase II biomarker study in advanced solid tumors and multiple novel immunotherapy combination phase I trials.

Roy S. Herbst, MD, PhD , has served on our scientific advisory board since July 2019. Dr. Roy S. Herbst is an Ensign Professor of Medicine (Medical Oncology) and Professor of Pharmacology, the Chief of Medical Oncology at Yale Cancer Center and Smilow Cancer Hospital, and an Associate Cancer Center Director for Translational Research, Yale Cancer Center in New Haven, CT. Dr. Herbst is nationally recognized for his leadership and expertise in lung cancer treatment and research. He is best known for his work in developmental therapeutics and the personalized therapy of non-small cell lung cancer, in particular the process of linking genetic abnormalities of cancer cells to novel therapies. Prior to his appointment at Yale, Dr. Herbst was the Barnhart Distinguished Professor and Chief of the Section of Thoracic Medical Oncology in the Department of Thoracic/Head and Neck Medical Oncology, at The University of Texas M.D. Anderson Cancer Center (UT-MDACC) in Houston, Texas. He also served as Professor in the Department of Cancer Biology and Co-Director of the Phase I Clinical Trials Program. He has led the Phase I development of several of the new generation of targeted agents for non-small cell lung cancer (NSCLC), including gefitinib, erlotinib, cetuximab, and bevacizumab. More recently, he participated in the successful registration of pembrolizumab for the treatment of advanced non-small cell lung cancer, following the successful Yale-led KEYNOTE 10 study of the immune therapy drug commonly used to treat other cancers. He was co-leader for the BATTLE-1 clinical trial program, co-leads the subsequent BATTLE-2 clinical trial program, and served as a Co-program Leader of the Developmental Therapeutics Program for the YCC Support Grant. Dr. Herbst's laboratory work is focused on immunotherapy angiogenesis; dual epidermal growth factor receptor (EGFR)/vascular endothelial growth factor receptor (VEGFR) inhibition in NSCLC, and targeting KRAS-activated pathways. More recently, he has explored predictive biomarkers for the use of immunotherapy agents. This work has been translated from the preclinical to clinical setting in multiple Phase II and III studies which he has led. After earning a B.S. and M.S. degree from Yale University, Dr. Herbst earned his M.D. at Cornell University Medical College and his Ph.D. in molecular cell biology at The Rockefeller University in New York City, New York. His postgraduate training included an internship and residency in medicine at Brigham and Women's Hospital in Boston, Massachusetts. His clinical fellowships in medicine and hematology were completed at the Dana-Farber Cancer Institute and Brigham and Women's Hospital, respectively. Subsequently, Dr. Herbst completed a M.S. degree in clinical translational research at Harvard University in Cambridge, Massachusetts. Dr. Herbst is an author or co-author of more than 275 publications, including peer-reviewed journal articles, abstracts, and book chapters. His work has been published in many prominent journals, such as the Journal of Clinical Oncology, Clinical Cancer Research, Lancet, the New England Journal of Medicine, and Nature. Dr. Herbst was a member of the National Cancer Policy Forum (1998-2014) for which he organized an Institute of Medicine meeting focused on policy issues in personalized medicine. He is a member of ASCO and, as a member of AACR, he chairs the Tobacco Task Force. He is a fellow of the American College of Physicians and an elected member of the Association of American Physicians. Dr. Herbst is also a member of the medical advisory committee for the Lung Cancer Research Foundation and chair of the communications committee for ASCO and the International Association for the Study of Lung Cancer. He is currently the Vice Chair for Developmental Therapeutics for the Southwestern Oncology Group (SWOG) Lung Committee, Principal Investigator of the SWOG 0819 trial, and steering committee chair for the Lung Master Protocol (Lung MAP).

B. Compensation of Directors and Executive Officers

For the fiscal year ended December 31, 2019, we paid an aggregate of approximately US$2.7 million for salaries and benefits in cash to our executive officers. We also completed a repurchase of 3,890,155 options held by a director of our company at the total consideration of US$21.9 million. We did not pay any compensation to our directors who are not our executive officers. We have not set aside or accrued any amount to provide pension, retirement or other similar benefits to our executive officers and directors. Our PRC subsidiaries are required by law to make contributions equal to certain percentages of each employee's salary for his or her pension insurance, medical insurance, unemployment insurance and other statutory benefits and a housing provident fund.

Employment Agreements and Indemnification Agreements

We have entered into employment agreements with all of our executive officers. Under these agreements, each of our executive officers is employed for a specified time period. We may terminate employment for cause, at any time, for certain acts of the executive officer, such as continued failure to satisfactorily perform, willful misconduct or gross negligence in the performance of agreed duties, conviction or nolo contendere plea of guilty to any felony or any misdemeanor involving moral turpitude, or dishonest act that result in material harm to our detriment, or material breach by the executive officer of the employment agreement. We may also terminate an executive officer's employment without cause upon a 60-day prior written notice. In such case of termination by us, we will provide severance payments to the executive officer as may be agreed between the executive officer and us. The executive officer may resign at any time with a 60-day prior written notice.

Under these agreements, each executive officer has agreed to hold, both during and after the termination or expiry of his or her employment agreement, in strict confidence and not to use, except as required in the performance of his or her duties in connection with the employment or pursuant to applicable law, any of our confidential information or trade secrets, any confidential information or trade secrets of our clients or prospective clients, or the confidential or proprietary information of any third party received by us and for which we have confidential obligations. The executive officers have also agreed to disclose in confidence to us all inventions, designs and trade secrets which they conceive, develop or reduce to practice during the executive officer's employment with us and to assign all right, title and interest in them to us, and assist us in obtaining and enforcing patents, copyrights and other legal rights for these inventions, designs and trade secrets.

In addition, under these agreements, each executive officer has agreed to be bound by non-competition and non-solicitation restrictions during the term of his or her employment and typically for one year following the last date of employment. Specifically, each executive officer has agreed not to (i) approach our suppliers, clients, direct or end customers or contacts or other persons or entities introduced to the executive officer in his or her capacity as a representative of us for the purpose of doing business with such persons or entities that will harm our business relationships with these persons or entities; (ii) assume employment with or provide services to any of our competitors, or engage, whether as principal, partner, licensor or otherwise, any of our competitors, without our express consent; or (iii) seek directly or indirectly, to solicit the services of any of our employees who is employed by us on or after the date of the executive officer's termination, or in the year preceding such termination, without our express consent.

We have also entered into indemnification agreements with each of our directors and executive officers. Under these agreements, we agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being a director or officer of our company.

Share Incentive Plans

Second Amended and Restated 2017 Employee Stock Option Plan

In October 2017, we adopted an equity incentive plan (as last amended and restated in December 2019), which we refer to as the 2017 Plan, to secure and retain the services of valuable employees, directors or consultants, and provide incentives for such persons to exert their best efforts for the success of our business. The maximum aggregate number of ordinary shares which may be issued pursuant to all awards under the 2017 Plan is 9,609,084, subject to certain adjustments. As of February 29, 2020, awards to purchase 9,450,315 ordinary shares under the 2017 Plan have been granted and outstanding, excluding awards that were forfeited or cancelled after the relevant grant dates.

The following paragraphs describe the principal terms of the 2017 Plan.

Types of awards. The 2017 Plan permits the awards of options.

Plan administration. Our board of directors will administer the 2017 Plan. The board of directors will determine, among other things, the participants to receive options, the number and subscription price of options to be granted to each participant, and the terms and conditions of each option granted.

Offer letter. Options granted under the 2017 Plan are evidenced by an offer letter that sets forth terms, conditions and limitations for each option, which may include the term of the option, and the provisions applicable in the event that the grantee's employment or service terminates.

Eligible participants. We may grant awards to employees, officers, directors, contractors, advisors and consultants of our company.

Vesting schedule. Unless otherwise approved by the board of directors and set forth in an offer letter, the vesting schedule shall be a three-year vesting schedule consisting of a cliff vesting 50% on the second anniversary of the applicable vesting commencement date, and a vesting of the remaining 50% on the third anniversary of the applicable vesting commencement date. Except as otherwise approved by the board of directors, vested portion of option shall become exercisable upon the earlier of a listing or the occurrence of a change in control.

Exercise of options. The board of directors determines the subscription price for each option, which is stated in the offer letter. The vested portion of each option will expire if not exercised prior to the time as the board of directors determines at the time of its grant. However, the maximum exercisable term is ten years from the applicable vesting commencement date or such shorter period specified in the award agreement. Further, an option will lapse upon the earliest of, among other circumstances, two years after the date when the option becomes exercisable upon the listing or the occurrence of a change in control, and a violation in transfer restrictions.

Transfer restrictions. Options may not be transferred in any manner by the participant other than in accordance with the exceptions provided in the 2017 Plan or the relevant offer letter or otherwise determined by the board of directors, such as transfers by will or the laws of descent and distribution.

Termination and amendment of the 2017 Plan. Unless terminated earlier, the 2017 Plan has a term of ten years. The board of directors has the authority to amend, suspend or terminate the plan, subject to the limitations of applicable laws. No amendment, suspension or termination may adversely affect in any material way any awards previously granted pursuant to the 2017 Plan unless agreed to by the participant.

The following table summarizes, as of February 29, 2020, the number of ordinary shares under our outstanding options that we granted under the 2017 Plan to several of our directors and executive officers, excluding awards that were forfeited or cancelled after the relevant grant dates.

NAME	ORDINARY SHARES UNDERLYING OUTSTANDING OPTIONS GRANTED	EXERCISE PRICE (US$/SHARE)	DATE OF GRANT	DATE OF EXPIRATION
Zheru Zhang	1,421,986	1.00	October 1, 2017	October 1, 2027
Joan Huaqiong Shen	1,505,128	1.00	October 1, 2017	October 1, 2027
Jielun Zhu	1,125,000	1.00	August 1, 2018	October 1, 2027
Weimin Tang	*	1.00	April 2, 2018	October 1, 2027
Yunhan Lin	*	1.00	October 1, 2017	October 1, 2027
Lili Qian	*	1.00	October 1, 2017	October 1, 2027
Other grantees	4,670,593	1.00	October 1, 2017 to July 25, 2019	October 1, 2027
Total	9,450,315			

Note:

* Less than 1% of our total outstanding shares.

Second Amended and Restated 2018 Employee Stock Option Plan

In February 2019, we adopted an equity incentive plan (as last amended and restated in December 2019), which we refer to as the 2018 Plan, to secure and retain the services of valuable employees, directors or consultants, and provide incentives for such persons to exert their best efforts for the success of our business. The maximum aggregate number of ordinary shares which may be issued pursuant to all awards under the 2018 Plan is 11,005,888, subject to certain adjustments. As of February 29, 2020, awards to purchase 10,991,671 ordinary shares under the 2018 Plan have been granted and outstanding, excluding awards that were forfeited or cancelled after the relevant grant dates.

The following paragraphs describe the principal terms of the 2018 Plan.

Types of awards. The 2018 Plan permits the awards of options.

Plan administration. Our board of directors will administer the 2018 Plan. The board of directors will determine, among other things, the participants to receive options, the number and subscription price of options to be granted to each participant, and the terms and conditions of each option granted.

Offer letter. Options granted under the 2018 Plan are evidenced by an offer letter that sets forth terms, conditions and limitations for each option, which may include the term of the option, and the provisions applicable in the event that the grantee's employment or service terminates.

Eligible participants. We may grant awards to employees or if approved by the board, designee of any employee.

Vesting schedule. Unless otherwise approved by the board of directors and set forth in an offer letter, the vesting schedule shall be a two-year vesting schedule consisting of a cliff vesting 50% on the first anniversary of the applicable vesting commencement date, and a vesting of the remaining 50% on the second anniversary of the applicable vesting commencement date. Notwithstanding the foregoing, if a listing occurs at anytime prior to any option granted under the 2018 Plan becoming full vested, and to the extent such option has been granted and outstanding, any such option shall vest in full with immediate effect upon the listing. Except as otherwise approved by the board of directors, vested portion of option shall become exercisable upon the earlier of six months after a listing or the occurrence of a change in control; provided, however that in each case, no option of an employee shall become exercisable until the third anniversary of such employee's employment commencement date.

Exercise of options . The board of directors determines the subscription price for each option, which is stated in the offer letter. The vested portion of each option will expire if not exercised prior to the time as the board of directors determines at the time of its grant. However, the maximum exercisable term is ten years from the applicable vesting commencement date or such shorter period specified in the award agreement. Further, an option will lapse upon the earliest of, among other circumstances, two years after the date when the option becomes exercisable upon the listing or the occurrence of a change in control, and a violation in transfer restrictions.

Transfer restrictions. Options may not be transferred in any manner by the participant other than in accordance with the exceptions provided in the 2018 Plan or the relevant offer letter or otherwise determined by the board of directors, such as transfers by will or the laws of descent and distribution.

Termination and amendment of the 2018 Plan. Unless terminated earlier, the 2018 Plan has a term of ten years. The board of directors has the authority to amend, suspend or terminate the plan, subject to the limitations of applicable laws. No amendment, suspension or termination may adversely affect in any material way any awards previously granted pursuant to the 2018 Plan unless agreed to by the participant.

The following table summarizes, as of Feburary 29, 2020, the number of ordinary shares underlying our outstanding options that we granted under the 2018 Plan, excluding awards that were forfeited or cancelled after the relevant grant dates.

NAME	ORDINARY SHARES UNDERLYING OUTSTANDING OPTIONS GRANTED	EXERCISE PRICE (US$/SHARE)	DATE OF GRANT	DATE OF EXPIRATION
Jingwu Zhang Zang	7,893,171	1.00	February 22, 2019	February 22, 2029
Zheru Zhang	*	1.00	July 25, 2019	February 22, 2029
Joan Huaqiong Shen	*	1.00	July 25, 2019	February 22, 2029
Jielun Zhu	*	1.00	July 25, 2019	February 22, 2029
Weimin Tang	*	1.00	July 25, 2019	February 22, 2029
Yunhan Lin	*	1.00	July 25, 2019	February 22, 2029
Lili Qian	*	1.00	July 25, 2019	February 22, 2029
Other grantees	1,110,209	1.00	July 25, 2019	February 22, 2029
Total	10,991,671			

Note:

* Less than 1% of our total outstanding shares.

2019 Share Incentive Plan

In October 2019, we adopted an equity incentive plan, which we refer to as 2019 Plan, to promote the success and enhance the value of our company. Under the 2019 Plan, the maximum aggregate number of ordinary shares available for issuance is 100,000. As of February 29, 2020, no award has been granted or outstanding under the 2019 Plan.

The following paragraphs describe the principal terms of the 2019 Plan:

Type of Awards. The plan permits the awards of options, restricted shares, restricted share units or other types of awards approved by the board of directors or a committee of one or more members of the board of directors.

Plan Administration. Our board of directors or a committee of one or more members of the board of directors will administer the plan. The committee or the board of directors, as applicable, will determine the participants to receive awards, the type and number of awards to be granted to each participant, and the terms and conditions of each grant.

Award Agreement. Awards granted under the plan are evidenced by an award agreement that sets forth the terms, conditions and limitations for each award, which may include the term of the award, the provisions applicable in the event that the grantee's employment or service terminates, and our authority to unilaterally or bilaterally amend, modify, suspend, cancel or rescind the award.

Eligibility. We may grant awards to our independent directors, as determined by a committee of one or more members of the board of directors. Vesting Schedule. In general, the plan administrator determines the vesting schedule, which is specified in the relevant award agreement.

Exercise of Options. The plan administrator determines the exercise price for each award, which is stated in the relevant award agreement. Options that are vested and exercisable will terminate if they are not exercised prior to the time as the plan administrator determines at the time of grant. However, the maximum exercisable term is ten years from the date of grant.

Transfer Restrictions. Awards may not be transferred in any manner by the participant other than in accordance with the exceptions provided in the plan or the relevant award agreement or otherwise determined by the plan administrator, such as transfers by will or the laws of descent and distribution.

Termination and Amendment of the Plan. Our board of directors has the authority to terminate, amend, suspend or modify the plan in accordance with our articles of association. However, without the prior written consent of the participant, no such action may adversely affect in any material way any award previously granted pursuant to the plan.

C. Board Practices

Our board of directors consists of 11 directors. A director is not required to hold any shares in our company by way of qualification. Subject to the Nasdaq Global Market rules and disqualification by the chairman of the relevant board meeting, a director may vote with respect to any contract, proposed contract or arrangement in which he is interested. A director who is interested in a contract, proposed contract or arrangement shall declare the nature of his or her interest at the earliest meeting of the board at which it is practicable for him or her to do so, either specifically or by way of a general notice. The directors may exercise all the powers of our company to borrow money, mortgage its undertaking, property and uncalled capital, and issue debentures or other securities whenever money is borrowed or as security for any obligation of our company or of any third party. None of our directors who are not our executive officers has a service contract with us that provides for benefits upon termination of service.

Committees of the Board of Directors

We have established three committees under the board of directors: an audit committee, a compensation committee and a nominating and corporate governance committee. We have adopted a charter for each of the three committees. Each committee's members and functions are described below.

Audit Committee . Our audit committee consists of Mr. Conor Chia-hung Yang, Mr. Chun Kwok Alan Au and Mr. Bing Yuan. Mr. Conor Chia-hung Yang is the chairman of our audit committee. We have determined that each of Mr. Conor Chia-hung Yang, Mr. Chun Kwok Alan Au and Mr. Bing Yuan satisfies the "independence" requirements of Rule 5605(c)(2) of the Nasdaq Stock Market Rules and meets the independence standards under Rule 10A-3 under the Exchange Act. We have determined that Mr. Conor Chia-hung Yang qualifies as an "audit committee financial expert." The audit committee will oversee our accounting and financial reporting processes and the audits of the financial statements of our company. The audit committee is responsible for, among other things:

- appointing the independent auditors and pre-approving all auditing and non-auditing services permitted to be performed by the independent auditors;

- reviewing with the independent auditors any audit problems or difficulties and management's response;
- discussing the annual audited financial statements with management and the independent auditors;
- reviewing the adequacy and effectiveness of our accounting and internal control policies and procedures and any steps taken to monitor and control major financial risk exposures;
- reviewing and approving all proposed related party transactions;
- meeting separately and periodically with management and the independent auditors; and
- monitoring compliance with our code of business conduct and ethics, including reviewing the adequacy and effectiveness of our procedures to ensure proper compliance.

Compensation Committee . Our compensation committee consists of Dr. Jingwu Zhang Zang, Mr. Chun Kwok Alan Au and Dr. Pamela M. Klein. Dr. Jingwu Zhang Zang is the chairman of our compensation committee. We have determined that each of Mr. Chun Kwok Alan Au and Dr. Pamela M. Klein satisfies the "independence" requirements of Rule 5605(a)(2) of the Nasdaq Stock Market Rules. The compensation committee will assist the board in reviewing and approving the compensation structure, including all forms of compensation, relating to our directors and executive officers. Our chief executive officer may not be present at any committee meeting during which his compensation is deliberated. The compensation committee is responsible for, among other things:

- reviewing and approving, or recommending to the board for its approval, the compensation for our chief executive officer and other executive officers;
- reviewing and recommending to the board for determination with respect to the compensation of our directors who are not our employees;
- reviewing periodically and approving any incentive compensation or equity plans, programs or similar arrangements; and
- selecting compensation consultant, legal counsel or other adviser only after taking into consideration all factors relevant to that person's independence from management.

Nominating and Corporate Governance Committee . Our nominating and corporate governance committee consists of Mr. Wei Fu, Mr. Chun Kwok Alan Au and Mr. Conor Chia-hung Yang. Mr. Wei Fu is the chairman of our nominating and corporate governance committee. We have determined that each of Mr. Chun Kwok Alan Au and Mr. Conor Chia-hung Yang satisfies the "independence" requirements of Rule 5605(a)(2) of the Nasdaq Stock Market Rules. The nominating and corporate governance committee will assist the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board and its committees. The nominating and corporate governance committee is responsible for, among other things:

- selecting and recommending to the board nominees for election by the shareholders or appointment by the board;
- reviewing annually with the board the current composition of the board with regards to characteristics such as independence, knowledge, skills, experience and diversity;
- making recommendations on the frequency and structure of board meetings and monitoring the functioning of the committees of the board; and
- advising the board periodically with regards to significant developments in the law and practice of corporate governance as well as our compliance with applicable laws and regulations, and making recommendations to the board on all matters of corporate governance and on any corrective action to be taken.

Duties of Directors

Under Cayman Islands law, our directors owe fiduciary duties to our company, including a duty of loyalty, a duty to act honestly, and a duty to act in what they consider in good faith to be in our best interests. Our directors must also exercise their powers only for a proper purpose. A director must exercise the skill and care of a reasonably diligent person having both – (a) the general knowledge, skill and experience that may reasonably be expected of a person in the same position (an objective test), and (b) if greater, the general knowledge, skill and experience that that director actually possesses (a subjective test). In fulfilling their duty of care to us, our directors must ensure compliance with our memorandum and articles of association, as amended from time to time, and the class rights vested thereunder in the holders of the shares. Our company has the right to seek damages if a duty owed by our directors is breached. A shareholder may in certain limited circumstances have the right to seek damages in our name if a duty owed by the directors is breached.

Our board of directors has all the powers necessary for managing, and for directing and supervising, our business affairs. The functions and powers of our board of directors include:

- convening shareholders' annual general meetings and reporting its work to shareholders at such meetings;
- declaring dividends and other distributions;
- appointing officers and determining the term of office of the officers;
- exercising the borrowing powers of our company and mortgaging the property of our company; and
- approving the transfer of shares in our company, including the registration of such shares in our share register.

Terms of Directors and Officers

Our directors may be elected by an ordinary resolution of our shareholders. Alternatively, our board of directors may, by the affirmative vote of a simple majority of the directors present and voting at a board meeting appoint any person as a director to fill a casual vacancy on our board or as an addition to the existing board. Our directors (other than independent directors) are not automatically subject to a term of office and hold office until such time as they are removed from office by an ordinary resolution of our shareholders. Our independent directors hold office until the earlier of (i) the date on which the independent director ceases to be a member of the board for any reason; (ii) the date of termination of an independent director's director agreement, which may be terminated by either the independent director or by us with a 30-day advance written notice or such other shorter period as mutually agreed; or (iii) three years from the effective date of the director agreement, subject to the terms of our current memorandum and articles of association of our company. In addition, a director will cease to be a director if he or she (i) becomes bankrupt or makes any arrangement or composition with his or her creditors; (ii) dies or is found to be or becomes of unsound mind; (iii) resigns his or her office by notice in writing; (iv) without special leave of absence from our board, is absent from meetings of our board for three consecutive meetings and our board resolves that his or her office be vacated; or (v) is removed from office pursuant to any other provision of our articles of association.

Our officers are appointed by and serve at the discretion of the board of directors, and may be removed by our board of directors. Under our articles of association, the board of directors may appoint one or more of their number to the office of managing director upon like terms, but any such appointment shall ipso facto terminate if any managing director ceases for any cause to be a director, or if our company by ordinary resolution of shareholders resolves that his tenure of office be terminated. In addition, the board of directors may appoint any natural person or corporation to be a secretary (and if need be an assistant secretary or assistant secretaries) who shall hold office for such term, at such remuneration and upon such conditions and with such powers as they think fit. Any secretary or assistant secretary so appointed by the board of directors may be removed by the board of directors or by ordinary resolution of shareholders.

D. Employees

We had 59, 134 and 185 employees as of December 31, 2017, 2018 and 2019, respectively. As of December 31, 2019, 166 employees were located in China and 19 were located outside China. The table below sets forth our employees by function as of December 31, 2019:

	NUMBER
Management	8
Research and development	102
Chemistry, manufacturing and controls	38
General and administrative	29
Business and corporate development	8
Total	185

We recruit our employees primarily through recruitment websites, recruiters, internal referrals and job fairs. We recruit our employees based on their qualification and potential. We promote culture diversity, and our employees come from the United States, Taiwan and South Korea, in addition to China. The remuneration package of our employees includes salary, benefits and bonus. Our compensation programs are designed to remunerate our employees based on their performance, measured against specified objective criteria. We are required to make contributions to social insurance and housing provident funds in accordance with PRC laws and regulations from time to time.

We provide new hire training to our employees and periodic on-the-job training to enhance the skills and knowledge of our employees. We have not established a labor union. We have not experienced any material labor disputes or strikes that may have a material and adverse effect on our business, financial condition or results of operations.

We enter into standard confidentiality and employment agreements with all of our key management and research staff. The contracts with our key personnel typically include a standard non-compete agreement that prohibits the employee from competing with us, directly or indirectly, during his or her employment and for one year after the termination of his or her employment. The contracts also typically include undertakings regarding assignment of innovations and discoveries made during the course of his or her employment. For further details regarding the terms of confidentiality and employment agreements with our key management, see “Item 6. Directors, Senior Management and Employees.”

E. Share Ownership

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of February 29, 2020 by:

- each of our directors and executive officers; and
- each person known to us to own beneficially more than 5% of our total outstanding shares.

Percentage of beneficial ownership is based on 133,006,644 total outstanding ordinary shares as of February 29, 2020.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, we have included shares that the person has the right to acquire within 60 days, including through the exercise of any option, warrant or other right or the conversion of any other security. These shares, however, are not included in the computation of the percentage ownership of any other person.

	Ordinary Shares Beneficially Owned		
	Total ordinary shares	Percentage of total ordinary shares	Percentage of aggregate voting power
Directors and Executive Officers:**			
Jingwu Zhang Zang (1)	11,825,284	8.4%	8.4%
Joan Huaqiong Shen	*	*	*
Zheru Zhang	*	*	*
Jielun Zhu	—	—	—
Wei Fu (2)	47,159,938	35.5%	35.5%
Mengjiao Jiang	—	—	—
Jie Yu	—	—	—
Bing Yuan	—	—	—
Chun Kwok Alan Au	—	—	—
Conor Chia-hung Yang	—	—	—
Pamela M. Klein	—	—	—
Lili Qian	*	*	*
Weimin Tang	*	*	*
Yunhan Lin	*	*	*
Neil Warma	—	—	—
All Directors and Executive Officers as a Group	61,168,392	42.8%	42.8%
Principal Shareholders:			
C-Bridge entities (2)	47,159,938	35.5%	35.5%
Tasly entities (3)	14,664,020	11.0%	11.0%
Hony entity (4)	9,465,631	7.1%	7.1%
Genexine (5)	10,572,823	7.9%	7.9%

Notes:

* Less than 1% of our total ordinary shares.

** Except as otherwise indicated below, the business address of our directors and executive officers is Suite 802, West Tower, OmniVision, 88 Shangke Road, Pudong District, Shanghai, China. The business address of Wei Fu and Mengjiao Jiang is Suite 3306-3307, Two Exchange Square, 8 Connaught Place, Central, Hong Kong. The business address of Jie Yu is Tasly Great Health Town, No. 2, East Puji River Road, Beichen District, Tianjin, China. The business address of Bing Yuan is Flat B, 31/F BLK 2, The Hermitage, Mongkok, Hong Knog. The business address of Chun Kwok Alan Au is 22 Pottinger Street, Central, Hong Kong. The business address of Conor Chia-hung Yang is 7th Floor, Building C, Luneng International Center, No. 209 Guoyao Road, Pudong New Area, Shanghai, China. The business address of Dr. Pamela M. Klein is 231 Fort Mason, San Francisco, California 94123, the United States.

(1) Represents (i) 3,932,113 ordinary shares directly held by Mabcore Limited, a British Virgin Islands company and (ii) 7,893,171 ordinary shares issuable upon exercise of options exercisable within 60 days after February 29, 2020 held by Dr. Zang. Dr. Zang, through himself and The Jingwu Zhang Zang 2018 Retained Annuity Trust, owns a 55.6% equity interest in Mabcore Limited. Dr. Lili Qian and two other individuals own the remaining equity interest in Mabcore Limited. Dr. Zang is the sole director of Mabcore Limited. The Jingwu Zhang Zang 2018 Retained Annuity Trust was established under the laws of New York and is managed by Dr. Zang, as the trustee, the settlor and the sole beneficiary. Pursuant to the currently effective memorandum and articles of association of Mabcore Limited, Dr. Zang, as the sole director, has the power to direct the actions of Mabcore Limited, including the voting and disposal of Mabcore Limited's shares in I-Mab. Accordingly, Dr. Zang is deemed to indirectly own all of the 3,932,113 ordinary shares held by Mabcore Limited, while Dr. Qian and the other two individuals are only entitled to their respective pro-rata economic interest in Mabcore Limited.

(2) Represents (i) 5,141,587 ordinary shares held by IBC Investment Seven Limited, a Hong Kong limited liability company, (ii) 8,361,823 ordinary shares held by CBC SPVII LIMITED, a Hong Kong limited liability company, (iii) 18,497,749 ordinary shares held by CBC Investment I-Mab Limited, a British Virgin Islands limited liability company, (iv) 2,369,546 ordinary shares held by C-Bridge II Investment Ten Limited, a British Virgin Islands limited liability company, (v) 5,851,481 ordinary shares held by C-Bridge II Investment Seven Limited, a British Virgin Islands limited liability company, (vi) 6,078,571 ordinary shares held by Everest, and (vii) 373,557 ADSs purchased by C-Bridge II Investment Thirteen Limited. IBC Investment Seven Limited, CBC SPVII LIMITED, CBC Investment I-Mab Limited, C-Bridge II Investment Ten Limited and C-Bridge II Investment Seven Limited are collectively referred to as the C-Bridge entities. CBC Investment I-Mab Limited, C-Bridge II Investment Ten Limited and C-Bridge II Investment Seven Limited are controlled by C-Bridge Healthcare Fund II, L.P., whose general partner is C-Bridge Healthcare Fund GP II, L.P., and its general partner is C-Bridge Capital GP, Ltd. CBC SPVII Limited and IBC Investment Seven Limited are controlled by I-Bridge Healthcare Fund, L.P., whose general partner is I-Bridge Healthcare GP, L.P., and its general partner is I-Bridge Capital GP, Ltd., which is indirectly controlled by C-Bridge Capital GP, Ltd. Wei Fu is the sole director of C-Bridge Capital GP, Ltd. Everest is controlled by funds which are under common control of the C-Bridge entities, which is C-Bridge Healthcare Fund II, LP., as its sole shareholder. The business address of C-Bridge entities is Suite 3306-3307, Two Exchange Square, 8 Connaught Place, Central, Hong Kong.

(3) Represents (i) 12,942,997 ordinary shares held by Tasly Biopharm Limited, a British Virgin Islands limited liability company, and (ii) 1,721,023 ordinary shares directly held by Tasly International BioInv One Limited. Tasly Biopharm Limited and Tasly International BioInv One Limited are collectively referred to as the Tasly entities. Tasly International BioInv One Limited is wholly-owned by Tasly International Capital Limited, whose sole shareholder is Tasly Holding Group Co., Ltd. Tasly Biopharm Limited's sole shareholder is Tasly Biopharmaceuticals Co., Ltd., which is controlled by Tasly Pharmaceutical Group Co., Ltd., which is in turn controlled by Tasly Holding Group Co., Ltd. Tasly Holding Group Co., Ltd. is controlled by Tianjin Tasly Health Industry Investment Group Co., Ltd., which is in turn controlled by Tianjin Fuhuade Science & Technology Development Co., Ltd. Kaijing Yan is the controlling shareholder of Tianjin Fuhuade Science & Technology Development Co., Ltd. and the ultimate beneficial owner of Tasly Biopharm Limited. The registered address of Tasly Biopharm Limited is P.O. Box 957, Offshore Incorporation Centre, Road Town, Tortola, British Virgin Islands. The registered address of Tasly International BioInv One Limited is 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman KY1-1002, Cayman Islands.

(4) Represents 9,465,631 ordinary shares held by Fortune Eight Jogging Limited, a British Virgin Islands limited liability company, which we refer to as the Hony entity. Fortune Eight Jogging Limited is wholly-owned by Hony Hongling (Shanghai) Investment Center, a PRC limited partnership, whose general partner is Hony Capital (Shanghai) Ltd. The sole shareholder of Hony Capital (Shanghai) Ltd is Beijing Hony Hezhong Management Ltd. Each of Yonggang Cao, Minsheng Xu and Lijie Wang holds 33.3% equity interests in Beijing Hony Hezhong Management Ltd. The registered address of Fortune Eight Jogging Limited is Kingston Chambers, PO Box 173, Road Town, Tortola, British Virgin Islands.

(5) Represents (i) 10,572,823 ordinary shares directly held by Genexine, Inc. (Genexine), (ii) 900,000 ordinary shares issuable to Genexine upon the full conversion of the US$9.0 million interest-free convertible promissory note based on a conversion price of US$10 per share, and (iii) 570,000 ADSs purchased by Genexine. Genexine is a Korean public company. The registered address of Genexine is 700 Daewangpangyo-ro, Korea Bio Park, Bldg. B4F, Bundang-gu, Seongnam-si, Gyeonggi-do, Korea.

To our knowledge, as of March 31, 2020, 18,804,225 of our ordinary shares were held by one record holder in the United States, which is Citibank, N.A., the depositary of our ADS program. The number of beneficial owners of our ADSs in the United States is likely to be much larger than the number of record holders of our ordinary shares in the United States.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

Please refer to "Item 6. Directors, Senior Management and Employees—E. Share Ownership."

B. Related Party Transactions

Shareholders Agreement

In July 2019, we entered into our fourth amended and restated shareholders agreement with our shareholders.

The shareholders agreement provides for certain special rights, including right of first refusal, co-sale rights, preemptive rights and contains provisions governing the board of directors and other corporate governance matters. Those special rights, as well as the corporate governance provisions, automatically terminated upon the completion of our initial public offering.

Pursuant to our shareholders agreement, we have granted certain registration rights to our shareholders. Set forth below is a description of the registration rights granted under the agreement.

Demand Registration Rights . At any time after the earlier of (i) December 31, 2020, or (ii) six months following the effectiveness of a registration statement for a firm underwritten public offering of our ordinary shares on The Stock Exchange of Hong Kong Limited, the New York Stock Exchange, the Nasdaq Stock Market or other internationally recognized securities exchange, with an offering price (exclusive of underwriting commissions and expenses) that reflects a market capitalization (immediately prior to the public offering) of not less than US$1.0 billion, the holders of a majority of the registrable securities then issued and outstanding may request in writing that we file a registration statement covering the registration of at least 20% of the registrable securities (or any lesser percentage if the anticipated gross receipts from the offering are to exceed US$5.0 million). Upon such a request, we shall, within ten business days of the receipt of such written request, give written notice of such request to all holders, and use our best efforts to effect, as soon as practicable, the registration of all registrable securities that the holders request to be registered and included in such registration by written notice given by such holders to us within 20 days after receipt of the request notice. We have the right to defer filing of a registration statement for a period of not more than 90 days after receipt of the request of the initiating holders if our board of directors determines in good faith that filing of such registration statement at such time will be materially detrimental to us or our shareholders, but we cannot exercise the deferral right more than once during any twelve-month period and cannot register any other securities during such twelve-month period. We are not obligated to effect any such registration if we have, within the six-month period preceding the date of such request, already effected a registration. We are not obligated to effect more than three demand registrations. This demand registration right is subject to the customary exclusion right of the underwriters.

Registration on Form F-3 . If we qualify for registration on Form F-3, any holder or holders of a majority of all registrable securities then issued and outstanding may request in writing that we effect a registration on Form F-3 (or an equivalent registration in a jurisdiction outside of the U.S.). We shall promptly give written notice of the proposed registration and as soon as practicable, effect such registration within 20 days after we provide the aforesaid written notice. The holders are entitled to an unlimited number of registrations on Form F-3 so long as such registration offerings are in excess of US$500,000. We are not obligated to effect any such registration if we have, within the six-month period preceding the date of such request, already effected a registration other than a registration from which registrable securities of the holders have been excluded, or if we would be required to qualify to do business or to execute a general consent to service of process in effecting such registration in any particular jurisdiction.

Piggyback Registration Rights . If we propose to register for a public offering of our securities (other than registration statements relating to demand registration, Form F-3 registration, any employee benefit plan or a corporate reorganization), we shall give written notice of such registration to all holders of registrable securities at least 30 days prior to filing any registration statement and afford each such holder an opportunity to be included in such registration. If a holder decides not to include all of its registrable securities in any registration statement thereafter filed by us, such holder shall nevertheless continue to have the right to include any registrable securities in any subsequent registration statement or registration statements as may be filed by us, subject to certain limitations. This piggyback registration right is subject to the customary exclusion right of the underwriters.

Expenses of Registration. We will bear all registration expenses. Each holder, however, should bear its proportionate share of all of the underwriting discounts and selling commissions applicable to the sale of registrable securities or other amounts payable to underwriter(s) or brokers in connection with such offering by the holders.

Termination of Obligations. Our obligations to effect any demand, Form F-3 or piggyback registration shall terminate upon the earlier of (i) the tenth anniversary of our initial public offering (ii) after listing, the date on which such shareholder is eligible to sell all of the registrable securities held by it under Rule 144 within any 90-day period without volume limitations.

Deed of Undertaking

In December 2019, a deed of undertaking was made by our company and a few shareholders of our company, each as a warrantor, to the other shareholders of our company (other than the shareholder warrantors), each as a warrantee, pursuant to which each warrantor represents and warrants to each warrantee that it has provided each warrantee with all information and documents in connection with our initial public offering that has the effect of establishing rights or otherwise benefiting any shareholder in a manner more favorable than the corresponding terms applicable to the relevant warrantee in relation to our initial public offering (collectively, the “More Favorable Arrangements”). Pursuant to the deed of undertaking, until the fifth anniversary of the completion of our initial public offering, we will not directly or indirectly enter into any agreements or arrangements or modify, amend or waive any existing agreements or arrangements of any kind that would have the effect of establishing the More Favorable Arrangements; provided that it shall be allowed to adopt or modify any employee incentive plans and grant options to the management or any employee of our company after our initial public offering pursuant to such plans and in accordance with the then effective memorandum and articles of association and the applicable listing rules for the purpose of rewarding their bona fide services.

Employment Agreements and Indemnification Agreements

See “Item 6. Directors, Senior Management and Employees—A. Directors and Senior Management — Employment Agreements and Indemnification Agreements.”

Share Option Grants

See “Item 6. Directors, Senior Management and Employees—B. Compensation of Directors and Executive Officers—Share Incentive Plans.”

Other Transactions with Related Parties

On September 25, 2017, I-Mab Tianjin and I-Mab Shanghai entered into a loan agreement with each of Qianhai Equity Investment Fund (Limited Partnership) ("Qianhai Fund"), Shanghai Tasly Pharmaceutical Co., Ltd. ("Shanghai Tasly"), and Tianjin Kangshijing Biopharmaceutical Technology Partnership (Limited Partnership) ("CBC RMB Fund"), pursuant to which each of Qianhai Fund, Shanghai Tasly and CBC RMB Fund made a loan to I-Mab Tianjin to fund its business operations in an aggregate principal amount in RMB equivalent to US$1.3 million, US$5.1 million and US$1.6 million, respectively. Each of these loans bears an annual compound interest rate of 8%. Pursuant to these loan agreements, each of Qianhai Fund, Shanghai Tasly and CBC RMB Fund has the right to contribute its interest in the respective loan to I-Mab Tianjin in exchange for I-Mab Tianjin's equity interests. We fully repaid the loans made by Qianhai Fund and Shanghai Tasly in 2018, and neither of these lenders exercised such right. The loan agreement with CBC RMB Fund was not performed by CBC RMB Fund and was mutually terminated on September 25, 2017.

In January 2018, we entered into a collaboration agreement with Everest, an affiliate of C-Bridge Capital Investment Management, Ltd., whereby both parties agreed to collaborate on programs to co-develop MorphoSys' proprietary CD38 antibody for all indications in hematologic oncology and commercialize the CD38 product in China, Hong Kong, Macau and Taiwan. For a detailed description of this collaboration agreement, see "Item 4. Information on the Company—B. Business Overview—Licensing and Collaboration Arrangements—(c) Collaboration Arrangements." Everest had paid us prepayments of RMB178.7 million and RMB53.1 million (US$7.6 million) for the year ended December 31, 2018 and 2019, respectively.

On November 4, 2019, we and Everest Medicines Limited, or Everest, terminated the collaboration agreement (including all the supplements and amendments thereto) with respect to the co-development and commercialization of TJ202 in Greater China. Upon the termination, Everest will not retain any rights or entitlements to develop or commercialize TJ202 or any economic interest in its commercialization. All intellectual property rights in respect of TJ202 arising from its development under the collaboration agreement are vested and owned by us, and we hold all intellectual property rights and have maximum flexibility to further develop, manufacture and commercialize TJ202 in Greater China. In consideration of the above arrangements, we issued a total value of US$37.0 million of ordinary shares (the "CPP Shares") to Everest, representing Everest's historical contribution to our collaboration and the associated time cost. The CPP Shares were issued concurrently with the completion of our initial public offering, at a per share price equal to the initial public offering price adjusted to reflect the ADS-to-ordinary share ratio. The total value of US$37.0 million was calculated based on the sum of (1) US$33.7 million, which equals cumulative paid-in contributions historically made by Everest under the collaboration agreement; and (2) a negotiated US$3.3 million time cost of the foregoing historical contribution in light of our exclusive rights over the commercialization of TJ202 after this termination.

Based on the initial public offering price of US$14.00 per ADS (or US$6.09 per ordinary share), Everest was issued 6,078,571 ordinary shares and became a minority shareholder of our company upon the completion of our initial public offering. Our issuance of ordinary shares to Everest is being made pursuant to an exemption from registration with the U.S. Securities and Exchange Commission under Regulation S of the U.S. Securities Act of 1933, as amended, or the Securities Act. Everest has agreed not to, directly or indirectly, sell, transfer or dispose of any CPP Shares for a period of 180 days after the date of the prospectus of our initial public offering.

In June 2018, we entered into a biologics master services agreement with CMAB Biopharma (Suzhou) Inc. ("CMAB"), an affiliate of Bridge Capital Partners LLC. In July 2018, we entered into Service Proposal: CMC Development of A Monoclonal Antibody with this entity. Pursuant to these two agreements, CMAB will provide us with CMC services in connection with the preparation of the IND filings to the FDA and the NMPA in a period of 18 to 22 months for US$3.6 million. We had paid CMAB RMB2.8 million for the year ended December 31, 2018.

In September 2016, I-Mab Tianjin entered into a CRO agreement with Tasly Pharmaceutical Group Co., Ltd. ("Tasly") and three ancillary agreements to this CRO agreement in November 2016, May 2017 and June 2017, respectively. Pursuant to these agreements, Tasly Pharmaceutical Group Co., Ltd. will provide I-Mab Tianjin with CRO services in connection with pre-clinical studies for G-CSF-HyFc fusion protein. All of these agreements were terminated on December 10, 2018. We had paid Tasly RMB0.8 million, nil and RMB5.6 million (US$0.8 million) for the year ended December 31, 2017, 2018 and 2019, respectively.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

We have appended consolidated financial statements filed as part of this annual report.

Legal Proceedings

From time to time we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Dividend Policy

Our board of directors has complete discretion on whether to pay dividends, subject to certain requirements of Cayman Islands law. Even if our board of directors decides to pay dividends on our ordinary shares, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our board of directors may deem relevant.

We do not have any present plan to pay any cash dividends on our ordinary shares in the foreseeable future after our initial public offering. We currently intend to retain most, if not all, of our available funds and any future earnings to operate and expand our business.

We are a holding company incorporated in the Cayman Islands. We may rely on dividends from our subsidiaries in China for our cash requirements, including any payment of dividends to our shareholders. PRC regulations may restrict the ability of our PRC subsidiaries to pay dividends to us. See “Item 4. Information on the Company—B. Business Overview—Regulation—PRC Regulation—Regulations Relating to Foreign Exchange and the Dividend Distribution.”

If we pay any dividends on our ordinary shares, we will pay those dividends which are payable in respect of the ordinary shares underlying our ADSs to the depositary, as the registered holder of such ordinary shares, and the depositary then will pay such amounts to our ADS holders in proportion to the ordinary shares underlying the ADSs held by such ADS holders, subject to the terms of the deposit agreement, including the fees and expenses payable thereunder. Cash dividends on our ordinary shares, if any, will be paid in U.S. dollars.

B. Significant Changes

We have not experienced any significant changes since the date of our audited consolidated financial statements included in this annual report.

ITEM 9. THE OFFER AND LISTING

A. Offering and Listing Details

Our ADSs, each ten (10) ADSs representing twenty-three (23) ordinary shares of ours, have been listed on the Nasdaq Global Market since January 17, 2020. Our ADSs trade under the symbol “IMAB.”

B. Plan of Distribution

Not applicable.

C. Markets

Our ADSs, each ten (10) ADSs representing twenty-three (23) ordinary shares of ours, have been listed on the Nasdaq Global Market since January 17, 2020. Our ADSs trade under the symbol "IMAB."

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

The following is a summary of the material provisions of the sixth memorandum and articles of association of our company and of the Companies Law (2020 Revision), insofar as they relate to the material terms of our ordinary shares.

Objects of Our Company . Under our current memorandum and articles of association, the objects of our company are unrestricted and we have the full power and authority to carry out any object not prohibited the Companies Law or any other law of the Cayman Islands.

Ordinary Shares . Certificates representing the ordinary shares are issued in registered form and our ordinary shares are issued when registered in our register of members. We may not issue shares to bearers. Our shareholders who are non-residents of the Cayman Islands may freely hold and vote their shares.

Dividends . Our directors may from time to time declare dividends (including interim dividends) and other distributions on our shares in issue and authorize payment of the same out of the funds of our company lawfully available therefor. In addition, our company may declare dividends by ordinary resolution, but no dividend shall exceed the amount recommended by our directors. Our current memorandum and articles of association provide that dividends may be declared and paid out of the funds of our company lawfully available therefor. Under the laws of the Cayman Islands, our company may pay a dividend out of either profit or the credit standing in our share premium account; provided that in no circumstances may a dividend be paid out of the share premium account if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business.

Voting Rights . Voting at any meeting of shareholders is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of such meeting or any one shareholder or shareholders collectively holding not less than 5% of the votes attaching to the shares present in person or by proxy.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast at a meeting, while a special resolution requires the affirmative vote of not less than two-thirds of the votes attaching to the ordinary shares cast at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our current memorandum and articles of association.

Alternation of Share Capital

We may from time to time by ordinary resolution:

- increase our share capital by such sum, to be divided into shares of such classes and amount, as the resolution shall prescribe;
- consolidate and divide all or any of our share capital into shares of a larger amount than its existing shares;
- subdivide our shares, or any of them, into shares of an amount smaller than that fixed by the memorandum of association, provided that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced share shall be the same as it was in case of the share from which the reduced share is derived; and
- cancel any shares that, at the date of the passing of the resolution, have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the amount of the shares so cancelled.

We may by special resolution, subject to any confirmation or consent required by the Companies Law, reduce our share capital and any capital redemption reserve in any manner authorized by law.

General Meetings of Shareholders . As a Cayman Islands exempted company, we are not obliged by the Companies Law to call shareholders' annual general meetings. Our current memorandum and articles of association provide that we may (but are not obliged to) in each year hold a general meeting as our annual general meeting in which case we shall specify the meeting as such in the notices calling it, and the annual general meeting shall be held at such time and place as may be determined by our directors.

Shareholders' general meetings may be convened by our directors (acting by a resolution of our board). Advance notice of at least 14 calendar days is required for any general shareholders' meeting. A quorum required for any general meeting of shareholders consists of, at the time when the meeting proceeds to business, one or more of our shareholders holding shares which carry in aggregate (or representing by proxy) not less than one-third of all votes attaching to all of our shares in issue and entitled to vote at such general meeting.

The Companies Law does not provide shareholders with any right to requisition a general meeting, nor any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our current articles of association allow our shareholders holding in aggregate not less than one-tenth of all votes attaching to all issued and outstanding shares of our company that as at the date of the deposit carry the right to vote at general meetings of the company to requisition an extraordinary general meeting of our shareholders, in which case our board is obliged to convene an extraordinary general meeting and to put the resolutions so requisitioned to a vote at such meeting. However, our current memorandum and articles of association do not provide our shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such shareholders.

Transfer of Ordinary Shares . Subject to the restrictions set out below, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of shares;

- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four; and
- a fee of such maximum sum as the Nasdaq Global Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer, they shall, within three calendar months after the date on which the instrument of transfer was lodged with our company, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, on ten calendar days' notice being given by advertisement in such one or more newspapers, by electronic means or by any other means in accordance with the rules of the Nasdaq Global Market be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine; provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 30 calendar days in any year.

Liquidation . On the winding up of our company, if the assets available for distribution amongst our shareholders shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus shall be distributed amongst our shareholders in proportion to the par value of the shares held by them at the commencement of the winding up, subject to a deduction from those shares in respect of which there are monies due, of all monies payable to our company for unpaid calls or otherwise. If our assets available for distribution are insufficient to repay the whole of the share capital, such assets will be distributed so that, as nearly as may be, the losses are borne by our shareholders in proportion to the par value of the shares held by them.

Calls on Shares and Forfeiture of Shares . Our board of directors may from time to time make calls upon shareholders in respect of any moneys unpaid on their shares in a notice served to such shareholders at least 14 calendar days prior to the specified time or times of payment. The shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption, Repurchase and Surrender of Shares . We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner as may be determined, before the issue of such shares, by our board of directors or by our shareholders by a special resolution. Our company may also repurchase any of our shares on such terms and in such manner as have been approved by our board of directors or by an ordinary resolution of our shareholders or are otherwise authorized by the articles of association. Under Cayman Islands law, any redemption or repurchase of shares by our company may be made out of profits of our company, out of our company's share premium account or out of the proceeds of a fresh issue of shares made for the purpose of the repurchase or, if so authorized by the articles of association and subject to provisions of the Companies Law, out of capital. Any premium payable on a redemption or repurchase over the par value of the shares to be repurchased or redeemed must be provided for out of profits of our company or from sums standing to the credit of the share premium account of our company or, if authorized by the articles of association and subject to the provisions of the Companies Law, out of capital. At no time may a company redeem or repurchase its shares unless they are fully paid. A company may not redeem or repurchase any of its shares if, as a result of the redemption or repurchase, there would no longer be any issued shares of the company other than shares held as treasury shares. In addition, our company may accept the surrender of any fully paid share for no consideration.

Variations of Rights of Shares . Whenever the capital of our company is divided into different classes the rights attached to any such class may, subject to any rights or restrictions for the time being attached to any class, only be varied with the consent in writing of the holders of all of the issued shares of that class or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued with preferred or other rights shall not, subject to any rights or restrictions for the time being attached to the shares of that class, be deemed to be varied by the creation, allotment or issue of further shares ranking *pari passu* with or subsequent to them or the redemption or purchase of any shares of any class by our company. The rights of the holders of shares shall not be deemed to be varied by the creation or issue of shares with preferred or other rights including, without limitation, the creation of shares with enhanced or weighted voting rights.

Issuance of Additional Shares . Our current memorandum and articles of association authorize our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine.

Our current memorandum and articles of association also authorize our board of directors to issue from time to time one or more series of preference shares and to determine, with respect to any series of preference shares, the terms and rights of that series, including:

- the designation of the series;
- the number of preferred shares to constitute such series;
- the dividend rights, dividend rates, conversion rights, voting rights; and
- the rights and terms of redemption and liquidation preferences.

Issuance of these shares may dilute the voting power of holders of ordinary shares.

Inspection of Books and Records . The notice of registered office is a matter of public record. A list of the names of the current directors and alternate directors (if applicable) are made available by the Registrar of Companies of the Cayman Islands for inspection by any person on payment of a fee. The register of mortgages is open to inspection by creditors and shareholders. Shareholders have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records. However, we intend to provide our shareholders with annual audited financial statements.

Anti-Takeover Provisions . Some provisions of our current memorandum and articles of association may discourage, delay or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that authorize our board of directors to issue preference shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preference shares.

However, under Cayman Islands law, our directors may only exercise the rights and powers granted to them under our current memorandum and articles of association for a proper purpose and for what they believe in good faith to be in the best interests of our company.

Exempted Company . We are an exempted company with limited liability incorporated under the Companies Law. The Companies Law distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

"Limited liability" means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company.

C. Material Contracts

We have not entered into any material contracts other than in the ordinary course of business and other than those described in "Item 4. Information on the Company", "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions," in this "Item 10. Additional Information—C. Material Contracts" or elsewhere in this annual report on Form 20-F.

D. Exchange Controls

See "Item 4. Information on the Company—B. Business Overview—Regulation—Regulations Relating to Foreign Exchange."

E. Taxation

The following summary of the material Cayman Islands, PRC and U.S. federal income tax consequences of an investment in our ADSs or ordinary shares is based upon laws and relevant interpretations thereof in effect as of the date of this annual report, all of which are subject to change. This summary does not deal with all possible tax consequences relating to an investment in our ADSs or ordinary shares, such as the tax consequences under U.S. state and local tax laws or under the tax laws of jurisdictions other than the Cayman Islands, China and the United States.

Cayman Islands Taxation

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to us levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or brought within the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of our shares will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of a dividend or capital to any holder of the shares, nor will gains derived from the disposal of our shares be subject to Cayman Islands income or corporation tax.

No stamp duty is payable in respect of the issue of shares by our company and no stamp duty is payable on transfers of shares of our company provided our company does not hold any interest in land in the Cayman Islands.

PRC Taxation

Under the PRC Enterprise Income Tax Law and its implementation rules, an enterprise established outside China with "de facto management body" within China is considered as a Tax Resident Enterprise for PRC enterprise income tax purposes and is generally subject to a uniform 25% enterprise income tax rate on its worldwide income. The implementation rules define the term "de facto management body" as the body that exercises full and substantial control and overall management over the business, productions, personnel, accounts and properties of an enterprise. In April 2009, the State Administration of Taxation issued Circular 82, which provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore is located in China. Although this circular only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the State Administration of Taxation's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises. According to Circular 82, an offshore incorporated enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China if all of the following conditions are met: (i) the primary location of the day-to-day operational management is in China; (ii) decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel located in China; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in China; and (iv) at least 50% of voting board members or senior executives habitually reside in China.

Our PRC counsel, JunHe LLP, is of the opinion that, based on its understanding of the current PRC Laws and Regulations, I-Mab should not be considered as a PRC resident enterprise for PRC income tax purposes because I-Mab does not meet all of the above conditions. I-Mab is incorporated outside of China and it is not controlled by a PRC enterprise or PRC enterprise group. We have structured a clear management guideline in place to segregate the policy set up and business operating execution responsibilities in order to differentiate the effective control from our headquarter office and subsidiaries including record keeping and offshore work location plan. I-Mab is a company incorporated outside the PRC. As a holding company, its key assets are its ownership interests in its subsidiaries, and its key assets are located, and its records (including the resolutions of its board of directors and the resolutions of its shareholders) are maintained, outside China. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term "de facto management body." However, we cannot guarantee you that PRC tax authorities will not take a different view.

If the PRC tax authorities determine that I-Mab is a PRC resident enterprise for enterprise income tax purposes, our worldwide income could be subject to 25% enterprise income tax; and any dividends payable to non-resident enterprise holders of our common shares or ADSs may be treated as income derived from sources within China and therefore, subject to a 10% withholding tax (or 20% in the case of non-resident individual holders) unless an applicable income tax treaty provides otherwise. In addition, capital gains realized by non-resident enterprise shareholders (including our ADS holders) upon the disposition of our common shares or ADSs may be treated as income derived from sources within PRC and therefore, subject to 10% income tax (or 20% in the case of non-resident individual shareholders or ADS holders) unless an applicable income tax treaty provides otherwise. It is unclear whether non-PRC shareholders of our company would be able to claim the benefits of any tax treaties between their country of tax residence and the PRC in the event that we are treated as a PRC resident enterprise. See "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—If we are classified as a PRC resident enterprise for PRC income tax purposes, such classification could result in unfavorable tax consequences to us and our non-PRC shareholders or ADS holders."

United States Federal Income Tax Considerations

The following discussion is a summary of U.S. federal income tax considerations relating to the ownership and disposition of our ADSs or ordinary shares by a U.S. Holder (as defined below) that acquires our ADSs in our initial public offering and holds our ADSs as "capital assets" (generally, property held for investment) under the U.S. Internal Revenue Code of 1986, as amended, or the Code. This discussion is based upon existing U.S. federal tax law, which is subject to differing interpretations or change, possibly with retroactive effect. No ruling has been sought from the U.S. Internal Revenue Service, or the IRS, with respect to any U.S. federal income tax consequences described below, and there can be no assurance that the IRS or a court will not take a contrary position. This discussion does not address the U.S. federal estate, gift, Medicare, and alternative minimum tax considerations, certain information reporting requirements pursuant to section 1471 through 1474 of the Code, or any state, local, and non-U.S. tax considerations, relating to the ownership or disposition of our ADSs or ordinary shares. This discussion, moreover, does not discuss all aspects of U.S. federal income taxation that may be important to particular investors in light of their individual investment circumstances or to investors subject to special tax situations such as:

- banks and other financial institutions;
- insurance companies;
- pension plans;
- cooperatives;
- regulated investment companies;
- real estate investment trusts;

- broker-dealers;
- traders in securities that elect to use a mark-to-market method of accounting;
- certain former U.S. citizens or long-term residents;
- tax-exempt entities (including private foundations);
- investors who are not U.S. Holders;
- investors who own (directly, indirectly or constructively) 10% or more of our stock (by vote or value);
- investors who acquire their ADSs or ordinary shares pursuant to any employee share option or otherwise as compensation;
- investors that will hold their ADSs or ordinary shares as part of a straddle, hedge, conversion, constructive sale or other integrated transaction for U.S. federal income tax purposes;
- investors required to accelerate the recognition of any item of gross income with respect to our ADSs or ordinary shares as a result of such income being recognized on an applicable financial statement; or
- investors that have a functional currency other than the U.S. dollar;

all of whom may be subject to tax rules that differ significantly from those discussed below. Each U.S. Holder is urged to consult its tax advisor regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of an investment in our ADSs or ordinary shares.

General

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of our ADSs or ordinary shares that is, for U.S. federal income tax purposes, (i) an individual who is a citizen or resident of the United States, (ii) a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created in, or organized under the law of, the United States or any state thereof or the District of Columbia, (iii) an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source, or (iv) a trust (A) the administration of which is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (B) that has otherwise validly elected to be treated as a U.S. person under the Code.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) is a beneficial owner of our ADSs or ordinary shares, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partner and the partnership. Partnerships holding our ADSs or ordinary shares and their partners are urged to consult their tax advisors regarding an investment in our ADSs or ordinary shares.

For U.S. federal income tax purposes, it is generally expected that a U.S. Holder of ADSs will be treated as the beneficial owner of the underlying shares represented by the ADSs. The remainder of this discussion assumes that a U.S. Holder of our ADSs will be treated as the beneficial owner of the underlying shares represented by the ADSs. Accordingly, deposits or withdrawals of ordinary shares for ADSs will generally not be subject to U.S. federal income tax.

Passive Foreign Investment Company Considerations

A non-U.S. corporation, such as our company, will be classified as a passive foreign investment company, or, or PFIC, for U.S. federal income tax purposes for any taxable year if either (i) 75% or more of its gross income for such year consists of certain types of "passive" income or (ii) 50% or more of the value of its assets (generally determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income. For this purpose, cash and assets readily convertible into cash are each categorized as a passive asset and the company's goodwill and other unbooked intangibles are taken into account. Passive income generally includes, among other things, dividends, interest, rents, royalties, and gains from the disposition of passive assets. We will be treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which we own, directly or indirectly, 25% or more (by value) of the stock.

No assurance can be given with respect to our PFIC status for our taxable year ended December 31, 2019 or for the current taxable year or any future taxable year. The determination of whether we are or will become a PFIC is uncertain, because it is a fact-intensive inquiry made on an annual basis that depends, in part, on the composition of our income and assets. Fluctuations in the market price of our ADSs may cause us to become a PFIC for the current or subsequent taxable years because the value of our assets for the purpose of the asset test may be determined by reference to the market price of our ADSs from time to time (which may be volatile for biopharmaceutical companies, such as ours, that have not yet achieved commercialization with respect to any of their products). The composition of our income and assets may also be affected by how, and how quickly, we use our liquid assets. Under circumstances where our revenue from activities that produce passive income increases relative to our revenue from activities that produce non-passive income, or where we determine not to deploy cash for active purposes, our risk of becoming classified as a PFIC will substantially increase. In addition, because there are uncertainties in the application of the relevant rules, it is possible that the IRS may challenge our classification of certain income and assets as non-passive or our valuation of our tangible and intangible assets, each of which may result in our being or becoming a PFIC for the current or subsequent taxable years.

The discussion below under "—Dividends" and "—Sale or Other Disposition of ADSs or Ordinary Shares" is written on the basis that we will not be classified as a PFIC for U.S. federal income tax purposes. The U.S. federal income tax rules that apply if we are treated as a PFIC are generally discussed below under "—Passive Foreign Investment Company Rules."

Dividends

Subject to the discussion below under "—Passive Foreign Investment Company Rules," any cash distributions (including the amount of any tax withheld) paid on our ADSs or ordinary shares out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, will generally be includible in the gross income of a U.S. Holder as dividend income on the day actually or constructively received by the U.S. Holder. Because we do not intend to determine our earnings and profits on the basis of U.S. federal income tax principles, any distribution we pay will generally be reported as a "dividend" for U.S. federal income tax purposes. Dividends received on our ADSs or ordinary shares will not be eligible for the dividends received deduction allowed to corporations in respect of dividends received from U.S. corporations.

A non-corporate U.S. Holder will generally be subject to tax on dividend income from a "qualified foreign corporation" at a lower applicable capital gains rate rather than the marginal tax rates generally applicable to ordinary income provided that certain conditions are satisfied, including that (1) our ADSs or ordinary shares on which the dividends are paid are readily tradable on an established securities market in the United States, or in the event that we are deemed to be a PRC resident enterprise under the PRC tax law, we are eligible for the benefits of the United States-PRC income tax treaty (the "Treaty"); (2) we are neither a PFIC nor treated as such with respect to a U.S. Holder for the taxable year in which the dividend is paid and the preceding taxable year, and (3) certain holding period requirements are met. The ADSs have been approved for listing on the Nasdaq Global Market. Provided the listing is approved, we believe that the ADSs will be readily tradable on an established securities market in the United States, and that we will be a qualified foreign corporation with respect to dividends paid on the ADSs. Since we do not expect that our ordinary shares will be listed on an established securities market, we do not believe that dividends that we pay on our ordinary shares that are not represented by ADSs will meet the conditions required for the reduced tax rate. There can be no assurance, however, that our ADSs will continue to be considered readily tradable on an established securities market in later years.

In the event that we are deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law, we may be eligible for the benefits of Treaty and in that case we would be treated as a qualified foreign corporation with respect to dividends paid on our ordinary shares or ADSs. Each non-corporate U.S. Holder is advised to consult its tax advisors regarding the availability of the reduced tax rate applicable to qualified dividend income for any dividends we pay with respect to our ADSs or ordinary shares.

Dividends will generally be treated as income from foreign sources for U.S. foreign tax credit purposes and will generally constitute passive category income. In the event that we are deemed to be a PRC resident enterprise under the PRC Enterprise Income Tax Law, a U.S. Holder may be subject to PRC withholding taxes on dividends paid on our ADSs or ordinary shares. See "—PRC Taxation" above. In that case, depending on the U.S. Holder's individual facts and circumstances, a U.S. Holder may be eligible, subject to a number of complex limitations, to claim a foreign tax credit not in excess of any applicable treaty rate in respect of any foreign withholding taxes imposed on dividends received on our ADSs or ordinary shares. A U.S. Holder who does not elect to claim a foreign tax credit for foreign tax withheld may instead claim a deduction, for U.S. federal income tax purposes, in respect of such withholding, but only for a year in which such holder elects to do so for all creditable foreign income taxes. The rules governing the foreign tax credit are complex and their outcome depends in large part on the U.S. Holder's individual facts and circumstances. Accordingly, U.S. Holders are urged to consult their tax advisors regarding the availability of the foreign tax credit under their particular circumstances.

Sale or Other Disposition of ADSs or Ordinary Shares

Subject to the discussion below under "—Passive Foreign Investment Company Rules," a U.S. Holder will generally recognize capital gain or loss upon the sale or other disposition of ADSs or ordinary shares in an amount equal to the difference between the amount realized upon the disposition and the holder's adjusted tax basis in such ADSs or ordinary shares. Any capital gain or loss will be long-term if the ADSs or ordinary shares have been held for more than one year and will generally be U.S. source gain or loss for U.S. foreign tax credit purposes. Long-term capital gain of non-corporate U.S. Holders is generally eligible for a reduced rate of taxation. The deductibility of a capital loss may be subject to limitations. In the event that we are treated as a PRC resident enterprise under the Enterprise Income Tax Law and gain from the disposition of the ADSs or ordinary shares is subject to tax in China, a U.S. Holder that is eligible for the benefits of the Treaty may elect to treat the gain as PRC source income. If a U.S. Holder is not eligible for the benefits of the Treaty or fails to make the election to treat any gain as foreign source, then such U.S. Holder may not be able to use the foreign tax credit arising from any PRC tax imposed on the disposition of the ADSs or ordinary shares unless such credit can be applied (subject to applicable limitations) against U.S. federal income tax due on other income derived from foreign sources in the same income category (generally, the passive category). U.S. Holders are urged to consult their tax advisors regarding the tax consequences if a foreign tax is imposed on a disposition of our ADSs or ordinary shares, including the availability of the foreign tax credit under their particular circumstances and the election to treat any gain as PRC source income.

Passive Foreign Investment Company Rules

If we are classified as a PFIC for any taxable year during which a U.S. Holder holds our ADSs or ordinary shares, and unless the U.S. Holder makes a mark-to-market election (as described below), the U.S. Holder will generally be subject to special tax rules that have a penalizing effect, regardless of whether we remain a PFIC, on (i) any excess distribution that we make to the U.S. Holder (which generally means any distribution paid during a taxable year to a U.S. Holder that is greater than 125 percent of the average annual distributions paid in the three preceding taxable years or, if shorter, the U.S. Holder's holding period for the ADSs or ordinary shares), and (ii) any gain realized on the sale or other disposition (including, under certain circumstances, a pledge) of ADSs or ordinary shares. Under the PFIC rules:

- the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period for the ADSs or ordinary shares;
- the amount allocated to the current taxable year and any taxable years in the U.S. Holder's holding period prior to the first taxable year in which we are classified as a PFIC (each, a "pre-PFIC year"), will be taxable as ordinary income; and
- the amount allocated to each prior taxable year, other than a pre-PFIC year, will be subject to tax at the highest tax rate in effect for individuals or corporations, as appropriate, for that year, increased by an additional tax equal to the interest on the resulting tax deemed deferred with respect to each such taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs or ordinary shares and any of our subsidiaries is also a PFIC, such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC for purposes of the application of these rules. U.S. Holders are urged to consult their tax advisors regarding the application of the PFIC rules to any of our subsidiaries.

As an alternative to the foregoing rules, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election with respect to such stock. If a U.S. Holder makes this election, the holder will generally (i) include as ordinary income for each taxable year that we are a PFIC the excess, if any, of the fair market value of ADSs held at the end of the taxable year over the adjusted tax basis of such ADSs and (ii) deduct as an ordinary loss the excess, if any, of the adjusted tax basis of the ADSs over the fair market value of such ADSs held at the end of the taxable year, but such deduction will only be allowed to the extent of the amount previously included in income as a result of the mark-to-market election. The U.S. Holder's adjusted tax basis in the ADSs would be adjusted to reflect any income or loss resulting from the mark-to-market election. If a U.S. Holder makes a mark-to-market election in respect of a corporation classified as a PFIC and such corporation ceases to be classified as a PFIC, the holder will not be required to take into account the gain or loss described above during any period that such corporation is not classified as a PFIC. If a U.S. Holder makes a mark-to-market election, any gain such U.S. Holder recognizes upon the sale or other disposition of our ADSs in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as ordinary loss, but such loss will only be treated as ordinary loss to the extent of the net amount previously included in income as a result of the mark-to-market election. If a U.S. Holder makes a mark-to-market election it will be effective for the taxable year for which the election is made and all subsequent taxable years unless the ADSs are no longer treated as marketable stock or the IRS consents to the revocation of the election.

The mark-to-market election is available only for "marketable stock," which is stock that is regularly traded on a qualified exchange or other market, as defined in applicable United States Treasury Regulations. We expect that our ADSs, but not our ordinary shares, will be treated as marketable stock upon their listing on the Nasdaq Global Market. However, we cannot guarantee that, once listed, our ADSs will continue to be listed and traded on the Nasdaq Global Market. Furthermore, while we anticipate that our ADSs should qualify as being regularly traded, but no assurances may be given in this regard.

Because a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the PFIC rules with respect to such U.S. Holder's indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes.

We do not intend to provide information necessary for U.S. Holders to make qualified electing fund elections which, if available, would result in tax treatment different from the general tax treatment for PFICs described above.

If a U.S. Holder owns our ADSs or ordinary shares during any taxable year that we are a PFIC, the holder must generally file an annual IRS Form 8621. Each U.S. Holder is urged to consult its tax advisor concerning the U.S. federal income tax consequences of purchasing, holding and disposing ADSs or ordinary shares if we are or become a PFIC, including the possibility of making a mark-to-market election.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers, and are required to file reports and other information with the SEC. Specifically, we are required to file annually an annual report on Form 20-F within four months after the end of each fiscal year, which is December 31. All information filed with the SEC can be obtained over the internet at the SEC's website at www.sec.gov. You can request copies of documents, upon payment of a duplicating fee, by writing to the SEC. As a foreign private issuer, we are exempt from the rules under the Exchange Act prescribing the furnishing and content of quarterly reports and proxy statements, and officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

We will furnish Citibank, N.A., the depositary of our ADSs, with our annual reports, which will include a review of operations and annual audited consolidated financial statements prepared in conformity with U.S. GAAP, and all notices of shareholders' meetings and other reports and communications that are made generally available to our shareholders. The depositary will make such notices, reports and communications available to holders of ADSs and, upon our request, will mail to all record holders of ADSs the information contained in any notice of a shareholders' meeting received by the depositary from us.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Inflation

To date, inflation in China has not materially impacted our results of operations. According to the National Bureau of Statistics of China, the year-over-year percent changes in the consumer price index for December 2017, 2018 and 2019 were increases of 1.8%, 1.9% and 4.5%, respectively. Although we have not been materially affected by inflation in the past, we can provide no assurance that we will not be affected by higher rates of inflation in China in the future.

Market Risks

Interest and Credit Risk

We had cash, cash equivalents and restricted cash of RMB412.7 million, RMB1,680.9 million and RMB1,193.3 million (US$171.4 million) as of December 31, 2017, 2018 and 2019, respectively. Our exposure to interest rate risk primarily relates to the interest income generated by excess cash, which is mostly held in interest-bearing bank deposits. Interest-earning instruments carry a degree of interest rate risk. We have not been exposed to material risks due to changes in interest rates, and we have not used any derivative financial instruments to manage our interest risk exposure.

Our credit risk is primarily attributable to the carrying amounts of cash and cash equivalents. The carrying amounts of cash and cash equivalents represent the maximum amount of loss due to credit risk. We mainly place or invest cash and cash equivalents with state-owned or reputable financial institutions in the PRC, and reputable financial institutions outside of the PRC. We do not believe that our cash and cash equivalents have significant risk of default or illiquidity, and we will continually monitor the credit worthiness of these financial institutions. While we believe our cash and cash equivalents do not contain excessive risk, future investments may be subject to adverse changes in market value.

Foreign Exchange Risk

Most of our revenues and expenses are denominated in RMB. We do not believe that we currently have any significant direct foreign exchange risk and have not used any derivative financial instruments to hedge exposure to such risk. Although our exposure to foreign exchange risks should be limited in general, the value of your investment in our ADSs will be affected by the exchange rate between U.S. dollar and RMB because the value of our business is effectively denominated in RMB, while our ADSs will be traded in U.S. dollars.

The conversion of RMB into foreign currencies, including U.S. dollars, is based on rates set by the People's Bank of China. The RMB has fluctuated against the U.S. dollar, at times significantly and unpredictably. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between RMB and the U.S. dollar in the future.

To the extent that we need to convert U.S. dollars into RMB for our operations, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares or ADSs or for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amounts available to us.

As of December 31, 2019, we had RMB-denominated cash and cash equivalents, restricted cash and short-term investments of RMB160.6 million (US$23.1 million). A 10% depreciation of RMB against U.S. dollar based on the foreign exchange rate on December 31, 2019 would result in a decrease of US$2.3 million in cash and cash equivalents. A 10% appreciation of RMB against U.S. dollar based on the foreign exchange rate on December 31, 2019 would result in an increase of US$2.3 million in cash and cash equivalents.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Charges Our ADS Holders May Have to Pay

The depositary of our ADS facility, Citibank, N.A., shall charge the following fees for the services performed under the terms of the deposit agreement:

ADS Fees

The following ADS fees are payable under the terms of the Deposit Agreement:

Service	Rate	By Whom Paid
(1) Issuance of ADSs (*e.g.* , an issuance upon a deposit of Shares, upon a change in the ADS(s)-to-Share(s) ratio, or for any other reason), excluding issuances as a result of distributions described in paragraph (4) below.	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) issued.	Person for whom ADSs are issued.
(2) Cancellation of ADSs (*e.g.* , a cancellation of ADSs for Delivery of deposited Shares, upon a change in the ADS(s)-to-Share(s) ratio, or for any other reason).	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) cancelled.	Person for whom ADSs are being cancelled.
(3) Distribution of cash dividends or other cash distributions (*e.g.* , upon a sale of rights and other entitlements).	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) held.	Person to whom the distribution is made.

(4) Distribution of ADSs pursuant to (i) stock dividends or other free stock distributions, or (ii) an exercise of rights to purchase additional ADSs.	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) held.	Person to whom the distribution is made.
(5) Distribution of securities other than ADSs or rights to purchase additional ADSs (*e.g.* , spin-off shares).	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) held.	Person to whom the distribution is made.
6) ADS Services.	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) held on the applicable record date(s) established by the Depositary.	Person holding ADSs on the applicable record date(s) established by the Depositary.
7) Registration of ADS Transfers (*e.g.* , upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and *vice versa* , or for any other reason).	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) transferred.	Person for whom or to whom ADSs are transferred.
8) Conversion of ADSs of one series for ADSs of another series (*e.g.* , upon conversion of Partial Entitlement ADSs for Full Entitlement ADSs, or upon conversion of Restricted ADSs into freely transferable ADSs, and *vice versa*).	Up to U.S. $5.00 per 100 ADSs (or fraction thereof) converted.	Person for whom ADSs are converted or to whom the converted ADSs are delivered.

Charges

An ADS holder will also be responsible for the following ADS charges:

(i) taxes (including applicable interest and penalties) and other governmental charges;

(ii) such registration fees as may from time to time be in effect for the registration of Shares or other Deposited Securities on the share register and applicable to transfers of Shares or other Deposited Securities to or from the name of the Custodian, the Depositary or any nominees upon the making of deposits and withdrawals, respectively;

(iii) such cable, telex and facsimile transmission and delivery expenses as are expressly provided in the Deposit Agreement to be at the expense of the person depositing Shares or withdrawing Deposited Property or of the Holders and Beneficial Owners of ADSs;

(iv) in connection with the conversion of Foreign Currency, the fees, expenses, spreads, taxes and other charges of the Depositary and/or conversion service providers (which may be a division, branch or Affiliate of the Depositary). Such fees, expenses, spreads, taxes, and other charges shall be deducted from the Foreign Currency;

(v) any reasonable and customary out-of-pocket expenses incurred in such conversion and/or on behalf of the Holders and Beneficial Owners in complying with currency exchange control or other governmental requirements; and

(vi) the fees, charges, costs and expenses incurred by the Depositary, the Custodian, or any nominee in connection with the ADR program.

The above fees and charges may at any time and from time to time be changed by agreement between the Depositary and us.

Fees and Other Payments Made by the Depositary to Us

Our depositary anticipates to reimburse us for certain expenses we incur in respect of the ADR program established pursuant to the Deposit Agreement, by making available a portion of the ADS fees charged in respect of the ADR program or otherwise, upon such terms and conditions as the Depositary agrees with us from time to time. As of the date of this annual report, we have not received such reimbursement from the depositary.

PART II.

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Material Modifications to the Rights of Security Holders

See "Item 10. Additional Information—B. Memorandum and Articles of Association" for a description of the rights of securities holders, which remain unchanged.

Use of Proceeds

The following "Use of Proceeds" information relates to the registration statement on Form F-1, as amended (File Number 333-234363) (the "F-1 Registration Statement") in relation to our initial public offering of 7,407,400 ADSs representing 17,037,020 ordinary shares, at an initial offering price of US$14.00 per ADS. Our initial public offering closed in February 2020. Jefferies LLC and China International Capital Corporation Hong Kong Securities Limited were the representatives of the underwriters for our initial public offering. Counting in the ADSs sold upon the exercise of the over-allotment option by our underwriters, we offered and sold 8,175,750 ADSs and received a total amont of US$105.3 million in net proceeds.

The F-1 Registration Statement was declared effective by the SEC on January 16, 2020. The total expenses incurred for our company's account in connection with our initial public offering was approximately US$14.1 million, which included US$9.1 million in underwriting discounts and commissions for the initial public offering and approximately US$5.0 million in other costs and expenses for our initial public offering. We received net proceeds of approximately US$96.4 million from our initial public offering. None of the transaction expenses included payments to directors or officers of our company or their associates, persons owning more than 10% or more of our equity securities or our affiliates. None of the net proceeds from the initial public offering were paid, directly or indirectly, to any of our directors or officers or their associates, persons owning 10% or more of our equity securities or our affiliates.

We still intend to use the proceeds from our initial public offering, as disclosed in our registration statements on Form F-1.

ITEM 15. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer, we carried out an evaluation of the effectiveness of our disclosure controls and procedures, which is defined in Rules 13a-15(e) under the Exchange Act, as of December 31, 2019. Based upon that evaluation, our management, with the participation of our chief executive officer and chief financial officer, has concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were not effective in ensuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report by our independent registered public accounting firm due to a transition period established by rules of the SEC for newly listed public companies.

Internal Control over Financial Reporting

In connection with the audits of our consolidated financial statements included in this annual report, we and our independent registered public accounting firm identified the following material weaknesses and other control deficiencies in our internal control over financial reporting. As defined in the standards established by the U.S. Public Company Accounting Oversight Board, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses that have been identified relate to (i) our lack of sufficient and competent financial reporting and accounting personnel with appropriate knowledge of U.S. GAAP and SEC reporting and compliance requirements, to formalize key controls over financial reporting and to prepare consolidated financial statements and related disclosures; and (ii) our lack of sufficient documented financial closing policies and procedures, specifically those related to (a) accounting for licensing and collaboration agreements and (b) period end expenses cut-off and accruals. These material weaknesses, if not timely remedied, may lead to significant misstatements in our consolidated financial statements in the future.

We have implemented and plan to implement a number of measures to address the material weaknesses that have been identified in connection with the audits of our consolidated financial statements as of and for the year ended December 31, 2019. We have hired additional qualified financial and accounting staff with working experience of U.S. GAAP and SEC reporting requirements, and plan to continue such hiring efforts. We intend to conduct regular and continuous U.S. GAAP accounting and financial reporting training programs for our financial reporting and accounting personnel. We further intend to establish sufficient and formal financial closing policies and procedures, specifically those related to accounting for licensing and collaboration arrangements and period end cut-off and accruals. We plan to, as work-in-progress, engage an external consulting firm to assist us to assess Sarbanes-Oxley Act compliance requirements and improve our overall internal controls. Furthermore, we plan to prepare more detailed guidance on accounting policies, manuals and closing procedures to improve the quality and accuracy of our period end financing closing process. We will continue to implement these and other measures to remediate our internal control deficiencies. We may incur significant costs in the implementation of such measures. However, the implementation of these measures may not fully address the deficiencies in our internal control over financial reporting, and we cannot assure you that all of these measures will be sufficient to remediate our material weakness in time, or at all.

As a company with less than US$1.07 billion in revenue for our last fiscal year, we qualify as an "emerging growth company" pursuant to the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. These provisions include exemption from the auditor attestation requirement under Section 404 of the Sarbanes-Oxley Act of 2002 in the assessment of the emerging growth company's internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

Other than as described above, there were no changes in our internal controls over financial reporting that occurred during the period covered by this annual report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Conor Chia-hung Yang, a member of our audit committee and independent director (under the standards under Rule 5605(c)(2) of the Nasdaq Stock Market Rules and Rule 10A-3 under the Securities Exchange Act of 1934), is an audit committee financial expert.

ITEM 16B. CODE OF ETHICS

Our board of directors adopted a code of business conduct and ethics that applies to our directors, officers and employees in November 2019. We have posted a copy of our code of business conduct and ethics on our website at *http://ir.i-mabbiopharma.com/* .

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by PricewaterhouseCoopers Zhong Tian LLP, our principal external auditors, for the periods indicated. We did not pay any other fees to our auditors during the periods indicated below.

	For the Year Ended December 31,	
	2018	2019
	(in thousands of RMB)	
Audit fees (1)	2,900	4,260
Tax fees (2)	—	230
All other fees	—	160

Notes:

(1) "Audit fees" means the aggregate fees billed for professional services rendered by our principal auditors for the audit of our annual financial statements and the review of our comparative interim financial statements, including audit fees relating to our initial public offering in 2020.
(2) "Tax fees" includes fees billed for tax consultations.

The policy of our audit committee is to pre-approve all audit and other service provided by PricewaterhouseCoopers Zhong Tian LLP as described above, other than those for *de minimis* services which are approved by the Audit Committee prior to the completion of the audit.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

None.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

As a Cayman Islands company listed on NASDAQ, we are subject to the NASDAQ corporate governance listing standards. However, NASDAQ rules permit a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the NASDAQ corporate governance listing standards. Currently, we do not plan to rely on home country exemption for corporate governance matters. However, if we choose to follow any home country practice in the future, our shareholders may be afforded less protection than they otherwise would under the NASDAQ corporate governance listing standards applicable to U.S. domestic issuers. See "Item 3. Key Information—D. Risk Factors—Risks Related to Our ADSs—We are a foreign private issuer within the meaning of the rules under the Exchange Act, and as such we are exempt from certain provisions applicable to U.S. domestic public companies."

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART III.

ITEM 17. FINANCIAL STATEMENTS

We have elected to provide financial statements pursuant to Item 18.

ITEM 18. FINANCIAL STATEMENTS

The consolidated financial statements of I-Mab are included at the end of this annual report.

ITEM 19. EXHIBITS

Exhibit Number	Description of Document
1.1	Sixth Amended and Restated Memorandum and Articles of Association of the Registrant (incorporated herein by reference to Exhibit 3.2 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
2.1	Registrant's Specimen American Depositary Receipt (incorporated herein by reference to Exhibit 4.3 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
2.2	Registrant's Specimen Certificate for Ordinary Shares (incorporated herein by reference to Exhibit 4.2 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
2.3	Form of Deposit Agreement, among the Registrant, the depositary and holder of the American Depositary Receipt (incorporated herein by reference to Exhibit 4.3 to to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
2.4	Fourth Amended and Restated Shareholders Agreement, dated as of July 25, 2019, between the Registrant and other parties thereto (incorporated herein by reference to Exhibit 4.4 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
2.5*	Description of American Depositary Shares of the Registrant
2.6*	Description of Ordinary Shares of the Registrant
4.1	Second Amended and Restated 2017 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.1 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.2	Second Amended and Restated 2018 Employee Stock Option Plan (incorporated herein by reference to Exhibit 10.2 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.3	2019 Share Incentive Plan (incorporated herein by reference to Exhibit 10.22 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.4	Form of Indemnification Agreement, between the Registrant and its directors and executive officers (incorporated herein by reference to Exhibit 10.3 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)

4.5	Form of Employment Agreement, between the Registrant and its executive officers (incorporated herein by reference to Exhibit 10.4 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.6	Framework Agreement, dated as of May 26, 2017, among the Registrant and the other parties thereto (incorporated herein by reference to Exhibit 10.8 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.7†	License and Collaboration Agreement, dated as of November 30, 2017, between the Registrant and MorphoSys AG (incorporated herein by reference to Exhibit 10.13 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.8	Intellectual Property Assignment and License Agreement, dated as of October 16, 2015, between Tasgen Bio-tech (Tianjin) Co., Ltd. and Genexine, Inc. (incorporated herein by reference to Exhibit 10.14 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.9	Intellectual Property License Agreement, dated as of December 22, 2017, between the Registrant and Genexine, Inc. (incorporated herein by reference to Exhibit 10.15 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.10	License and Sublicense Agreement, dated as of November 4, 2016, between the Registrant and Ferring International Center SA (incorporated herein by reference to Exhibit 10.16 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.11†	Collaboration Agreement, dated as of July 9, 2019, between I-Mab Biopharma, US Limited and MacroGenics, Inc. (incorporated herein by reference to Exhibit 10.17 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.12*†	License and Collaboration Agreement, dated as of July 26, 2018, between the Registrant and ABL Bio
4.13	English translation of Product Development Agreement, dated as of December 10, 2018, between I-Mab Shanghai and CSPC Baike (Shandong) Biopharmaceutical Co., Ltd. (incorporated herein by reference to Exhibit 10.19 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.14	CD38 Product Collaboration Agreement, dated as of January 22, 2018, between the Registrant and Everest Medicines Limited (incorporated herein by reference to Exhibit 10.20 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.15	Supplemental Agreement to CD38 Product Collaboration Agreement, dated as of November 7, 2018, between the Registrant and Everest Medicines Limited (incorporated herein by reference to Exhibit 10.21 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
4.16	Termination and Settlement Agreement, dated as of November 4, 2019, between the Registrant and Everest Medicines Limited (incorporated herein by reference to Exhibit 10.23 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
8.1*	Principal Subsidiaries of the Registrant

11.1	Code of Business Conduct and Ethics of the Registrant (incorporated herein by reference to Exhibit 99.1 to the registration statement on Form F-1(File No. 333-234363), as amended, initially filed on October 29, 2019)
12.1*	CEO Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2*	CFO Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1**	CEO Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2**	CFO Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1*	Consent of JunHe LLP
101.INS*	XBRL INSTANCE DOCUMENT
101.SCH*	XBRL TAXONOMY EXTENSION SCHEMA
101.CAL*	XBRL TAXONOMY EXTENSION CALCULATION LINKBASE
101.DEF*	XBRL TAXONOMY EXTENSION DEFINITION LINKBASE
101.LAB*	XBRL TAXONOMY EXTENSION LABEL LINKBASE
101.PRE*	XBRL TAXONOMY EXTENSION PRESENTATION LINKBASE

* Filed herewith.
** Furnished herewith.
† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

I-MAB

By: /s/ Jielun Zhu
Name: Jielun Zhu
Title: Director and Chief Financial Officer

Date: April 29, 2020

I-Mab

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of I-Mab

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of I-Mab and its subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of comprehensive loss, of changes in shareholders' deficit and of cash flows for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/PricewaterhouseCoopers Zhong Tian LLP
Shanghai, the People's Republic of China
April 29, 2020

We have served as the Company's auditor since 2018.

I-MAB
Consolidated Balance Sheets
As of December 31, 2018 and 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

		As of December 31,				
		2018	2019		2019	
	Notes	RMB	RMB	US$ (Note 2.5)	RMB (Pro forma) (Note 26)	US$ (Note 2.5) (Pro forma) (Note 26)
Assets						
Current assets						
Cash and cash equivalents		1,588,278	1,137,473	163,388	1,137,473	163,388
Restricted cash	9	92,653	55,810	8,017	55,810	8,017
Contract assets	18	11,000	—	—	—	—
Short-term investments	2.8	—	32,000	4,597	32,000	4,597
Prepayments and other receivables	3	88,972	136,036	19,540	136,036	19,540
Other financial assets	2.4, 4	255,958	—	—	—	—
Total current assets		2,036,861	1,361,319	195,542	1,361,319	195,542
Property, equipment and software	5	27,659	30,069	4,319	30,069	4,319
Operating lease right-of-use assets	6	—	16,435	2,361	16,435	2,361
Intangible assets	7	148,844	148,844	21,380	148,844	21,380
Goodwill	8	162,574	162,574	23,352	162,574	23,352
Other non-current assets		—	18,331	2,633	18,331	2,633
Total assets		**2,375,938**	**1,737,572**	**249,587**	**1,737,572**	**249,587**
Liabilities, mezzanine equity and shareholders' equity (deficit)						
Current liabilities						
Short-term borrowings	9	80,000	50,000	7,182	50,000	7,182
Accruals and other payables	10	67,674	273,553	39,293	273,553	39,293
Advance from customers	18	14,151	—	—	—	—
Operating lease liabilities, current	6	—	6,807	978	6,807	978
Research and development funding received	23	178,715	—	—	—	—
Ordinary shares to be issued to Everest	23	—	258,119	37,076	—	—
Warrant liabilities	2.4, 15	5,618	—	—	—	—
Total current liabilities		346,158	588,479	84,529	330,360	47,453
Convertible promissory notes	14	67,026	68,199	9,796	68,199	9,796
Operating lease liabilities, non-current	6	—	7,492	1,076	7,492	1,076
Deferred subsidy income	2.13	2,500	3,920	563	3,920	563
Total liabilities		**415,684**	**668,090**	**95,964**	**409,971**	**58,888**
Commitments and contingencies	22					
Mezzanine equity						
Series A convertible preferred shares (US$0.0001 par value, 30,227,056 shares authorized, issued and outstanding on an actual basis as of December 31, 2018 and 2019, and nil outstanding on a pro forma basis as of December 31, 2019)	13	687,482	687,482	98,751	—	—
Series B convertible preferred shares (US$0.0001 par value, 30,305,212 shares authorized, issued and outstanding on an actual basis as of December 31, 2018 and 2019, and nil outstanding on a pro forma basis as of December 31, 2019)	13	921,243	921,243	132,328	—	—
Series C convertible preferred shares (US$0.0001 par value, 31,046,360 shares authorized, issued and outstanding on an actual basis as of December 31, 2018 and 2019, and nil outstanding on a pro forma basis as of December 31, 2019)	13	1,306,633	1,306,633	187,686	—	—
Series C-1 convertible preferred shares (US$0.0001 par value, nil and 3,857,143 shares authorized, issued and outstanding on an actual basis as of December 31, 2018 and 2019, respectively, and nil outstanding on a pro forma basis as of December 31, 2019)	13	—	188,819	27,122	—	—
Total mezzanine equity		**2,915,358**	**3,104,177**	**445,887**	**—**	**—**

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Consolidated Balance Sheets (Continued)
As of December 31, 2018 and 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

		As of December 31,				
		2018	2019		2019	
	Notes	RMB	RMB	US$ (Note 2.5)	RMB	US$ (Note 2.5) (Note 26)
Shareholders' equity (deficit)						
Ordinary shares (US$0.0001 par value, 500,000,000 shares authorized as of December 31, 2018 and 2019; 800,000,000 shares authorized on a pro forma basis as of December 31, 2019, 8,363,719 shares issued and outstanding as of December 31, 2018 and 2019, 114,202,419 shares issued and outstanding on a pro forma basis as of December 31, 2019)	12	6	6	1	80	11
Treasury stock		(1)	—	—	—	—
Additional paid-in capital		—	389,379	55,931	3,751,601	538,884
Accumulated other comprehensive income		59,380	70,127	10,074	70,127	10,074
Accumulated deficit		(1,014,489)	(2,494,207)	(358,270)	(2,494,207)	(358,270)
Total shareholders' equity (deficit)		**(955,104)**	**(2,034,695)**	**(292,264)**	**1,327,601**	**190,699**
Total liabilities, mezzanine equity and shareholders' equity (deficit)		**2,375,938**	**1,737,572**	**249,587**	**1,737,572**	**249,587**

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB
Consolidated Statements of Comprehensive Loss
For the Years Ended December 31, 2017, 2018 and 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	Year Ended December 31, 2017 RMB	2018 RMB	2019 RMB	2019 US$ (Note 2.5)
Revenues					
Licensing and collaboration revenue	18	11,556	53,781	30,000	4,309
Expenses					
Research and development expenses	2.16	(267,075)	(426,028)	(840,415)	(120,718)
Administrative expenses		(25,436)	(66,391)	(654,553)	(94,021)
Loss from operations		**(280,955)**	**(438,638)**	**(1,464,968)**	**(210,430)**
Interest income		858	4,597	30,570	4,391
Interest expense		(5,643)	(11,695)	(2,991)	(430)
Other income (expenses), net	19	1,527	(16,780)	(20,205)	(2,902)
Fair value change of warrants	2.4	(14,027)	61,405	5,644	811
Loss before income tax expense		**(298,240)**	**(401,111)**	**(1,451,950)**	**(208,560)**
Income tax expense	11	—	(1,722)	—	—
Net loss attributable to I-MAB		**(298,240)**	**(402,833)**	**(1,451,950)**	**(208,560)**
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	20	—	—	(5,283)	(759)
Deemed dividend to Series B-1, B-2 and C preferred shareholders at modification of Series B-1, B-2 and C Preferred Shares	20	—	—	(27,768)	(3,989)
Net loss attributable to ordinary shareholders		**(298,240)**	**(402,833)**	**(1,485,001)**	**(213,308)**
Net loss attributable to I-MAB		**(298,240)**	**(402,833)**	**(1,451,950)**	**(208,560)**
Other comprehensive income:					
Foreign currency translation adjustments, net of nil tax		5,918	53,689	10,747	1,544
Total comprehensive loss attributable to I-MAB		**(292,322)**	**(349,144)**	**(1,441,203)**	**(207,016)**
Net loss attributable to ordinary shareholders		**(298,240)**	**(402,833)**	**(1,485,001)**	**(213,308)**
Weighted-average number of ordinary shares used in calculating net loss per share - basic and diluted	20	5,742,669	6,529,092	7,381,230	7,381,230
Net loss per share attributable to ordinary shareholders					
—Basic	20	(51.93)	(61.70)	(201.19)	(28.90)
—Diluted	20	(51.93)	(61.70)	(201.19)	(28.90)

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB
Consolidated Statements of Changes in Shareholders' Deficit
For the Years Ended December 31, 2017, 2018 and 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Ordinary share (Note 12) (US$0.001 par value)						
	Number of shares	Amount	Treasury stock	Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total shareholders' deficit
		RMB	RMB	RMB	RMB	RMB	RMB
Balance as of December 31, 2016	**8,363,719**	**6**	**(2)**	**45,331**	**(227)**	**(59,620)**	**(14,512)**
Foreign currency translation adjustments	—	—	—	—	5,918	—	5,918
Net loss	—	—	—	—	—	(298,240)	(298,240)
Share-based compensation	—	—	1	7,038	—	—	7,039
Balance as of December 31, 2017	**8,363,719**	**6**	**(1)**	**52,369**	**5,691**	**(357,860)**	**(299,795)**
Foreign currency translation adjustments	—	—	—	—	53,689	—	53,689
Net loss	—	—	—	—	—	(402,833)	(402,833)
Share-based compensation	—	—	—	3,520	—	—	3,520
Transaction with redeemable non- controlling interests (Note 16)	—	—	—	(55,889)	—	(253,796)	(309,685)
Balance as of December 31, 2018	**8,363,719**	**6**	**(1)**	**—**	**59,380**	**(1,014,489)**	**(955,104)**
Foreign currency translation adjustments	—	—	—	—	10,747	—	10,747
Net loss	—	—	—	—	—	(1,451,950)	(1,451,950)
Share-based compensation	—	—	1	366,894	—	—	366,895
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	—	—	—	(5,283)	—	—	(5,283)
Deemed dividend to Series B-1, B-2 and C preferred shareholders at modification of Series B-1, B-2 and C Preferred Shares	—	—	—	27,768	—	(27,768)	—
Balance as of December 31, 2019	**8,363,719**	**6**	**—**	**389,379**	**70,127**	**(2,494,207)**	**(2,034,695)**

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2017, 2018 and 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
Cash flows from operating activities				
Net loss	(298,240)	(402,833)	(1,451,950)	(208,560)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation of property, equipment and software	1,634	6,740	9,831	1,412
Loss on disposal of property, equipment and software	79	—	—	—
Interest expenses of convertible promissory notes and onshore convertible loans	3,835	6,963	—	—
Fair value change of warrants	14,027	(61,405)	(5,644)	(811)
Fair value change of other financial assets	—	—	(42)	(6)
Income from other financial assets	(5,572)	(13,622)	—	—
Share-based compensation	7,039	3,520	366,895	52,701
Loss from conversion of 2017 Notes	—	18,375	—	—
Loss from conversion of onshore convertible loans	—	8,548	—	—
Loss from issuance of 2018 Notes	—	5,081	—	—
Loss on termination agreement with Everest	—	—	23,039	3,309
Amortization of right-of use assets and interest of lease liabilities	—	—	5,803	834
Fair value change of short-term investments	—	—	(703)	(101)
Changes in operating assets and liabilities				
Contract assets	—	(11,000)	11,000	1,580
Prepayments and other receivables	8,830	(76,276)	(48,831)	(7,013)
Accruals and other payables	408	55,641	188,375	27,059
Contract liabilities	15,803	(15,803)	—	—
Advance from customers	—	14,151	(14,151)	(2,033)
Research and development funding received	—	178,715	53,148	7,634
Deferred subsidy income	—	2,500	1,420	204
Lease liabilities	—	—	(6,172)	(887)
Net cash used in operating activities	**(252,157)**	**(280,705)**	**(867,982)**	**(124,678)**
Cash flows from investing activities				
Cash acquired from acquisition of a subsidiary	93,335	—	—	—
Purchase of property, equipment and software	(20,327)	(14,409)	(12,241)	(1,758)
Proceeds from disposal of short-term investments	—	—	102,000	14,651
Purchase of short-term investments	—	—	(134,000)	(19,248)
Cash paid for investments in other financial assets	(369,000)	(30,000)	—	—
Cash received from disposal of other financial assets	133,000	40,000	256,000	36,772
Cash received on income from short-term investments	—	—	703	101
Cash received on income from other financial assets	5,327	13,909	—	—
Net cash (used in) generated from investing activities	**(157,665)**	**9,500**	**212,462**	**30,518**

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Consolidated Statements of Cash Flows (Continued)
For the Years ended December 31, 2017, 2018 and 2019
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
Cash flows from financing activities				
Proceeds from issuance of convertible preferred shares, net of issuance cost	346,515	1,306,633	183,536	26,363
Proceeds from issuance of redeemable non-controlling interest	161,196	—	—	—
Proceeds from issuance of convertible promissory notes	75,970	59,704	—	—
Proceeds from issuance of onshore convertible loans	35,341	—	—	—
Proceeds from issuance of warrants	40,563	—	—	—
Proceeds from exercise of warrants	—	132,332	—	—
Proceeds from bank borrowings	99,000	80,000	50,000	7,182
Repayment of bank borrowings	—	(99,000)	(80,000)	(11,491)
Payment of initial public offering costs	—	—	(827)	(118)
Net cash generated from financing activities	**758,585**	**1,479,669**	**152,709**	**21,936**
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(132)	59,754	15,163	2,178
Net increase (decrease) in cash and cash equivalents and restricted cash	348,631	1,268,218	(487,648)	(70,046)
Cash, cash equivalents, and restricted cash, beginning of year	64,082	412,713	1,680,931	241,451
Cash, cash equivalents, and restricted cash, end of the year	**412,713**	**1,680,931**	**1,193,283**	**171,405**
Additional ASC 842 supplemental disclosures				
Cash paid for fixed operating lease costs included in the measurement of lease obligations in operating activities	—	—	6,172	887
Right-of-use assets obtained in exchange for operating lease obligations	—	—	8,595	1,235
Other supplemental cash flow disclosures				
Interest paid	1,677	4,862	2,991	430
Non-cash activities				
Exercise of warrants	—	1,314	—	—
Payables for purchase of property, equipment and software	2,346	—	—	—
Payables for in-licensed patent rights	—	5,970	—	—
Convertible preferred shares issued for business combination	289,024	—	—	—
Accrued initial public offering costs payable	—	—	17,504	2,514
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	—	—	5,283	759
Deemed dividend to Series B-1, B-2 and C preferred shareholders at modification of Series B-1, B-2 and C Preferred Shares	—	—	27,768	3,989

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts in thousands, except for share and per share data, unless otherwise noted)

1. PRINCIPAL ACTIVITIES AND ORGANIZATION

I-Mab (the "Company") was incorporated in the Cayman Islands on June 30, 2016 as an exempted company with limited liability under the Companies Law of the Cayman Islands. The Company and its subsidiaries (together the "Group") are principally engaged in discovering and developing transformational biologics in the fields of immuno-oncology and immuno-inflammation diseases in the People's Republic of China (the "PRC") and other countries and regions.

Prior to the incorporation of the Company, the Group carried out its operation in the PRC since November 2014 mainly through Third Venture Biopharma (Nanjing) Co., Ltd. ("Third Venture"), which was incorporated on November 17, 2014 in the PRC. For the purpose of introduction of overseas investors and in preparation for a listing of the Company's shares on the overseas capital markets, the Group underwent a reorganization (the "Reorganization") in 2016. The Reorganization was approved by the Board of Directors and a restructuring framework agreement was entered into by Third Venture, the Company, and the shareholders of the Company based on Reorganization framework agreement, pursuant to which on July 7, 2016, Third Venture transferred all of its assets and operations to the Company's wholly owned subsidiary, I-Mab Biopharma Co., Ltd. ("I-Mab Shanghai"), which was a transaction in which shareholders had identical ownership interests before and after the transaction and was accounted for in a manner similar to a common control transaction.

The Reorganization, as described above has been accounted for at historical cost. That Reorganization was reverse merger of Third Venture and Third Venture is the predecessor of the Company. As such, the assets and liabilities of Third Venture are consolidated in the Company's financial statements at historical cost.

As of December 31, 2019, the Company's principal subsidiaries are as follows:

Subsidiaries	Place of incorporation	Date of incorporation or acquisition	Percentage of direct or indirect ownership by the Company	Principal activities
I-Mab Biopharma Hong Kong Limited	Hong Kong	July 8, 2016	100%	Investment holding
I-Mab Shanghai	PRC	August 24, 2016	100%	Research and development of innovative medicines
I-Mab Bio-tech (Tianjin) Co., Ltd. ("I-Mab Tianjin")	PRC	July 15, 2017	100%	Research and development of innovative medicines
I-Mab Biopharma US Ltd.	U.S.	February 28, 2018	100%	Research and development of innovative medicines

On January 17, 2020, the Company completed its Initial Public Offering and became listed on the Nasdaq Global Market (see Note 25 for details).

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. PRINCIPAL ACCOUNTING POLICIES

2.1 Basis of presentation

The accompanying consolidated financial statements of the Group have been prepared in accordance with the accounting principles generally accepted in the United States of America ("U.S. GAAP").

Significant accounting policies followed by the Group in the preparation of the accompanying consolidated financial statements are summarized below.

2.2 Basis of consolidation

The accompanying consolidated financial statements reflect the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. All inter-company balances and transactions have been eliminated in consolidation.

2.3 Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosures of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities and other intangible assets as well as subsequent fair value measurements. Additionally, estimates are used in determining items such as useful lives of property, equipment and software, impairment of contract assets and other receivables, impairment of long-lived assets and goodwill, share-based compensation, leases, tax valuation allowances and revenues from licensing and collaboration arrangements. Management bases the estimates on historical experience, known trends and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from those estimates.

2.4 Fair value measurements

Financial assets and liabilities of the Group primarily comprise of cash and cash equivalents, restricted cash, short-term investments, other financial assets, contract assets, other receivables, short-term borrowings, accruals and other payables and warrants liabilities. As of December 31, 2018 and 2019, except for short-term investments, other financial assets and warrant liabilities, the carrying values of these financial assets and liabilities approximated their fair values because of their generally short maturities. The Group reports short-term investments, other financial assets and warrant liabilities at fair value at each balance sheet date and changes in fair value are reflected in the consolidated statements of comprehensive loss.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.4 Fair value measurements (continued)

The Group measures its financial assets and liabilities using inputs from the following three levels of the fair value hierarchy. The three levels are as follows:

Level 1 inputs are unadjusted quoted prices in active markets for identical assets that the management has the ability to access at the measurement date.

Level 2 inputs include quoted prices for similar assets in active markets, quoted prices for identical or similar assets in markets that are not active, inputs other than quoted prices that are observable for the asset (i.e., interest rates, yield curves, etc.), and inputs that are derived principally from or corroborated by observable market data by correlation or other means (market corroborated inputs).

Level 3 includes unobservable inputs that reflect the management's assumptions about the assumptions that market participants would use in pricing the asset. The management develops these inputs based on the best information available, including the own data.

Assets and liabilities measured at fair value on a recurring basis

The Group measured its short-term investments, other financial assets and warrant liabilities at fair value on a recurring basis. As the Group's short-term investments, other financial assets and warrants liabilities are not traded in an active market with readily observable prices, the Group uses significant unobservable inputs to measure the fair value of short-term investments, other financial assets and warrant liabilities. These instruments are categorized in the Level 3 valuation hierarchy based on the significance of unobservable factors in the overall fair value measurement.

The following table summarizes the Group's financial assets and liabilities measured and recorded at fair value on a recurring basis as of December 31, 2018 and 2019:

	As of December 31, 2018			
	Active market (Level 1) RMB	Observable input (Level 2) RMB	Non-observable input (Level 3) RMB	Total RMB
Assets:				
Other financial assets	—	—	255,958	255,958
Liabilities:				
Warrant liabilities	—	—	5,618	5,618

	As of December 31, 2019			
	Active market (Level 1) RMB	Observable input (Level 2) RMB	Non-observable input (Level 3) RMB	Total RMB
Assets:				
Short-term investments	—	—	32,000	32,000

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.4 Fair value measurements (continued)

The roll forward of major Level 3 financial assets and financial liability are as follows:

	Short-term investments	Other financial assets	Warrant liabilities
Fair value of Level 3 financial asset and liability as of December 31, 2017	—	266,245	(65,832)
Investment in other financial assets	—	30,000	—
Disposal of other financial assets	—	(40,000)	—
Fair value change	—	13,622	61,405
Exercise of warrants	—	—	1,314
Income received from other financial assets	—	(13,909)	—
Currency translation differences	—	—	(2,505)
Fair value of Level 3 financial asset and liability as of December 31, 2018	—	255,958	(5,618)
Purchase of short-term investments	134,000	—	—
Disposal of short-term investments	(102,703)	—	—
Disposal of other financial assets due to Termination Agreement (Note 4)	—	(256,000)	—
Fair value changes	703	42	5,644
Currency translation differences	—	—	(26)
Fair value of Level 3 financial assets and liability as of December 31, 2019	**32,000**	**—**	**—**

Refer to Note 15 for additional information about Level 3 warrant liabilities measured at fair value on a recurring basis for the year ended December 31, 2018.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.5 Foreign currency translation

The Group uses Chinese Renminbi ("RMB") as its reporting currency. The United States Dollar ("US$") is the functional currency of the Group's entities incorporated in the Cayman Islands, the United States of America ("U.S.") and Hong Kong, the Australia Dollar ("AUD") is the functional currency of the Group's entity incorporated in Australia and the RMB is the functional currency of the Company's PRC subsidiaries.

Transactions denominated in other than the functional currencies are translated into the functional currency of the entity at the exchange rates prevailing on the transaction dates. Assets and liabilities denominated in other than the functional currencies are translated at the balance sheet date exchange rate. The resulting exchange differences are recorded in the consolidated statements of comprehensive loss.

The consolidated financial statements of the Group are translated from the functional currency to the reporting currency, RMB. Assets and liabilities of the subsidiaries are translated into RMB using the exchange rate in effect at each balance sheet date. Income and expenses are translated at the average exchange rates prevailing for the year. Foreign currency translation adjustments arising from these are reflected in the accumulated other comprehensive income. The exchange rates used for translation on December 31, 2018 and 2019 were US$1.00 = RMB6.8632 and RMB6.9762 respectively, representing the index rates stipulated by the People's Bank of China.

Translations of balances in the consolidated balance sheets, consolidated statements of comprehensive loss, consolidated statements of changes in shareholders' equity (deficit) and consolidated statements of cash flows from RMB into US$ as of and for the year ended December 31, 2019 are solely for the convenience of the readers and were calculated at the rate of US$1.00=RMB6.9618, representing the noon buying rate in The City of New York for cable transfers of RMB as certified for customs purposes by the Federal Reserve Bank of New York on December 31, 2019. No representation is made that the RMB amounts could have been, or could be, converted, realized or settled into US$ at that rate on December 31, 2019, or at any other rate. The US$ convenience translation is not required under U.S. GAAP and all US$ convenience translation amounts in the accompanying consolidated financial statements are unaudited.

2.6 Cash and cash equivalents

Cash and cash equivalents consist of cash on hand and bank deposits, which are unrestricted as to withdrawal and use. The Company considers all highly liquid investments with an original maturity date of three months or less at the date of purchase to be cash equivalents.

2.7 Restricted cash

Restricted cash consists of the guarantee deposits held in a designated bank account as security deposits under bank borrowing agreements. Such restricted cash will be released when the Group repays the related bank borrowings.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.8 Short-term investments

Short-term investments represent the investments issued by commercial banks or other financial institutions with a variable interest rate indexed to the performance of underlying assets within one year. These investments are stated at fair value. Changes in the fair value are reflected in the consolidated statements of comprehensive loss.

2.9 Property, equipment and software

Property, equipment and software are stated at cost less accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the following estimated useful lives, taking into account any estimated residual value:

Laboratory equipment	3 to 5 years
Software	2 to 5 years
Office furniture and equipment	5 years
Leasehold improvements	Lesser of useful life or lease term

The Group recognized the gain or loss on the disposal of property, equipment and software in the consolidated statements of comprehensive loss.

2.10 Intangible assets

Intangible assets with definite useful lives are amortized to their estimated residual values over their estimated useful lives and reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Amortization is initiated for in-process research and development (IPR&D) intangible assets that are acquired from business combination when their useful lives have been determined. IPR&D intangible assets which are determined to have an impairment in their fair value are adjusted downward and an expense recognized in research and development in the consolidated statements of comprehensive loss. These IPR&D intangible assets are tested at least an annual basis on December 31 or when a triggering event occurs that could indicate a potential impairment. (see Note 7).

2.11 Impairment of long-lived assets

Long-lived assets are reviewed for impairment in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. Long-lived assets are reported at the lower of carrying amount or fair value less cost to sell. For the years ended December 31, 2018 and 2019, there was no impairment of the value of the Group’s long-lived assets.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.12 Goodwill

Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that are not individually identified and separately recognized. The Group allocates the cost of an acquired entity to the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The excess of the purchase price for acquisitions over the fair value of the net assets acquired, including other intangible assets, is recorded as goodwill. Goodwill is not amortized, but impairment of goodwill assessment is performed on at least an annual basis on December 31 or whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable.

The Group has elected to first assess qualitative factors to determine whether it is more likely than not that the fair value of the Group's reporting unit is less than its carrying amount, including goodwill. The qualitative assessment includes the Group's evaluation of relevant events and circumstances affecting the Group's single reporting unit, including macroeconomic, industry, market conditions and the Group's overall financial performance. If qualitative factors indicate that it is more likely than not that the Group's reporting unit's fair value is less than its carrying amount, then the Group will perform the quantitative impairment test by comparing the reporting unit's carrying amount, including goodwill, to its fair value. If the carrying amount of the reporting unit exceeds its fair value, an impairment loss will be recognized in an amount equal to that excess. For the years ended December 31, 2018 and 2019, the Group determined that there were no indicators of impairment of the goodwill.

2.13 Deferred subsidy income

Deferred subsidy income consists of deferred income from government grants. Government grants consist of cash subsidies received by the Group's subsidiaries in the PRC from local governments as support on expenses relating to certain projects. Grants received with government specified performance obligations are recognized when all the obligations have been fulfilled. If such obligations are not satisfied, the Group may be required to refund the subsidy. Cash grants of RMB3,920 was recorded in deferred subsidy income as of December 31, 2019, which will be recognized when the government specified performance obligation is satisfied, which is expected to be more than 12 months after December 31, 2019.

2.14 Revenue recognition

The Group adopted Accounting Standard Codification ("ASC") 606, *Revenue from Contracts with Customers* (Topic 606) ("ASC 606") for all periods presented. Consistent with the criteria of Topic 606, the Group recognizes revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to receive in exchange for those goods or services.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.14 Revenue recognition (continued)

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Group only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of ASC 606 at contract inception, the Group audits the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Group recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Collaboration revenue

At contract inception, the Group analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Group first determines if the collaboration is deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For the collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently.

The Group's collaborative arrangements may contain more than one unit of account, or performance obligation, including grants of licenses to intellectual property rights, agreement to provide research and development services and other deliverables. The collaborative arrangements do not include a right of return for any deliverable. As part of the accounting for these arrangements, the Group must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. In developing the stand-alone selling price for a performance obligation, the Group considers competitor pricing for a similar or identical product, market awareness of and perception of the product, expected product life and current market trends. In general, the consideration allocated to each performance obligation is recognized when the respective obligation is satisfied either by delivering a good or providing a service, limited to the consideration that is not constrained.

When the timing of the delivery of product is different from the timing of payments made by the customers, the Group recognizes either a contract asset (performance precedes the contractual due date) or a contract liability (customer payment precedes performance). The Group's contractual payment terms are typically due in no more than 30 days from invoicing. In limited situations, certain customer contractual payment terms require the Group to bill in arrears; thus, the Group satisfies some or all of the performance obligations before the Group is contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. For example, certain of the contractual arrangements do not permit the Group to bill until the completion of the production of the samples. In other limited situations, certain customer contractual payment terms allow the Group to bill in advance; thus, the Group receives customer cash payment before satisfying some or all of its performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.14 Revenue recognition (continued)

Licenses of Intellectual Property: Upfront non-refundable payments for licensing the Group's intellectual property are evaluated to determine if the license is distinct from the other performance obligations identified in the arrangement. For licenses determined to be distinct, the Group recognizes revenues from non-refundable, up-front fees allocated to the license at a point in time, when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

Research and Development Services: The portion of the transaction price allocated to research and development services performance obligations is deferred and recognized as collaboration revenue over time as delivery or performance of such services occurs.

Milestone Payments : At the inception of each arrangement that includes development, commercialization, and regulatory milestone payments, the Group evaluates whether the milestones are considered probable of being reached and to the extent that a significant reversal of cumulative revenue would not occur in future periods, estimates the amount to be included in the transaction price using the most likely amount method. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Group recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Group re-evaluates the probability of achieving such development milestones and any related constraint, and if necessary, adjust the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties : For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Group recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

2.15 Value-added-tax ("VAT") recoverable and surcharges

Value added tax recoverable represent amounts paid by the Group for purchases. The surcharges (i.e., Urban construction and maintenance tax, educational surtax, local educational surtax), vary from 6% to 17% of the value-added-tax depending on the tax-payer's location.

2.16 Research and development expenses

Elements of research and development expenses primarily include (1) payroll and other related expenses of personnel engaged in research and development activities, (2) in-licensed patent rights fee of exclusive development rights of drugs granted to the Group, (3) expenses related to preclinical testing of the Group's technologies under development and clinical trials such as payments to contract research organizations ("CRO"), investigators and clinical trial sites that conduct the clinical studies (4) expenses to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to the Group's research and development services and have no alternative future uses.

The Group has acquired rights to develop and commercialize product candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a "business" as defined under U.S. GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval would be capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. The conditions enabling capitalization of development expenses as an asset have not yet been met and, therefore, all development expenditures are recognized in profit or loss when incurred.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.17 Leases

Prior to the adoption of ASC 842 on January 1, 2019:

Leases, mainly leases of offices, where substantially all the rewards and risks of ownership of assets remain with the lessor are accounted for as operating leases. Payments made under operating leases are recognized as an expense on a straight-line basis over the lease term. The Group had no capital leases for any of the years stated herein.

Upon and hereafter the adoption of ASC 842 on January 1, 2019:

The Group determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, operating lease liability, and operating lease liability, non-current in the Group's consolidated balance sheets.

ROU assets represent the Group's right to use an underlying asset for the lease term and lease liabilities represent the Group's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. When determining the lease term, the Group includes options to extend or terminate the lease when it is reasonably certain that it will exercise that option, if any. As the Group's leases do not provide an implicit rate, the Group uses its incremental borrowing rate, which it calculates based on the credit quality of the Group and by comparing interest rates available in the market for similar borrowings, and adjusting this amount based on the impact of collateral over the term of each lease.

The Group has elected to adopt the following lease policies in conjunction with the adoption of ASU 2016-02: (i) elect for each lease not to separate non-lease components from lease components and instead to account for each separate lease component and the non-lease components associated with that lease component as a single lease component; (ii) for leases that have lease terms of 12 months or less and does not include a purchase option that is reasonably certain to exercise, the Group elected not to apply ASC 842 recognition requirements; and (iii) the Group elected to apply the package of practical expedients for existing arrangements entered into prior to January 1, 2019 to not reassess (a) whether an arrangement is or contains a lease, (b) the lease classification applied to existing leases, and(c) initial direct costs.

In connection with the adoption of ASC 842, on January 1, 2019, the Company recorded an impact of RMB13,100 on its assets and RMB11,333 on its liabilities for the recognition of operating lease right-of-use-assets and operating lease liabilities, respectively, which are primarily related to the lease of the Group's offices and warehouses. The adoption of ASC 842 did not have a material impact on the Company's results of operations or cash flows.

2.18 Comprehensive loss

Comprehensive loss is defined as the changes in equity of the Group during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. Among other disclosures, ASC 220, Comprehensive Income, requires that all items that are required to be recognized under current accounting standards as components of comprehensive loss be reported in a financial statement that is displayed with the same prominence as other financial statements. For each of the periods presented, the Group's comprehensive loss includes net loss and foreign currency translation adjustments, which are presented in the consolidated statements of comprehensive loss.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.19 Share-based compensation

The Company grants restricted shares and stock options to eligible employees and accounts for share-based compensation in accordance with ASC 718, Compensation—Stock Compensation.

Employees' share-based compensation awards are measured at the grant date fair value of the awards and recognized as expenses a) immediately at the grant date if no vesting conditions are required; or b) for share based awards granted with only service conditions, using the graded vesting method net of estimated forfeitures over the vesting period; or c) for share-based awards granted with service conditions and the occurrence of an initial public offering ("IPO") as performance condition cumulative share-based compensation expenses for the options that have satisfied the service condition should be recorded upon the completion of the IPO using the graded vesting method.

A change in any of the terms or conditions of share-based awards is accounted for as a modification of the awards. The Group calculates incremental compensation expense of a modification as the excess of the fair value of the modified awards over the fair value of the original awards immediately before its terms are modified at the modification date. For vested awards, the Group recognizes incremental compensation cost in the period when the modification occurs. For awards not being fully vested, the Group recognizes the sum of the incremental compensation expense and the remaining unrecognized compensation expense for the original awards over the remaining requisite service period after modification.

Share-based compensation in relation to the restricted shares is measured based on the fair market value of the Group's ordinary shares at the grant date of the award. Prior to the listing, estimation of the fair value of the Group's ordinary shares involves significant assumptions that might not be observable in the market, and a number of complex and subjective variables, including discount rate, and subjective judgments regarding the Group's projected financial and operating results, its unique business risks, the liquidity of its ordinary shares and its operating history and prospects at the time the grants are made. Share-based compensation in relation to the share options is estimated using the Binominal Option Pricing Model. The determination of the fair value of share options is affected by the share price of the Group's ordinary shares as well as the assumptions regarding a number of complex and subjective variables, including the expected share price volatility, risk-free interest rate, exercise multiple and expected dividend yield. The fair value of these awards was determined with the assistance from an independent valuation firm.

2.20 Income taxes

The Group accounts for income taxes under the liability method. Under the liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and income tax bases of assets and liabilities and are measured using the tax income rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded if it is more likely than not that some portion or all of the deferred income tax assets will not be utilized in the foreseeable future.

The Group evaluates its uncertain tax positions using the provisions of ASC 740-10, Income Taxes, which prescribes a recognition threshold that a tax position is required to meet before being recognized in the financial statements. The Group recognizes in the financial statements the benefit of a tax position which is ''more likely than not'' to be sustained under examination based solely on the technical merits of the position assuming a review by tax authorities having all relevant information. Tax positions that meet the recognition threshold are measured using a cumulative probability approach, at the largest amount of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. It is the Group's policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense.

2.21 Borrowings

Borrowings are recognized initially at fair value, net of transaction costs incurred. Borrowings are subsequently stated at amortized cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognized in the consolidated statements of comprehensive loss over the period of the borrowings using the effective interest method.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.22 Business combination

The Group accounts for its business combinations using the acquisition method of accounting in accordance with ASC topic 805, Business Combinations ("ASC 805"). The acquisition method of accounting requires all of the following steps: (i) identifying the acquirer, (ii) determining the acquisition date, (iii) recognizing and measuring the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree, and (iv) recognizing and measuring goodwill or a gain from a bargain purchase. The consideration transferred in a business combination is measured as the aggregate of the fair values at the date of exchange of the assets given, liabilities incurred, and equity instruments issued as well as the contingent considerations and all contractual contingencies as of the acquisition date.

The Group allocates the fair value of purchase consideration to the tangible assets acquired, liabilities assumed and intangible assets acquired based on their estimated fair values. The excess of the fair value of purchase consideration over the fair values of these identifiable assets and liabilities is recorded as goodwill. Such valuations require management to make significant estimates and assumptions, especially with respect to intangible assets. Significant estimates in valuing certain intangible assets may include, but are not limited to, future expected cash flows from acquired assets, timing and probability of success of clinical events and regulatory approvals, and assumptions on useful lives of the patents and discount rates. Management's estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Additional information, such as that related to income tax and other contingencies, existing as of the acquisition date but unknown to us may become known during the remainder of the measurement period, not to exceed one year from the acquisition date, which may result in changes to the amounts and allocations recorded.

Acquisitions that do not meet the accounting definition of a business combination are accounted for as asset acquisitions. For transactions determined to be asset acquisitions, the Group allocates the total cost of the acquisition, including transaction costs, to the net assets acquired based on their relative fair values.

2.23 Segment information

In accordance with ASC 280, Segment Reporting, the Group's chief operating decision maker, the Chief Executive Officer, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence, the Group has only one reportable segment. The Group does not distinguish between markets or segments for the purpose of internal reporting. As the Group's long-lived assets are substantially located in and derived from the PRC, no geographical segments are presented.

2.24 Loss per share

Basic loss per share is computed by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period using the two-class method. Under the two-class method, the net loss is allocated between ordinary shares and other participating securities based on their participating rights. Net loss is not allocated to other participating securities if based on their contractual terms they are not obligated to share in the loss. Diluted loss per share is calculated by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary and dilutive ordinary equivalent shares outstanding during the period. Ordinary equivalent shares consist of shares issuable upon the conversion of the preferred shares using the if-converted method, shares issuable upon the exercise of share options using the treasury stock method, shares issuable upon the conversion of the convertible promissory notes using the if-converted method, and shares issuable upon the exercise of warrants using the treasury stock method. Ordinary equivalent shares are not included in the denominator of the diluted loss per share calculation when inclusion of such shares would be anti-dilutive.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.25 Adopted accounting pronouncements

In 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU requires lessees to recognize lease assets and lease liabilities on the balance sheet for the rights and obligations created by all leases with terms greater than 12 months. As we are not a lessor, other changes in the guidance applicable to lessors do not apply. Additionally, in 2018, the FASB issued codification and targeted improvements to this guidance effective for fiscal years and interim periods within those years beginning after December 15, 2018, with early adoption permitted. The Group adopted the new guidance on January 1, 2019, using the alternative transition approach. For additional information, see Note 6—"Leases."

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230) ("ASU 2016-18"). This ASU affects all entities that have restricted cash or restricted cash equivalents and are required to present a statement of cash flows under Topic 230. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. This update was required to be adopted for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019, and early adoption is permitted in any interim or annual period. The Group elected to early adopt this ASU and applied this guidance retrospectively to all periods presented.

2.26 Recent accounting pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). This guidance requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability. In November 2018, the FASB issued ASU 2018-19, Codification Improvements to Topic 326, Financial Instruments-Credit Losses ("ASU 2018-19"), which clarifies certain topics included within ASU 2016-13. ASU 2016-13 and ASU 2018-19 are effective for the annual reporting period beginning after December 15, 2019, including interim periods within that reporting period. The impact of this ASU to the consolidated financial statements is immaterial.

In August 2018 the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement. This standard modifies certain disclosure requirements on fair value measurements. This standard became effective for us on January 1, 2020. The impact of this ASU to the consolidated financial statements is immaterial.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.26 Recent accounting pronouncements (continued)

In November 2018 the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606. This standard makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, Revenue from Contracts with Customers, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements;
- Adds unit-of-account guidance to ASC 808, Collaborative Arrangements, to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606; and
- Precludes a company from presenting transactions with collaborative arrangement participants that are not directly related to sales to third parties with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer.

This standard became effective for us on January 1, 2020. A retrospective transition approach is required for either all contracts or only for contracts that are not completed at the date of initial application of ASC 606, with a cumulative adjustment to opening retained earnings, as of January 1, 2018. The impact of this ASU to the consolidated financial statements is immaterial.

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3. PREPAYMENTS AND OTHER RECEIVABLES

	As of December 31,		
	2018	2019	
	RMB	RMB	US$ (Note 2.5)
Prepayments:			
- Prepayments to CRO vendors	71,894	78,740	11,310
- Prepayments for other services	3,160	880	126
Receivables due from employees (Note)	—	16,201	2,327
Value-added tax recoverable	4,235	12,517	1,798
Rental deposits	1,012	546	78
Interest receivables	1,502	764	110
Others	7,169	26,388	3,791
	88,972	136,036	19,540

Note: The balance mainly represented the receivables due from employees, which were arising from the Group's obligation to pay the withholding individual income tax ("IIT") for those employees' stock option activities and was collected by the Group in January 2020.

4. OTHER FINANCIAL ASSETS

	As of December 31,		
	2018	2019	
	RMB	RMB	US$ (Note 2.5)
Financial asset at fair value through profit or loss	215,571	—	—
Note receivables	40,387	—	—
	255,958	—	—

The Group placed the principal amount for investments through a contractual arrangement with a third party for the period from June 30, 2017 to June 30, 2020 ("Principal Amount"). The Principal Amount can be redeemed from the third party at the discretion of the Group from time to time whereby the Group is expecting to earn an income on the Principal Amount with an average yield in the range from 4.50% to 5.25% per annum. The Group initially records these assets at cost, which approximates its fair value at inception and subsequently records these assets at fair value. Changes in the fair value are reflected in the consolidated statements of comprehensive loss.

On June 22, 2019, the Group entered into an agreement with the relevant party involved for early termination of the contractual arrangement ("Termination Agreement"). Pursuant to the Termination Agreement, the Group shall receive cash with an amount of RMB95,056 and commercial bills with a total face value of RMB160,944 (including those commercial bills redeemed during the year ended December 31, 2018 with a face value of RMB40,387). No material gain or loss was arising from such termination. As of December 31, 2019, cash of RMB95,056 was received and all commercial bills have been collected upon maturity.

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5. PROPERTY, EQUIPMENT AND SOFTWARE

Property, equipment and software consist of the following:

	As of December 31, 2018	As of December 31, 2019	
	RMB	RMB	US$ (Note 2.5)
Cost			
Laboratory equipment	20,796	24,265	3,486
Leasehold improvement	10,271	11,856	1,703
Software	3,632	10,220	1,468
Office furniture and equipment	1,350	1,526	219
Total property, equipment and software	36,049	47,867	6,876
Less: accumulated depreciation and amortization	(8,390)	(18,221)	(2,618)
Net book value	27,659	29,646	4,258
Construction in process	—	423	61
Total net book value of property, equipment and software	27,659	30,069	4,319

The total amounts charged to the consolidated statements of comprehensive loss for depreciation and amortization expenses amounted to approximately RMB1.6 million, RMB6.7 million and RMB9.8 million for the years ended December 31, 2017, 2018 and 2019, respectively.

6. LEASES

As of December 31, 2019, the Company has operating leases recorded on its balance sheet for certain office spaces and facilities that expire on various dates through 2027. The Group does not plan to cancel the existing lease agreements for its existing facilities prior to their respective expiration dates. When determining the lease term, the Group includes options to extend or terminate the lease when it is reasonably certain that it will exercise that option, if any. All of the Group's leases qualify as operating leases.

Information related to operating leases as of December 31, 2019 is as follows (in thousands, except for percentages and years).

	As of December 31, 2019	
	RMB	US$ (Note 2.5)
Assets		
Operating lease right-of-use assets	16,435	2,361
Liabilities		
Operating lease liabilities, current	6,807	978
Operating lease liabilities, non-current	7,492	1,076
Weighted average remaining lease term (years)	2.4	2.4
Weighted average discount rate	5%	5%

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6. LEASES (CONTINUED)

Information related to operating lease activity during the year ended December 31, 2019 is as follows:

	For the Year Ended December 31, 2019	
	RMB	US$ (Note 2.5)
Operating lease rental expense		
Amortization of right-of-use assets	5,260	756
Expense for short-term leases within 12 months	592	85
Interest of lease liabilities	543	78
	6,395	919

Future annual minimum lease payments for operating leases as of December 31, 2018 under ASC 840 were as follows:

	Operating Leases RMB
2019	5,754
2020	5,274
2021	3,511
2022	60
2023	60
Thereafter	276
Total	**14,935**

Maturities of lease liabilities were as follows:

	As of December 31, 2019	
	RMB	US$ (Note 2.5)
2020	7,634	1,095
2021	5,617	807
2022	1,885	271
2023	60	9
2024	60	9
Thereafter	181	26
Total undiscounted lease payments	15,437	2,217
Less: imputed interest	(1,138)	(163)
Total lease liabilities	**14,299**	**2,054**

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7. INTANGIBLE ASSETS

Intangible assets as of December 31, 2018 and 2019 are summarized as follows:

	As of December 31,		
	2018	2019	
	RMB	RMB	US$ (Note 2.5)
Cost			
IPR&D	148,844	148,844	21,380
Less: accumulated amortization	—	—	—
Net book value	148,844	148,844	21,380

IPR&D represents the fair value assigned to research and development assets that the Group acquired from business combination of I-Mab Tianjin and its subsidiaries including Chengdu Tasgen Bio-Tech Co., Ltd. and Shanghai Tianyunjian Bio-Tech Co., Ltd. (together the "Tasgen Group") in 2017 and had not reached technological feasibility at the date of acquisition. Upon commercialization, the Group will determine the estimated useful life and amortize these amounts based upon an economic consumption method. As of December 31, 2018 and 2019, there was no impairment of the value of the Group's intangible assets.

8. GOODWILL

On July 15, 2017, the Group acquired 66.67% of the equity interests in the Tasgen Group by issuing convertible preferred shares, and controlled the board of directors and business of I-Mab Tianjin since then. Tasgen Group is principally engaged in the research and development of innovative medicines and the Group acquired Tasgen Group for its research team, technical experience, and IPR&D pipeline assets (see Note 7). As of December 31, 2018 and 2019, the goodwill of RMB162,574 (US$23,352) represented the goodwill generated from the aforementioned acquisition of Tasgen Group and the business of Tasgen Group was fully integrated into the Company after the acquisition.

As of December 31, 2018 and 2019, the Group performed a qualitative assessment by evaluating relevant events and circumstances that would affect the Group's single reporting unit and did not note any indicator that it is more likely than not that the fair value of the Group's reporting unit is less than its carrying amount and therefore the Group's goodwill was not impaired.

9. SHORT-TERM BORROWINGS

In July 2018, I-Mab Bio-tech (Tianjin) Co., Ltd. borrowed a loan of RMB80,000 from China Merchant Bank Co., Ltd. for a term of one year and at the interest rate of 4.20% per annum. To facilitate this borrowing, another subsidiary of the Company in Hong Kong placed cash deposits of US$13,500 (equivalent to approximately RMB92,653) with the bank. The use of such cash deposits and the interest earned thereon are restricted by the bank during the period of the borrowing. The deposits have a one-year term and bear interest at 3.26% per annum. The borrowing was fully repaid during the year ended December 31, 2019.

In June 2019, I-Mab Bio-tech (Tianjin) Co., Ltd. borrowed a loan of RMB50,000 from China Merchant Bank Co., Ltd. for a term of one year and at the interest rate of 4.15% per annum. To facilitate this borrowing, another subsidiary of the Company in Hong Kong placed cash deposits of US$8,000 (equivalent to approximately RMB55,810) with the bank. The use of such cash deposits and the interest earned thereon are restricted by the bank during the period of the borrowing. The deposits have a one-year term and bear interest at 2.63% per annum. The borrowing will be due for repayment in June 2020.

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10. ACCRUALS AND OTHER PAYABLES

	As of December 31,		
	2018	2019	
	RMB	RMB	US$ (Note 2.5)
Staff salaries and welfare payables	18,869	30,166	4,333
Accrued external research and development activities related expenses	39,068	144,000	20,684
Accrued initial public offering costs payable	—	17,504	2,514
Withholding IIT payable related to stock options	—	16,201	2,327
Accrued travelling expenses, office expenses and others	9,737	65,682	9,435
	67,674	273,553	39,293

11. INCOME TAXES

Cayman Islands

I-Mab is incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, I-Mab is not subject to tax on income or capital gain. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

Hong Kong

I-Mab Biopharma Hong Kong Limited is incorporated in Hong Kong. Companies registered in Hong Kong are subject to Hong Kong profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with the relevant Hong Kong tax laws. The applicable tax rate in Hong Kong is 16.5%. For the years ended December 31, 2017, 2018 and 2019, I-Mab Biopharma Hong Kong Limited did not make any provisions for Hong Kong profit tax as there were no assessable profits derived from or earnings in Hong Kong for any of the periods presented. Under the Hong Kong tax law, I-Mab Biopharma Hong Kong Limited is exempted from income tax on its foreign-derived income and there are no withholding taxes in Hong Kong on remittance of dividends.

Australia

Mab Biopharma Australia Pty Ltd is incorporated in Australia. Companies registered in Australia are subject to Australia profits tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with the relevant Australia tax laws. The applicable tax rate in Australia is 30%. I-Mab Biopharma Australia Pty Ltd has no taxable income for all periods presented, therefore, no provision for income taxes is required.

United States

I-Mab Biopharma US Ltd. is incorporated in U.S. and is subject to U.S. federal corporate income tax at a rate of 21%. I-Mab Biopharma US Ltd. is also subject to state income tax in Maryland of 8.25%. I-Mab Biopharma US Ltd. has no taxable income for all periods presented, therefore, no provision for income taxes is required.

China

On March 16, 2007, the National People's Congress of PRC enacted a new Enterprise Income Tax Law ("new EIT law"), under which Foreign Investment Enterprises ("FIEs") and domestic companies would be subject to corporate income tax at a uniform rate of 25%. The new EIT law became effective on January 1, 2008. Under the new EIT law, preferential tax treatments will continue to be granted to entities which conduct businesses in certain encouraged sectors and to entities otherwise classified as "High and New Technology Enterprises".

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11. INCOME TAXES (CONTINUED)

China (continued)

I-Mab Shanghai has been qualified as "High and New Technology Enterprise" and enjoys a preferential income tax rate of 15% from 2018 to 2020.

The Company's other PRC subsidiaries are subject to the statutory income tax rate of 25%.

No provision for income taxes has been made because the Group are in cumulative loss positions for all the periods presented.

Reconciliations of the differences between the PRC statutory income tax rate and the Group's effective income tax rate for the years ended December 31, 2017, 2018 and 2019 are as follows:

	Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
Loss before income tax	(298,240)	(401,111)	(1,451,950)	(208,560)
Income tax computed at respective applicable tax rate	(37,672)	(56,093)	(148,871)	(21,384)
Non-deductible expenses	3,889	2,548	87,021	12,499
Research and development expenses plus deduction	(2,846)	(6,762)	(9,254)	(1,329)
Changes in valuation allowance	36,629	62,029	71,104	10,214
	—	1,722	—	—
Effect of tax holidays entitled by the PRC subsidiaries on basic loss per share	—	3.07	9.55	1.37

The principal components of the deferred tax assets and liabilities are as follows:

	Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
Deferred tax assets:				
Net operating loss carryforward	73,105	92,185	136,443	19,599
Depreciation and amortization of property, equipment, software and intangible asset, net	—	18,405	44,398	6,378
Accrual expense	13,647	21,132	21,867	3,141
Less: valuation allowance	(49,541)	(94,511)	(165,497)	(23,773)
Total deferred tax assets	37,211	37,211	37,211	5,345
Deferred tax liabilities:				
Acquired intangible assets	37,211	37,211	37,211	5,345
Total deferred tax liabilities	37,211	37,211	37,211	5,345
Deferred tax assets, net	—	—	—	—

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11. INCOME TAXES (CONTINUED)

Movement of the valuation allowance is as follows:

	Year Ended December 31			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
Balance as of January 1	(6,472)	(49,541)	(94,511)	(13,576)
Business combination	(6,440)	—	—	—
Additions	(36,629)	(62,029)	(71,104)	(10,214)
Decrease due to the change of tax rate	—	17,059	118	17
Balance as of December 31	(49,541)	(94,511)	(165,497)	(23,773)

As of December 31, 2019, the Group had a majority of net operating losses of approximately RMB715,156 which arose from the subsidiaries established in the PRC. The tax losses carried forward various in the PRC will expire during the period beginning from 2021 to 2029 based on entity's preferential tax status.

A valuation allowance is provided to reduce the amount of deferred tax assets if it is considered as more likely than not that some portion or all of the deferred tax assets will not be realized in the foreseeable future. In making such determination, the Group evaluates a variety of positive and negative factors including the Group's operating history, accumulated deficit, the existence of taxable temporary differences and reversal periods.

The Group has incurred net accumulated operating losses for income tax purposes since its inception. The Group believes that it is more likely than not that these net accumulated operating losses together with other deferred tax assets will not be utilized in the foreseeable future. Therefore, the Group has provided full valuation allowances for the deferred tax assets as of December 31, 2018 and 2019.

The Group evaluates each uncertain tax position (including the potential application of interest and penalties) based on the technical merits, and measure the unrecognized benefits associated with the tax positions. As of December 31, 2018 and 2019, the Group did not have any significant unrecognized uncertain tax positions.

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12. ORDINARY SHARES

As of December 31, 2018 and 2019, 500,000,000 ordinary shares had been authorized by the Company. Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors of the Company.

On October 29, 2019, the Company's shareholders and board of directors approved that immediately prior to the completion of initial public offering, the Company's authorized share capital will be changed into US$80,000 divided into 800,000,000 ordinary shares of a par value of US$0.0001 each.

13. CONVERTIBLE PREFERRED SHARES

On October 18, 2016, the Company issued 5,141,587 shares of Series A-1 and A-2 Preferred Shares with a consideration of US$11,282 (equivalent to approximately RMB74,742). In connection with the Series A-1 and A-2 Preferred Shares issuance, the Company also issued 2,246,744 warrant to purchase its Series A-3 Preferred Shares ("Series A-3 Warrants" and see Note 15).

On September 6, 2017, in connection with the Group's acquisition of Tasgen Group, the Company issued 16,723,646 shares of Series A-3 Preferred Shares at a price of US$2.55 per share with a total consideration of US$42,645 (equivalent to approximately RMB289,024).

Series A-1 Preferred Shares, Series A-2 Preferred Shares and Series A-3 Preferred Shares are also referred to as Series A Preferred Shares.

On September 22, 2017, the Company issued 15,894,594 shares of Series B Preferred Shares with a consideration of US$52,546 (equivalent to approximately RMB346,515). In connection with the Series B Preferred Shares issuance, the Company also issued convertible promissory notes that are convertible into Series B-1 Preferred Shares ("2017 Notes" and see Notes 14) and 5,633,780 warrants to purchase its Series B-2 Preferred Shares ("Series B Warrant" and see Note 15).

Concurrently with the Company's issuance of Series B Preferred Shares, the Company also completed a round of onshore financing with respect to the Group's subsidiary I-MAB Tianjin ("Series B Onshore Financing"). Series B Onshore Financing comprised 1) capital injection to I-Mab Tianjin by a number of investors ("Series B Onshore Investors") (see Note 14), 2) I-Mab Tianjin's issuance of convertible loans ("Onshore Convertible Loans" and see Note 14), and 3) the Company's issuance of 2,620,842 warrants to purchase its Series B-2 Preferred Shares ("Series B Warrants" and see Note 15).

On June 29, 2018, the Company issued total 8,361,823 shares of Series A-3 Preferred Shares upon exercise of Series A-3 Option held by its holder.

On June 29, 2018, the Company issued 2,535,201 shares of Series B-1 Preferred Shares upon conversion of 2017 Notes and issued 2,253,512 shares of Series B-2 Preferred Shares upon exercise of Series B Warrant by Series B preferred shareholders.

On June 29, 2018, the Company issued 5,938,640 shares of Series B Preferred Shares upon exercise of the Series B Option held by a Series B Onshore Investor and issued 947,218 shares of Series B-1 Preferred Shares upon conversion of Onshore Convertible Loans by a Series B Onshore Investor (see Note 14), respectively.

On July 6, 2018, the Company issued 1,455,549 shares of Series B Preferred Shares upon exercise of the Series B Option held by a Series B Onshore Investor, issued 232,161 shares of Series B-1 Preferred Shares upon conversion of Onshore Convertible Loans by a Series B Onshore Investor (see Note 14) and issued 1,048,337 shares of Series B-2 Preferred Shares upon exercise of Series B Warrant by Series B Onshore Investors, respectively.

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13. CONVERTIBLE PREFERRED SHARES (CONTINUED)

Series B Preferred Shares, Series B-1 Preferred Shares and Series B-2 Preferred Shares are also referred to as Series B Preferred Shares.

On July 6, 2018, the Company issued 31,046,360 shares of Series C Preferred Shares at a price of US$6.4419 per share with a total consideration of US$200,000 (equivalent to approximately RMB1,323,363). In connection with the offering of the Series C Preferred Shares, the Company incurred issuance costs of RMB16,730.

On July 25, 2019, the Group entered into a share purchase agreement with certain third party investors, under which these investors will subscribe for an aggregate of 3,857,143 Series C-1 convertible preferred shares of the Company for an aggregate purchase price of US$27.0 million. Out of the aforementioned subscription of 3,857,143 Series C-1 convertible preferred shares by certain third party investors, 1,428,571 Series C-1 convertible preferred shares were issued to an investor on October 17, 2019, and the Group also received the cash consideration of US$10,000 (equivalent to approximately RMB70,036). On November 6, 2019, the Group received cash consideration of US$17,000 (equivalent to approximately RMB119,387) for the remaining 2,428,572 Series C-1 convertible preferred shares from the investors and the issuance of such 2,428,572 Series C-1 convertible preferred shares was consummated on that day. In connection with the offering of the Series C-1 convertible preferred shares, the Company incurred issuance costs of approximately US$840 (equivalent to approximately RMB5,887).

Series A Preferred Shares, Series B Preferred Shares, Series C Preferred Shares and Series C-1 Preferred Shares are collectively referred to as Preferred Shares.

Key terms of the Preferred Shares are summarized as follows:

Dividends

The holders of Preferred Shares are entitled to receive dividends, out of any assets legally available therefore, prior and in preference to any declaration or payment of any dividend on the ordinary shares or any other class or series of shares of the Group at the rate of eight percent (8%) of the original issue price per share per annum on each Preferred Share, payable in US$ and annually when, as and if declared by the Board of Directors. Such distributions shall not be cumulative. No dividend, whether in cash, in property or in shares of the capital of the Group, shall be paid on or declared and set aside for any ordinary shares or any other class or series of shares of the Group unless and until all dividends have been paid in full on the Preferred Shares (on an as-converted basis).

Conversion

Each Preferred Share may be converted at any time into ordinary shares at the option of the preferred shares holders at the then applicable conversion price. The initial conversion ratio is 1:1, subject to adjustment in the event of (i) share splits, share combinations, share dividends or distribution, other dividends, recapitalizations and similar events, or (ii) issuance of ordinary shares (excluding certain events such as issuance of ordinary shares pursuant to a public offering) at a price per share less than the conversion price in effect on the date of or immediately prior to such issuance.

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13. CONVERTIBLE PREFERRED SHARES (CONTINUED)

Conversion (continued)

The Preferred Shares shall be automatically converted into ordinary shares immediately upon the closing of a public offering of the Company's shares with an offering price (exclusive of underwriting commissions and expenses) that reflects a market capitalization (immediately prior to the public offering) of not less than US$1,000,000,000 or otherwise approved by all directors and certain preferred shareholders as specified in the Company's memorandum and articles of association (the "Qualified Public Offering").

The Group determined that there were no beneficial conversion features ("BCF") identified for any of the Preferred Shares during any of the periods. In making this determination, the Company compared the fair value of the ordinary shares into which the Preferred Shares are convertible with the respective effective conversion price at the issuance date. In all instances, the effective conversion price was greater than the fair value of the ordinary shares. To the extent a conversion price adjustment occurs, as described above, the Group will reevaluate whether or not a beneficial conversion feature should be recognized.

Liquidation

In the event of any liquidation (unless waived by the preferred shareholders) including deemed liquidation, dissolution or winding up of the Company, holders of the Preferred Shares shall be entitled to receive a per share amount equal to one hundred percent (100%) of the original issue price on each Preferred Share, plus an amount representing an internal rate of return of twelve percent (12%) per annum on the original issue price as adjusted for share dividends, share splits, combinations, recapitalizations or similar events, plus all accrued and declared but unpaid dividends thereon, in the sequence of Series C Preferred Shares, Series B Preferred Shares and Series A Preferred Shares. After such liquidation amounts have been paid in full, any remaining funds or assets of the Company legally available for distribution to shareholders shall be distributed on a pro rata basis among the holders of the Preferred Shares, on an as-converted basis, together with the holders of the ordinary shares.

Accounting of preferred shares

The Preferred Shares are redeemable by the holders upon a liquidation event, including a deemed liquidation event (e.g., change in control), and as such are presented as mezzanine equity on the consolidated balance sheets. In accordance with ASC 480-10-S99, each issuance of the convertible preferred shares should be recognized at the date of issuance after deducting fair value allocated to the detachable warrants and issuance costs.

Modification of preferred shares

The Company assesses whether an amendment to the terms of its convertible preferred shares is an extinguishment or a modification using the fair value model.

When convertible redeemable preferred shares are extinguished, the difference between the fair value of the consideration transferred to the convertible redeemable Preferred Shareholders and the carrying amount of such preferred shares (net of issuance costs) is treated as a deemed dividend to the Preferred Shareholders. When convertible redeemable preferred shares are modified and such modification results in value transfer between Preferred Shareholders and ordinary shareholders, the change in fair value resulted from the amendment is treated as a deemed dividend to or from the Preferred Shareholders.

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13. CONVERTIBLE PREFERRED SHARES (CONTINUED)

Modification of preferred shares(continued)

On December 25, 2019, the Company's shareholders and board of directors approved that, where the final offering price of a Qualified Public Offering is no less than US$4.176 per ordinary share, the agreed provisions related to the number of shares to be converted into the Company's ordinary shares shall apply with respect to the Series C-1 Preferred Shares, Series C Preferred Shares, Series B-2 Preferred Shares and Series B-1 Preferred Shares, which will generally give rise to a one to multiple conversion of the such rounds of Preferred Shares, provided that unanimous consent of the directors on the final offering price needs to be obtained in the event that the final offering price per ordinary share of such IPO is fixed at a price equal to or higher than US$4.176 per ordinary share but lower than US$5.22 per ordinary share.

The Company evaluated the aforementioned modifications and concluded that they represented modifications, rather than extinguishment, to Series B-1, B-2 and C Preferred Shares, which resulted in a transfer of value from ordinary shareholders to preferred shareholders. The combined change in fair value of Series B-1, B-2 and C Preferred Shares immediately before and after the modification was US$4.0 million (equivalent to approximately RMB27.8 million) on December 25, 2019. This decrease in fair value of the ordinary shares of US$4.0 million (equivalent to approximately RMB27.8 million) on December 25, 2019 was, in substance, a transfer of wealth mostly from ordinary shareholders to preferred shareholders, and therefore was recorded as a deemed dividend to the preferred shareholders **.**

The Company evaluated the aforementioned modifications and concluded that they represented extinguishment to Series C-1 Preferred Shares. The difference between the fair value of the modified Series C-1 Preferred Shares and the carrying value of the original Series C-1 Preferred Shares was amounting US$0.8 million on December 25, 2019 and represented the fair value of the consideration transferred, and therefore was recognized as a deemed dividend to the preferred shareholders and adjustment to the carrying amount of Series C-1 Preferred Shares **.**

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13. CONVERTIBLE PREFERRED SHARES (CONTINUED)

The Company's convertible preferred shares activities for the years ended December 31, 2018 and 2019 are summarized below:

	Series A Preferred Shares			Series B Preferred Shares			Series C Preferred Shares			Series C-1 Preferred Shares		
	Number of shares	Amount US$	Amount RMB	Number of shares	Amount US$	Amount RMB	Number of shares	Amount US$	Amount RMB	Number of shares	Amount US$	Amount RMB
Balance as of January 1, 2018	21,865,233	53,927	363,766	15,894,594	52,546	346,515	—	—	—	—	—	—
Issuance of Series A Preferred Shares upon exercise of Series A-3 Option	8,361,823	48,925	323,716	—	—	—	—	—	—	—	—	—
Issuance of Series B Preferred Shares upon exercise of Series-B Option	—	—	—	7,394,189	44,083	291,677	—	—	—	—	—	—
Issuance of Series B Preferred Shares upon conversion of 2017 Notes	—	—	—	2,535,201	15,401	101,906	—	—	—	—	—	—
Issuance of Series B Preferred Shares upon conversion of Onshore Convertible Loans	—	—	—	1,179,379	7,165	47,407	—	—	—	—	—	—
Issuance of Series B Preferred Shares upon exercise of Tranche I of Series B Warrants	—	—	—	3,301,849	20,212	133,738	—	—	—	—	—	—
Issuance of Series C Preferred Shares, net of issuance costs	—	—	—	—	—	—	31,046,360	197,478	1,306,633	—	—	—
Balance as of December 31, 2018	30,227,056	102,852	687,482	30,305,212	139,407	921,243	31,046,360	197,478	1,306,633	—	—	—
Balance as of January 1, 2019	30,227,056	102,852	687,482	30,305,212	139,407	921,243	31,046,360	197,478	1,306,633	—	—	—
Issuance of Series C-1 Preferred Shares, net of issuance costs	—	—	—	—	—	—	—	—	—	3,857,143	26,160	183,536
Adjustment at extinguishment of Series C-1 Preferred Shares	—	—	—	—	—	—	—	—	—	—	754	5,283
Balance as of December 31, 2019	30,227,056	102,852	687,482	30,305,212	139,407	921,243	31,046,360	197,478	1,306,633	3,857,143	26,914	188,819

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14. CONVERTIBLE PROMISSORY NOTES AND ONSHORE CONVERTIBLE LOANS

2017 Notes

On September 25, 2017, the Company issued US$11,520 convertible promissory notes ("2017 Notes") to investors of Series B Preferred Shares (see Note 13) at a compound interest rate of 8% per annum, maturing on 36 months after the issuance date. Under the agreement, the holder of the 2017 Notes may convert the outstanding principal amount into Series B-1 Preferred Shares at the conversion price of US$5.38 per share or a lower price as may be agreed by the investors and the Company at any time from six months prior to the maturity date and prior to the repayment in full of the 2017 Note. No interest shall be accrued if the 2017 Notes have been converted into Series B-1 Preferred Shares.

As the fair value of the Company's ordinary shares on September 25, 2017 was lower than the effective conversion price of US$5.38, the Company did not record a BCF.

On June 29, 2018, the Company's 2017 Notes were converted into the Company's 2,535,201 Series B-1 Preferred Shares at the nominal conversion price of US$5.38 per share.

2018 Notes

On February 3, 2018, the Company issued US$9,000 (equivalent to approximately RMB59,704) convertible promissory notes ("2018 Notes") to an investor of Series A-3 Preferred Shares at an annual interest rate of 0%, maturing on 36 months after the issuance date. Under the agreement, the holder of the 2018 Notes may convert the 2018 Notes outstanding principal amount into Series B-1 Preferred Shares at the conversion price being lower of US$10 per share and fair market value at any time prior to the maturity date. Alternatively, the 2018 Notes shall be automatically converted into the Company's Series B Preferred Shares upon the maturity. As the fair value of the Company's ordinary shares on February 3, 2018 of US$3.96 was equal to the effective conversion price (being lower of US$10 per share and fair market value), the Company did not record a BCF.

Onshore Convertible Loans

On September 25, 2017, I-Mab Tianjin issued a US$5,359 convertible loan to Series B Onshore Investors at a compound interest rate of 8% per annum, maturing on 36 months after the issuance date. Under the agreement, the holder of the Onshore Convertible Loans may convert the outstanding principal amount into I-Mab Tianjin's equity interest a stipulated conversion price at any time from six months prior to the maturity date and prior to the repayment in full of the Onshore Convertible Loans. No interest shall be accrued if the Onshore Convertible Loans have been converted into I-Mab Tianjin's equity interest. As the fair value of the I-Mab Tianjin's ordinary shares on September 25, 2017 was lower than the effective conversion price of US$4.31, the Company did not record a BCF.

In June and July 2018, the Company reached agreements with holders of Onshore Convertible Loans and the principal amount of Onshore Convertible Loans were then effectively converted into 1,179,379 Series B-1 Preferred Shares of the Company and the accrued interests were waived, resulting in an extinguishment loss of RMB8,548.

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15. WARRANTS

In connection with the issuance of the Series A-1 and A-2 Preferred Shares on October 18, 2016, 2,246,744 Series A-3 Warrants were issued to Series A-1 and A-2 preferred shareholders, which provided the holder the right to purchase Series A-3 Preferred Shares. The Series A-3 Warrants were later terminated on September 6, 2017 without being exercised.

In connection with the issuance of the Series B Preferred Shares on September 22, 2017, 5,633,780 Series B Warrants were issued to Series B preferred shareholders, which provided the holders the right to purchase Series B-2 Preferred Shares.

In connection with the Company's Series B Onshore Financing that took place on September 25, 2017, 2,620,842 Series B Warrants were issued to Series B Onshore Investors, which provided the holders the right to purchase Series B-2 Preferred Shares.

During the period from June 29, 2018 to July 6, 2018, 3,301,849 Series B Warrants (representing Tranche I of Series B Warrants) were exercised to purchase 3,301,849 Series B-2 Preferred Shares with proceeds of US$20,000 (equivalent to approximately RMB132,332).

On July 6, 2018, the Series B Warrants holders agreed that the Series B Warrants shall be divided into two tranches and exercisable in accordance with different time schedules, such that: (i) the holders have exercised part of the Series B Warrants in the total consideration of US$20,000 ("Tranche I of Series B Warrants") and 3,301,849 Series B-2 Preferred Shares of the Company in aggregate have been newly issued to such holders on a pro rata basis; (ii) only when the Company fails to submit a Qualified Public Offering application at an internationally recognized securities exchange by March 31, 2019, the Warrant Holders may exercise the remaining part of Series B Warrants, in the total consideration of US$30,000 ("Tranche II of Series B Warrants") and 4,952,773 Series B-2 Preferred Shares of the Company in aggregate will be issued to such holders on a pro rata basis; (iii) provided that the Company successfully submits a Qualified Public Offering application at an internationally recognized securities exchange by March 31, 2019, the holders shall unconditionally and irrevocably waive and cancel Tranche II of Series B Warrants; and (iv) the Tranche II of Series B Warrants may only be concurrently exercised by all the Warrant Holders in one lump. This is considered to be a modification to Series B Warrants.

According to the confirmations issued by the Company's Series B Warrants holders in July 2019, the holders of Series B Warrants has unconditionally and irrevocably waived and cancelled the Tranche II of Series B Warrants. The fair value gain of warrants for the year ended December 31, 2019 was amounting to RMB5,644.

Accounting of warrants

The warrant is a freestanding instrument and is recorded as liability in accordance with ASC 480, *Distinguishing Liabilities from Equity* .

As the Company's issuance of warrants were bundled with other instruments (such as convertible preferred shares, convertible promissory notes, etc.), out of total considerations, the warrants are initially recognized at fair value and the remaining were allocated to other instruments on a relative fair value basis (if applicable). The fair value changes of the warrants (including the fair value changes arising from modification of warrants) up to the time of exercise or termination were recognized in earnings. Upon exercise, the total carrying value of the associated warrant liabilities was reclassified into the carrying value of the Preferred Shares into which it was converted.

The Company determined the fair value of the warrants with the assistance of an independent third party valuation firm.

The Group has measured the warrant liabilities at fair values on a recurring basis using significant unobservable inputs (Level 3) for the years ended December 31, 2018. The Group used the binomial model to estimate the fair value of warrant liabilities using the following assumptions:

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15. WARRANTS (CONTINUED)

	As of December 31, 2018	
Risk-free rate of return		2.49%
Maturity date		September 25, 2019
Estimated volatility rate		50.9%
Exercise price	US$	6.06
Fair value of underlying convertible preferred shares	US$	6.91

The model requires the input of highly subjective assumptions including the risk-free rate of return, maturity date, estimated volatility rate and fair value of underlying preferred shares. The risk-free rate for periods within the contractual life is based on the US treasury strip bond with maturity similar to the maturity of the warrants as of valuation dates plus a China country risk premium. For expected volatilities, the Group has made reference to the historical daily stock prices volatilities of ordinary shares of several comparable companies in the same industry as the Group. The estimated fair value of the preferred shares was determined with assistance from an independent third party valuation firm. The Group's management is ultimately responsible for the determination of the estimated fair value of its preferred shares.

The significant unobservable inputs used in the fair value measurement of the warrant liabilities include risk-free rate of return, interval between valuation date and maturity date, estimated volatility rate and fair value of underlying preferred shares. Significant decreases in interval between valuation date and maturity date, estimated volatility rate and fair value of underlying preferred shares would result in a significantly lower fair value measurement. Significant increases in risk-free rate of return would result in a significantly lower fair value measurement.

16. REDEEMABLE NON-CONTROLLING INTERESTS

In connection with the Company's acquisition of Tasgen Group on September 6, 2017, the Company also entered into an option agreement with the third party investor of I-Mab Tianjin, pursuant to which the Company granted the third party investor an option to subscribe for certain number of Series A-3 Preferred Shares of the Company at a price that stipulated in the agreement, and at the same time, the third party investor transferred its equity interests in I-Mab Tianjin to the Company at the same price ("Series A-3 Option"). This Series A-3 can be exercised at any time at the holder's own discretion or upon the request of the Company if the shareholders of the Company approves an initial public offering. In addition, in the event that the exercise of Series A-3 Option has not been completed within 6 months after the option holder delivers the share purchase option notice, the Company shall purchase the third party investor's equity interest in I-Mab Tianjin and the Series A-3 Option at a price that stipulated in the agreement.

Concurrently with the Company's issuance of Series B Preferred Shares (see Note 13), on September 25, 2017, the Group's subsidiary I-MAB Tianjin entered into a capital increase subscription agreement with Series B Onshore Investors, pursuant to which Series B Onshore Investors subscribed for additional equity in I-MAB Tianjin of US$24,444 (equivalent to approximately RMB161,196). On September 25, 2017 and in tandem with the aforementioned I-Mab Tianjin's capital increase subscription agreement, the Company also entered into option agreements with Series B Onshore Investors, pursuant to which the Company granted Series B Onshore Investors options to subscribe for certain numbers of Series B-1 Preferred Shares of the Company at a price that stipulated in the agreements, and at the same time, the Series B Onshore Investors shall transfer their equity interests in I-Mab Tianjin to the Company at the same price ("Series B Option"). The Series B Option can be exercised at any time at the holders' own discretion or upon the request of the Company if the shareholders of the Company approve an initial public offering. In addition, in the event that the exercise of Series B Option has not been completed within 6 months after the option holders deliver the share purchase option notice, the Company shall purchase the third party investor's equity interest in I-Mab Tianjin and the Series B Option at a price that stipulated in the agreements.

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16. REDEEMABLE NON-CONTROLLING INTERESTS (CONTINUED)

Based on the accounting assessments, the Company considers that the aforementioned Series A-3 and Series B Options are embedded features of the non-controlling interests that are not required to be bifurcated. Since the aforementioned non-controlling interests in I-Mab Tianjin are redeemable at a determinable price, upon occurrence of an event that is not solely within the control of I-Mab Tianjin, the aforementioned non-controlling interests in I-Mab Tianjin are accounted for as redeemable non-controlling interests in the Group's consolidated balance sheets. Subsequently, the redeemable non-controlling interests should be carried at the higher of (1) the carrying amount after the attribution of net income of the Company and (2) the expected redemption value.

The Series A-3 Option and Series B Option were exercised by respective holders on June 29, 2018 and July 6, 2018 to acquire 8,361,823 Series A-3 Preferred Shares and 7,394,189 Series B Preferred Shares, respectively. The transactions were accounted for as equity transactions, and the differences between the carrying amount of redeemable non-controlling interests of RMB305,708 and the fair value of convertible preferred shares of RMB615,393 that issued was recognized in additional paid-in capital.

The Group's redeemable non-controlling interest activities for the years ended December 31, 2017, 2018 and 2019 is summarized as follows:

	Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
Beginning balance	—	305,708	—	—
Capital injection by Series B Onshore Investors	161,196	—	—	—
Redeemable non-controlling interests arising from business combination	144,512	—	—	—
Exercise of Series A-3 Option	—	(144,512)	—	—
Exercise of Series B Option	—	(161,196)	—	—
Ending balance	305,708	—	—	—

17. SHARE-BASED COMPENSATION

(a) Restricted shares

During the year ended December 31, 2016, the Company issued 4,019,554 ordinary shares to Mr. Zang Jingwu Zhang, Ms. Qian Lili, Mr. Wang Zhengyi and Mr. Fang Lei (collectively the "Founders"), including the 369,301 shares which represented the equity interests of Third Venture held by the Founders, and the Company recorded share-based compensation expense of RMB18.7 million for issuance and grant of 3,650,253 ordinary shares to the Founders in June 2016.

In October 2016, the Founders entered into an arrangement with other investors of the Company, and the 87,441 ordinary shares issued to the Founders in June 2016 were canceled and out of the remaining 3,932,113 ordinary shares held by the Founders, 70% became restricted and subject to service vesting conditions, that should vest 20%, 20% and 30% over the next three years, respectively. There shall be no acceleration of the vesting schedule except that, in case of a change of control of the Company or a Qualified Public Offering, or the termination of the Founder's employment with the Group without cause.

Deferred share-based compensation was measured for the restricted shares using the estimated fair value of the Company's ordinary shares of US$0.77 at the date of imposition of the restriction in October 2016, and was amortized to the consolidated statements of comprehensive loss by using graded vesting method over the vesting term of 3 years.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(a) Restricted shares (continued)

The following table summarizes the Group's Founders' restricted shares activities:

	Numbers of shares	Weighted-average grant date fair value
Outstanding at December 31, 2016	2,752,479	0.77
Vested	(786,423)	
Outstanding at December 31, 2017	1,966,056	0.77
Vested	(786,423)	
Outstanding at December 31, 2018	1,179,633	0.77
Vested	(1,179,633)	
Outstanding at December 31, 2019	—	—

The amounts of shared-based compensation expense in relation to the restricted shares recognized in the years ended December 31, 2017, 2018 and 2019 were RMB7,039, RMB3,520 and RMB1,566, respectively.

Share-based compensation expenses related to restricted shares were included in:

	Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	2,112	1,056	470	68
Administrative expenses	4,927	2,464	1,096	157
	7,039	3,520	1,566	225

(b) 2017 Employee Stock Option Plan ("2017 Plan")

In October 2017, the Company adopted the 2017 Plan. Under the 2017 Plan, a maximum aggregate number of 13,376,865 shares that may be issued pursuant to all awards granted was approved. Stock options granted to an employee under the 2017 Plan will be exercisable upon the Company completes a listing and the employee renders service to the Company in accordance with a stipulated service schedule starting from the employee's date of employment. Employees are generally subject to a three-year service schedule, under which an employee earns an entitlement to vest in 50% of the option grants on the second anniversary of the grant date, a vesting of the remaining 50% on the third anniversary of the applicable grant date. The stock option under 2017 Plan, to the extent then vested, shall become exercisable only upon the earlier of (i) a listing, and (ii) occurrence of a change in control.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(b) 2017 Employee Stock Option Plan ("2017 Plan") (continued)

On December 25, 2019, the Second Amended and Restated 2017 Plan was approved by the shareholders and board of directors of the Company, pursuant to which, in connection with the Company's IPO, the maximum aggregate number of shares that may be granted pursuant to all awards under 2017 Plan shall be adjusted in accordance with a formula pre-approved by the shareholders. In connection with above amendments to 2017 Plan, each of the Company's founders, namely Zheru Zhang, Lili Qian, Zhengyi Wang and Lei Fang, is willing to irrevocably surrender by him or her, for no consideration, a portion of the unvested options granted to him or her, which, if vested, would entitle him or her to acquire up to 130,000 ordinary shares of the Company, par value US$0.0001 per share, at an exercise price of US$1.0, respectively, under the Second Amended and Restated 2017 Plan (in respect of each individual, the "Founder's Surrendered Options"). On December 25, 2019, the board of directors of the Company approved that the Company accepts all Founder's Surrendered Options from each of the founders, Zheru Zhang, Lili Qian, Zhengyi Wang and Lei Fang, for no consideration, with effect immediately prior to the completion of the IPO and such surrendered options be cancelled with effect immediately prior to the completion of the IPO.

Prior to the Company completes a listing, all stock options granted to an employee shall be forfeited at the time the employee terminates his employment with the Group. After the Company completes a listing, vested options not exercised by an employee shall be exercised until later of: (i) 90 days after the date when the options become exercisable, or (ii) 30 days after the date of cessation of employment or directorship, or such longer period as the Board of Directors may otherwise determine.

For the years ended December 31, 2017, 2018 and 2019, the Group granted 11,051,230 stock options, 1,470,000 stock options and 640,000 stock options, respectively, to its employees (all with an exercise price of US$1). No options are exercisable as of December 31, 2017, 2018, and 2019 and prior to the Group completes a listing.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(b) 2017 Employee Stock Option Plan ("2017 Plan") (continued)

The following table sets forth the stock options activities of 2017 Plan for the periods presented:

	Number of shares	Weighted average exercise price US$	Weighted average remaining contractual term	Aggregate intrinsic value US$
Outstanding as of December 31, 2016	—	—	—	—
Granted	11,051,230	1.00	—	—
Other addition (note)	710,366	0.06	—	—
Outstanding as of December 31, 2017	11,761,596	0.94	9.50	24,890
Granted	1,470,000	1.00	—	—
Forfeited	(226,000)	1.00	—	—
Outstanding as of December 31, 2018	13,005,596	0.95	8.61	70,129
Granted	640,000	1.00	—	—
Forfeited	(397,500)	1.00	—	—
Repurchased (Note 17(d))	(3,435,215)	1.00	—	—
Outstanding as of December 31 ,2019	9,812,881	0.93	7.76	47,671
Exercisable as of December 31, 2019	—	—	—	—

Note: Other addition represented the modified share options that originally granted to two senior management employees in October 2016 (see (f) other share-based compensation).

Stock options granted to the employees were measured at fair value on the dates of grant using the Binomial Option Pricing Model with the following assumptions:

	Year ended December 31,		
	2017	2018	2019
Expected volatility	62.34%	61.32%-62.13%	54.64%
Risk-free interest rate (per annum)	2.32%	2.81%-3.06%	2.15%
Exercise multiple	2.80	2.80	2.80
Expected dividend yield	—	—	—
Contractual term (in years)	10	10	10

The expected volatility was estimated based on the historical volatility of comparable peer public companies with a time horizon close to the expected term of the Group's options. The risk-free interest rate was estimated based on the yield to maturity of U.S. treasury bonds denominated in US$ for a term consistent with the expected term of the Group's options in effect at the option valuation date. The expected exercise multiple was estimated as the average ratio of the stock price to the exercise price when employees would decide to voluntarily exercise their vested options. As the Group did not have sufficient information of past employee exercise history, it was estimated by referencing to a widely-accepted academic research publication. Expected dividend yield is zero as the Group has never declared or paid any cash dividends on its shares, and the Group does not anticipate any dividend payments in the foreseeable future. Expected term is the contract life of the option.

There were 640,000 stock options granted to employees under 2017 Plan for the year ended December 31, 2019. Since the exercisability is dependent upon the listing, and it is not probable that this performance condition can be achieved until a listing, no share-based compensation expense relating to the 2017 Plan was recorded for the years ended December 31, 2017, 2018 and 2019. The Group will recognize compensation expenses relating to options vested cumulatively upon the completion of the Company's listing.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(c) 2018 Employee Stock Option Plan ("2018 Plan")

On February 22, 2019, the Group adopted the 2018 Plan, which was subsequently amended on July 22, 2019.Under the amended and restated 2018 Plan, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards is 14,005,745, and if the Group successfully lists on an internationally recognized securities exchange for a Qualified Public Offering by December 31, 2019, the maximum aggregate number of ordinary shares which may be issued shall be 15,452,620.

On December 25, 2019, the Second Amended and Restated 2018 Plan were approved by the shareholders and board of directors of the Company, pursuant to which, in connection with the Company's IPO, the maximum aggregate number of shares that may be granted pursuant to all awards under 2018 Plan shall be adjusted in accordance with a formula pre-approved by the shareholders. In connection with above amendments to 2018 Plan, the director of the Company, Dr. Jingwu Zhang Zang is willing to irrevocably surrender by him, for no consideration, of the right to acquire a certain amount of ordinary shares of the Company, par value US$0.0001 per share, at an exercise price of US$1.0 pursuant to the options granted to him under the Second Amended and Restated 2018 Plan (the "Dr. Zang's Surrendered Options"). On December 25, 2019, the board of directors of the Company approved that the Company accepts the irrevocable surrender of Dr. Zang's Surrendered Options for no consideration, with effect immediately prior to the completion of the IPO and such surrendered options be cancelled with effect immediately prior to the completion of the IPO.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(c) 2018 Employee Stock Option Plan ("2018 Plan")

Stock options granted to an employee under the 2018 Plan will be generally exercisable when the Company completes a listing and the employee renders service to the Company in accordance with a stipulated service schedule starting from the employee's date of employment. The vesting schedule shall generally be a two-year vesting schedule consisting of a cliff vesting 50% on the first anniversary of the applicable vesting commencement date, and a vesting of the remaining 50% on the second anniversary of the applicable vesting commencement date. If a listing occurs at anytime prior to any option granted under the 2018 Plan becoming full vested, and to the extent such option has been granted and outstanding, any such option shall vest in full with immediate effect upon the listing. Except as otherwise approved by the board of directors, vested portion of option shall become exercisable upon the earlier of six months after a listing or the occurrence of a change in control; provided, however that in each case, no option of an employee shall become exercisable until the third anniversary of such employee's employment commencement date.

Pursuant to the Board of Director's approval of 2018 Plan on February 22, 2019, the 10,893,028 stock options granted to a director of the Group under 2018 Plan were fully vested and exercisable upon the adoption of 2018 Plan. Out of aforementioned total 10,893,028 stock options, 454,940 stock options were repurchased by the Group (see Note 17 (d) for further details).

The amounts of shared-based compensation expense in relation to the aforementioned grant of stock options to a director of the Group (except for those repurchased by the Group as described in Note 17(d)) recognized in the year ended December 31, 2019 was RMB365,329, included in administrative expenses.

The following table sets forth the stock options activities of 2018 Plan for the year ended December 31, 2019:

	Number of shares	Weighted average exercise price US$	Weighted average remaining contractual term	Aggregate intrinsic value US$
Outstanding as of January 1, 2019	—	—	—	—
Granted	13,991,528	1.00	—	—
Repurchased (Note 17 (d))	(454,940)	1.00	—	—
Outstanding as of December 31, 2019	13,536,588	1.00	8.86	64,840
Exercisable as of December 31 , 2019	10,438,088	1.00	9.15	49,998

Stock options granted to certain directors and employees of the Group were measured at fair value on the dates of grant using the Binomial Option Pricing Model with the following assumptions:

	Year ended December 31, 2019
Expected volatility	54.64%-56.31%
Risk-free interest rate (per annum)	2.15%-2.75%
Exercise multiple	2.80
Expected dividend yield	—
Contractual term (in years)	10

17. SHARE-BASED COMPENSATION (CONTINUED)

(c) 2018 Employee Stock Option Plan ("2018 Plan") (continued)

The expected volatility was estimated based on the historical volatility of comparable peer public companies with a time horizon close to the expected term of the Group's options. The risk-free interest rate was estimated based on the yield to maturity of U.S. treasury bonds denominated in US$ for a term consistent with the expected term of the Group's options in effect at the option valuation date. The expected exercise multiple was estimated as the average ratio of the stock price to the exercise price when employees would decide to voluntarily exercise their vested options. As the Group did not have sufficient information of past employee exercise history, it was estimated by referencing to a widely-accepted academic research publication. Expected dividend yield is zero as the Group has never declared or paid any cash dividends on its shares, and the Group does not anticipate any dividend payments in the foreseeable future. Expected term is the contract life of the option.

Except for the aforementioned grant of stock options to a director of the Group under 2018 Plan, since the exercisability is dependent upon the listing, and it is not probable that this performance condition can be achieved until a listing, no share-based compensation expense related to the 2018 Plan was recorded for the year ended December 31, 2019. The Group will recognize compensation expenses relating to options vested cumulatively upon the completion of the Company's listing.

(d) Repurchase of share awards held by a director

On February 22, 2019, the amendment and restated 2017 equity incentive plan was approved by the Board of Directors of the Group, pursuant to which only the 3,435,215 stock options held by the director (see Note 17(c)) under the 2017 equity incentive plan became fully vested and exercisable on February 22, 2019. As a result of the performance condition being waived, the stock options held by the director of the Group were accounted for as a Type III modification where a condition that the Group expects will not be satisfied is changed to a condition that the Group expects will be satisfied.

Additionally, on the same day, the Group repurchased such 3,435,215 stock options under the amendment and restated 2017 equity incentive plan that was held by the director of the Group along with 454,940 of his stock options under the 2018 equity incentive plan for which the share awards also became fully vested and exercisable, at a total consideration of US$21,902 (equivalent to approximately RMB148,308) at an average share price of US$5.63 per share.

For the year ended December 31, 2019, the Group recorded the total payment of US$21,902 (equivalent to approximately RMB148,308) as share-based compensation costs (included in administrative expenses) in the consolidated statement of comprehensive loss. There was no impact to the overall stockholder's equity balance as the amended shares vested immediately and were repurchased.

(e) 2019 Share Incentive Plan ("2019 Plan")

On October 29, 2019, the Group adopted 2019 Share Incentive Plan (the "2019 Plan"), which will become effective immediately prior to the completion of the Company's initial public offering. Under the 2019 Plan, the maximum aggregate number of ordinary shares available for issuance shall initially be 100,000.

(f) Other share-based compensation

In October 2017, in connection with the adoption of 2017 Plan, the Group amended the stock option agreement with the two aforementioned employees, under which the stock options would become exercisable only upon the earlier of (i) a listing, and (ii) occurrence of a change in control that defined in the stock option agreements. As the modification of terms and conditions of share-based compensation were not beneficial to its employees, no further accounting impact was resulting from it.

(g) Establishment of Biomaster Trust

Biomaster Trust was established under the trust deed dated October 23, 2019, between the Company and TMF Trust (HK) Limited, or TMF Trust, as the trustee of the Biomaster Trust. Through the Biomaster Trust, the Company's ordinary shares and other rights and interests under awards granted pursuant to 2017 Plan and 2018 Plan may be provided to certain recipients of equity awards. Upon satisfaction of vesting conditions, TMF Trust will exercise the equity awards and transfer the relevant ordinary shares and other rights and interests under the equity awards to the relevant grant recipients with the consent of the advisory committee of Biomaster Trust. TMF Trust shall not exercise the voting rights attached to such ordinary shares unless otherwise directed by the advisory committee, whose members shall be appointed by I-Mab. The Company has the power to direct the relevant activities of Biomaster Trust and it has the ability to use its power over the Biomaster Trust to affect its exposure to returns. Therefore, the assets and liabilities of the Biomaster Trust are included in the Group's consolidated statement of financial position.

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18. LICENSING AND COLLABORATION ARRANGEMENTS

The following is a description of the Group's significant licensing and collaboration agreements entered into from January 1, 2017 to December 31, 2019.

A. In-Licensing Arrangements

Licensing Agreement with MorphoSys AG ("MorphoSys")

In November 2017, the Group entered into a license and collaboration agreement with MorphoSys, with respect to the development and commercialization of MOR202/TJ202, MorphoSys´s proprietary investigational antibody against CD38 (the "CD38 product").

Under this agreement, MorphoSys granted to the Group an exclusive, royalty-bearing, sublicensable license to exploit MOR202/TJ202 for any human therapeutic or diagnostic purpose in the licensed territory, namely mainland China, Hong Kong, Macau and Taiwan (collectively "Greater China").

Pursuant to this agreement, the Group granted to MorphoSys an exclusive license to its rights in any inventions that the Group make while exploiting the CD38 product under this agreement, solely to exploit the CD38 product outside of Greater China.

Pursuant to this agreement, the Group paid to MorphoSys an upfront license fee of US$20.0 million (equivalent to approximately RMB132.7 million). The Group also agreed to make milestone payments to MorphoSys, conditioned upon the achievement of certain development, regulatory and commercial milestones, in the aggregate amount of US$98.5 million (equivalent to approximately RMB653.5 million). Such milestones include first patient dosed in human clinical trials, marketing approval, and first annual net sales of CD38 products covered by the agreement in excess of a certain amount.

In addition, the Group is required to pay tiered low-double-digit royalties to MorphoSys on a country-by-country and product-by-product basis during the term, commencing with the first commercial sale of a relevant licensed product in Greater China. Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect until the expiration of the Group's last payment obligation under the agreement.

In 2017, the Group paid US$20.0 million (equivalent to approximately RMB132.7 million) upfront fee to MorphoSys, which was recorded as research and development expense in the consolidated statement of comprehensive loss for the year ended December 31, 2017. No additional payments were made in 2018. Due to the uncertainty involved in meeting these development and commercialization based targets, the Group evaluated and concluded that the remaining milestones are still not probable as of December 31, 2018. In March and April 2019, the project achieved the first and second milestone and the Group paid US$8.0 million (equivalent to approximately RMB55.7 million) of milestone fees to MorphoSys, which was recorded as research and development expense in the consolidated statement of comprehensive loss for the year ended December 31, 2019.

Summarized financial information related to the above agreement is presented below:

	Year ended December 31,				As of December 31,
	Research and Development Expense				
	Upfront Fees	Milestones	Extension/Termination of agreements	Amortization of prepaid research and development	Intangible asset balance
2019	—	US$8,000	—	—	—
2018	—	—	—	—	—
2017	US$20,000	—	—	—	—

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

Licensing Agreement with Genexine, Inc. ("Genexine")

In December 2017, the Group entered into an intellectual property license agreement with Genexine with respect to GX-I7/TJ107, a long-acting IL-7 cytokine. Under this agreement, the Group obtained an exclusive, sublicensable and transferable license to use and otherwise exploit certain intellectual property in connection with the pre-clinical and clinical development, manufacturing, sale and distribution of GX-I7 to treat cancer in Greater China.

Under the terms of the agreement, the Group made an upfront payment of US$12.0 million (equivalent to approximately RMB79.6 million) to Genexine which was recorded as a research and development expense in January 2018. The Group also agreed to make milestone payments in the aggregate amount of US$23.0 million (equivalent to approximately RMB152.6 million), conditioned upon the achievement of certain development milestones, including completion of Phase 2 and Phase 3 clinical studies and new drug application ("NDA") or biologic license application ("BLA") approval in Greater China.

Further, the Group agreed to make milestone payments in the aggregate amount of US$525.0 million (equivalent to approximately RMB3,482.7 million), conditioned upon the achievement of certain cumulative net sales of GX *-I7* up to US$2,000 million. The Group also is required to pay Genexine a low-single-digit percentage royalty in respect of the total annual net sales of GX-I7. The aforesaid milestones and royalties (other than the upfront payment) will be reduced by 50% following the entry of a generic version of GX-I7 in China, Hong Kong, Macau and Taiwan without the consent or authorization of the Group or any of the Group's sublicensees.

Unless terminated earlier in accordance with the terms thereof, this agreement will remain in effect until the later of (i) the expiry of the last to expire patent of the licensed intellectual property that includes a valid claim for Greater China and that covers the composition of GX-I7; and (ii) 15 years from the date of the first commercial sale of GX-I7.

No additional payments to Genexine were made in the year ended December 31, 2019. Due to the uncertainty involved in meeting these development and commercialization based targets, the Group evaluated and concluded that the remaining milestones are still not probable as of December 31, 2018 and 2019.

Summarized financial information related to the above agreement is presented below:

	Year ended December 31, Research and Development Expense				As of December 31,
	Upfront Fees	Milestones	Extension/Termination of agreements	Amortization of prepaid research and development	Intangible asset balance
2019	—	—	—	—	—
2018	US$12,000	—	—	—	—

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

Licensing Agreement with MorphoSys

In November 2018, the Group entered into a license and collaboration agreement with MorphoSys for MorphoSys´s proprietary antibody (MOR210/TJ210) directed against C5aR (the "C5aR Agreement"). Under this agreement, the Group obtained an exclusive, royalty-bearing license to explore, develop and commercialize certain anti-C5aR antibodies in Greater China and South Korea.

The Group will perform and fund all global development activities related to the development of MOR210/TJ210 in Greater China and South Korea, including all relevant clinical trials (including in the U.S. and China) and all development activities required for IND filing in the US as well as CMC development of manufacturing processes. MorphoSys retains rights in respect of development and commercialization of MOR210/TJ210 in the rest of the world.

Under the terms of the agreement, the Group also agreed to make milestone payments conditional upon the achievement of certain development milestones and certain annual net sales of anti-C5aR antibodies. The Group is also required to pay to MorphoSys tiered mid-single-digit royalties on annual net sales of anti-C5aR antibody products within the licensed territory.

In 2018, the Group paid US$3.5 million (equivalent to approximately RMB23.2 million) upfront fee to MorphoSys, which was recorded as research and development expense in the consolidated statement of comprehensive loss for the year ended December 31, 2018. No additional payments were made in the year ended December 31, 2019. Due to the uncertainty involved in meeting these development and commercialization based targets, the Group evaluated and concluded that the remaining milestones are still not probable as of December 31, 2018 and 2019.

Summarized financial information related to the above agreement is presented below:

	Years Ended December 31,				As of December 31,
	Research and Development Expense				
	Upfront Fees	Milestones	Extension/Termination of agreements	Amortization of prepaid research and development	Intangible asset balance
2019	—	—	—	—	—
2018	US$ 3,500	—	—	—	—

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

Licensing Agreement with MacroGenics

In July 2019, the Group entered into a license and collaboration agreement with MacroGenics, Inc. for development and commercialization of an Fc-optimized antibody known as enoblituzumab that targets B7-H3, including in combination with other agents, such as the anti-PD-1 antibody known as MGA012, in the People's Republic of China, Hong Kong, Macau and Taiwan("Greater China"). Under this agreement, the Group obtained an exclusive, sublicenseable, royalty-bearing license to MacroGenics' patents and know-how to develop and commercialize the enoblituzumab product, and a combination regimen of enoblituzumab and MGA012, in Greater China during the term of the agreement.

In exchange for these rights, in addition to certain financial consideration, the Group will grant to MacroGenics a royalty-free, sublicenseable, license outside of Greater China, to our patents and know-how that are related to the enoblituzumab product or useful or necessary for MacroGenics to develop or commercialize the enoblituzumab product or a product containing MGA012, and combinations thereof. The license is (i) non-exclusive with respect to the enoblituzumab product, and (ii) exclusive with regard to MGA012.

Pursuant to the agreement, the Group paid an upfront fee of US$15.0 million (equivalent to approximately RMB104.4 million) to MacroGenics, which was recorded as research and development expense in the consolidated statement of comprehensive loss for the year ended December 31, 2019. Under the terms of the agreement, the Group also agreed to pay MacroGenics development milestone fees of up to US$75.0 million and regulatory milestones fees of up to US$60.0 million, respectively, and tiered double-digit royalties (ranging from mid-teens to twenty percent) based on annual net sales in the territories.

The Group is responsible for all development costs in Greater China. MacroGenics is responsible for all development costs in the rest of the world, except that the Group is responsible for 20% of the costs incurred in (i) activities supporting global clinical trials in which we participate, (ii) certain CMC activities for material intended to be used in clinical trials in Greater China, and (iii) companion diagnostic development and validation for indications being studied in Greater China.

Due to the uncertainty involved in meeting these development and commercialization based targets, the Group evaluated and concluded that no milestones are probable as of December 31, 2019.

	Year ended December 31, Research and Development Expense				As of December 31,
	Upfront Fees	Milestones	Extension/Termination of agreements	Amortization of prepaid research and development	Intangible asset balance
2019	US$15,000	—	—	—	—

Other In-Licensing Arrangements

In addition to the above arrangements, the Group has entered into other various in-licensing and collaboration agreements with third party licensors to develop and commercialize drug candidates. Based on the terms of these agreements the Group is contingently obligated to make additional material payments upon the achievement of certain contractually defined milestones. The Group recorded US$0.6 million (equivalent to approximately RMB4.0 million) upfront fee and US$0.3 million (equivalent to approximately RMB2.0 million) milestone payment under these agreements for the year ended December 31, 2018. The Group recorded US$1.2 million (equivalent to approximately RMB8.4 million) milestone payment during the year ended December 31, 2019. Under the terms of the agreements, the licensors are eligible to receive from the Group up to an aggregate of approximately US$164.4 million (equivalent to approximately RMB1,144.5 million) in milestone payments upon the achievement of contractually specified development milestones and sales milestones, such as regulatory approval for the drug candidates, which may be before the Group has commercialized the drug or received any revenue from sales of such drug candidate, which may never occur.

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

B. Out-Licensing and collaboration Arrangements

Licensing Agreement among HDYM, I-Mab and Hangzhou HealSun Biopharm Co., Ltd. ("HealSun")

In April 2017, one of the Company's subsidiaries, I-Mab Shanghai, entered into a technology transfer agreement with HDYM and HealSun with respect to anti-PD-L1 humanized monoclonal antibodies. Under the agreement, I-Mab Shanghai agreed to grant to HDYM exclusive, worldwide and sublicensable rights to develop, manufacture, have manufactured, use, sell, have sold, import, or otherwise exploit certain PD-L1 related patents, patent applications, know-hows, data and information of I-Mab Shanghai, relevant cell lines as well as any anti-PD-L1 monoclonal antibody arising from such cell lines for the treatment of diseases. Further, I-Mab Shanghai and its cooperative party, HealSun agreed to provide subsequent research and development services on such intellectual property to HDYM, including the selection and examination of innovative anti-PD-L1 humanized monoclonal antibodies, cultivation and selection of stable cell lines, establishment of cell bank, research and development of manufacturing processes and preparation of samples, toxicological and pharmacological testing, pre-clinical pharmaceutical experiment report drafting, and application for and registration of clinical trials. HDYM agreed to make milestone payments conditioned upon achieving certain contractually defined milestones.

The Group determined that this collaboration is more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. Under this agreement, due to the early stage nature of the development, the Group determined the license to the intellectual property and research and development services are not distinct and thus were accounted for as a single performance obligation that is satisfied over time. The Group would receive RMB51.0 million (inclusive of VAT) milestone payments under this agreement, and considered that the achievements of milestone II, III, IV are constrained such that the transaction price shall initially only include the milestones payment which have been achieved (that means when uncertainty associated with the variable consideration is subsequently resolved), the additional milestone payment shall be included in the total transaction price when it is no longer probable that a significant reversal of cumulative revenue would occur in future periods.

The Group used a cost-to-cost input method to measure progress as that method best depicts its performance under the agreement. For the year ended December 31, 2017, the Group achieved milestones I and II and received milestone payments totaling of RMB29.0 million (inclusive of VAT). The cumulative percentage complete in the cost-to-cost input method related to this agreement as of December 31, 2017 is estimated to approximate 42%, the Group recognized RMB11.6 million (exclusive of VAT of RMB0.7 million) of revenue in the consolidated statement of comprehensive loss, and RMB15.8 million (exclusive of VAT of RMB0.9 million) were deferred as contract liability related to this arrangement.

During the year ended December 31, 2018, the Group achieved milestones III and IV and received milestone III payment of RMB11.0 million (inclusive of VAT), milestone IV payment of RMB 11.0 million(inclusive of VAT) was recognized as contract assets as of December 31, 2018. As of December 31, 2018, the cumulative percentage complete in the cost-to cost input method related to this arrangement is estimated to approximate 100%. The Group recognized RMB36.5 million (exclusive of VAT of RMB1.3 million) of revenue in the consolidated statement of comprehensive loss for the year ended December 31, 2018. All of the milestone payments were received by the Group as of December 31, 2019.

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

Collaboration Agreement with Everest ("Everest")

In January 2018, the Group entered into a collaboration agreement with Everest, which is controlled by the ultimate controlling party of a principal shareholder of the Group. Under the agreement, both parties agreed to collaborate on programs to co-develop MorphoSys' proprietary anti-CD38 antibody for all indications in hematologic oncology and commercialize of MOR202/TJ202 in Greater China.

A joint steering committee with equal representation from each party was established to coordinate and oversee the development and commercialization of the CD38 product. All decisions of the joint steering committee shall be made by unanimous vote.

Under the agreement, the Group is primarily responsible for carrying out the development, manufacture and supply of the CD38 product, as well as seeking regulatory approval of the CD38 product. Everest is primarily responsible for sharing the development costs of the CD38 product, including payments due to MorphoSys under the Licensing Agreement, dated November 30, 2017, in the proportion of 75% by Everest and 25% by the Group.

The joint steering committee will decide which party shall be responsible for conducting the commercialization of the CD38 product pursuant to the commercialization plan approved by the committee. If Everest is selected to be responsible for commercialization, the Group shall grant an exclusive royalty-free license to Everest to commercialize the CD38 product for all indications in hematologic oncology in Greater China.

The Group and Everest will share the profit and loss and out-licensing revenue derived from the CD 38 product in proportion to the costs that each party incur in developing the product. The parties will also split out-license revenue according to the proportion of development costs incurred, with the Group getting an additional five percent (5%) share and Everest receiving five percent (5%) less. Everest cannot share in any profit from the commercialization of CD38 product until it has fulfilled its payment obligations under this agreement.

Upon any termination of this arrangement, the terminating party has the right to continue the development and commercialization of CD38 product. If Everest is the rightful terminating party, the Group shall reasonably cooperate with Everest to facilitate the following: (i) assign the MorphoSys license to Everest (subject to the terms and conditions of such license); (ii) grant to Everest an exclusive license to all intellectual property rights that the Group owns or controls to further develop, manufacture, and commercialize the CD38 product; (iii) transfer the development, manufacture and commercialization of the CD38 product to Everest. The terminating party shall be solely responsible for the cost and expense of such development and commercialization after termination. In the event that such continuing party successfully develops and commercializes the CD38 product, it shall pay to the other party a percentage of the product profit and out-license revenue generated therefrom in accordance with the terms of this agreement.

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

During the year ended December 31, 2018, the US$26.0 million in aggregate proceeds from Everest under the agreement represented the funding available under the agreement, and was recorded as a research and development funding received liability (equivalent to approximately RMB178.7 million) on the consolidated balance sheet as of December 31, 2018, in accordance with ASC 730, Research and Development. Because there is a significant related party relationship between the Group and Everest, the Group is treating its obligation to make payments under the commercialization stage as an implicit obligation to repay the funds advanced by Everest (see Note 23). During the year ended December 31, 2019, an additional US$7.6million (equivalent to approximately RMB53.1 million) of funding was received and recorded as a research and development funding received liability. No additional milestone has been achieved in the year ended December 31, 2019.

Termination Agreement with Everest

On November 4, 2019, the Group and Everest have terminated the collaboration agreement with respect to the co-development and commercialization of TJ202 in Greater China. Upon the termination, Everest will not retain any rights or entitlements to develop or commercialize TJ202 or any economic interest in its commercialization. All intellectual property rights in respect of TJ202 arising from its development under the collaboration agreement are vested and owned by I-Mab, and the Group holds all intellectual property rights and have maximum flexibility to further develop, manufacture and commercialize TJ202 in Greater China. In consideration of the above arrangements, the board of directors of the Group has approved the issuance of a total value of US$37.0 million of ordinary shares (the “CPP Shares”) to Everest, representing Everest’s historical contribution to the collaboration and the associated time cost. The CPP Shares will be issued concurrently with, and subject to, the completion of the Company’s initial public offering within 180 days from termination of the collaboration agreement. The total value of US$37.0 million was calculated based on the sum of (1) US$33.7 million, which equals cumulative paid-in contributions historically made by Everest under the collaboration agreement; and (2) a negotiated US$3.3 million time cost of the foregoing historical contribution in light of I-Mab’s exclusive rights over the commercialization of TJ202 after this termination. The issuance of the CPP Shares was approved by I-Mab’s existing shareholders on December 25, 2019. In the event that the initial public offering has not been completed within 180 days from the termination of the collaboration agreement, the Company will issue 4,762,751 ordinary shares (the “Subject Shares”) to Everest on the 181st day. As a result of the aforementioned termination of the collaboration agreement with Everest, the Group derecognized the research and development funding received from Everest and recognized a liability that represented the ordinary shares to be issued to Everest, which was measured at fair value in accordance with ASC 480, and the difference of US$3.3 million (equivalent to approximately RMB23.0 million) between the initial fair value of the liability and the carrying amount of research and development funding received was recognized as other expenses in the consolidated statements of comprehensive loss.

Licensing Agreement with ABL Bio

In July 2018, the Group entered into a license and collaboration agreement with ABL Bio, under which the Group granted to ABL Bio exclusive, worldwide (excluding Greater China), royalty-bearing rights to develop and commercialize a bispecific antibody (“BsAb”).

The Group agreed to share costs fifty-fifty (50:50) with ABL Bio through the completion of in vivo studies, with ABL Bio responsible for all costs and activities following that time. For the year ended December 31, 2019, US$0.2 million (equivalent to approximately RMB1.4 million) expenses were incurred by ABL Bio. Accordingly, the Group recorded US$0.1 million (equivalent to approximately RMB0.7 million) (50% cost sharing) of expenses in the Group’s consolidated statement of comprehensive loss for the year ended December 31, 2019.

In consideration of the license and a memorandum of understanding signed with ABL Bio in January 2020, ABL Bio agreed to pay the Group an upfront fee of US$2.5 million (equivalent to approximately RMB17.2 million), and milestone payments in the aggregate amount of US$97.5 million (equivalent to approximately RMB646.8 million) conditioned upon achieving certain research, clinical development and sales milestones. These include clinical milestones of up to US$32.5 million (equivalent to approximately RMB215.6 million) and sales milestones of up to US$65 million (equivalent to approximately RMB431.2 million). Further, ABL Bio agreed to pay the Group royalties at mid-single-digit percentages in respect of the total annual net sales of the licensed BsAb product.

In addition, ABL Bio granted to the Group an exclusive, royalty-free, sublicensable license to use the BsAb technology solely to exploit the licensed BsAb product for all indications in Greater China.

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

Licensing Agreement with ABL Bio (continued)

The Group determined that this collaboration is more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. Under this agreement, the only one performance obligation was to grant the BsAb license to ABL Bio, considering that the achievements of milestones are constrained such that the transaction price shall initially only include upfront payment and subsequently, once another milestone was achieved (that means when uncertainty associated with the variable consideration is subsequently resolved), the additional milestone payment shall be included in the total transaction price when it is no longer probable that a significant reversal of cumulative revenue would occur in future periods.

As of December 31, 2018 and 2019, no milestone has been achieved, and the Group recognized revenue of US$2.5 million (equivalent to RMB17.2 million) of revenue in the consolidated statements of comprehensive loss for the year ended December 31, 2018, which was the upfront fee related to the grant of the rights of BsAb to ABL Bio as mentioned above.

Collaboration Agreement with ABL Bio

In July 2018, the Group and ABL Bio entered into a collaboration agreement (the "ABL Bio Collaboration") whereby both parties agreed to collaborate to develop three PD-L1 based bispecific antibodies by using ABL Bio's proprietary BsAb technology and commercialize them in their respective territories, which, collectively, include Greater China and South Korea, and other territories throughout the rest of the world if both parties agree to do so in such other territories during the performance of the agreement.

At contract inception, as both I-Mab and ABL Bio participate actively in the research and development activity. Also, the parties share the risk of failure of the BsAb products and share the income of licensing, so this contract meet the criteria of the definition of a collaborative arrangement, the Group categorized this agreement within the scope ASC 808. Prior to commercialization, the Group recorded the share of the expenses incurred by the collaboration for the development of three PD-L1 based bispecific antibodies products in research and development expense in the consolidated statements of comprehensive loss. As of December 31, 2018, RMB1.0 million expenses were incurred by the Group and ABL Bio did not incur any expense. According to the terms set out in the agreement, the Group recorded RMB0.5 million (50% cost sharing) of expense in the Group's consolidated statement of comprehensive loss for the year ended December 31, 2018. For the year ended December 31, 2019, RMB11.2 million expenses were incurred by the Group and RMB8.0 million expenses were incurred by ABL Bio. Accordingly, the Group recorded RMB9.6 million (50% cost sharing) of expenses in the Group's consolidated statement of comprehensive loss for the year ended December 31, 2019.

Collaboration Agreements with Tracon Pharmaceuticals, Inc. ("Tracon")

In November 2018, the Group entered into collaboration agreements with Tracon, under which both parties agreed to co-develop the Group's proprietary CD73 antibody, TJD5 (the "TJD5 Agreement") and co-develop up to five BsAbs (the "BsAbs Agreement"). Both agreements may be terminated by either party for the other party's uncured material breach, bankruptcy or insolvency or for safety reasons. In addition, the agreement in respect of TJD5 may be terminated by the Group: (i) for convenience within a certain period upon completing different clinical stages subject to certain payments and royalties, based on the clinical stage, that would be owed to Tracon upon the exercise of such termination for convenience; (ii) in the event that Tracon causes the Phase 1 study timeline to be delayed beyond the agreed extension periods; or (iii) if the Group decides to end the development of the collaborative product prior to its first commercial sale. Further, prior to the first commercial sale, Tracon may deem this agreement to be terminated by the Group if it reasonably believes that the Group has discontinued all meaningful development of the collaborative product for at least 12 months and certain other conditions are met. As of December 31, 2019, no payments or royalties are due under this agreement. As of December 31, 2019, the Group has recorded US$4.0 million (equivalent to approximately RMB27.8 million) of research and development costs in the consolidated statement of comprehensive loss for the year ended December 31, 2019. Additionally, in March 2019, the Group agreed with Tracon and F. Hoffmann-La Roche Ltd ("Roche") on a clinical supply agreement for Roche to supply atezolizumab for use in clinical studies under the collaboration agreement with Tracon.

Licensing Agreement with CSPC Pharmaceutical Group Limited ("CSPC")

In December 2018, the Group entered into a product development agreement with CSPC. The Group granted to CSPC exclusive, non-transferable, non-irrevocable and sublicensable rights in the PRC (excluding Hong Kong, Macau and Taiwan) to develop and commercialize TJ103 for treating type 2 diabetes.

CSPC is responsible for developing, obtaining market approval and commercializing the licensed products. The Group is responsible for transferring the manufacturing technology of the licensed products to CSPC and assisting CSPC in the continued optimization of such manufacturing technology thereafter.

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

In consideration of the license, CSPC agreed to pay the Group an upfront fee of RMB15.0 million and milestone payments in an aggregate amount of RMB135.0 million conditioned upon achieving certain clinical development and regulatory approval milestones. In addition, the Group is also entitled to royalties of up to low-double-digit percentages in respect of the total annual net sales of the products after its commercialization in the PRC.

The Group determined that this collaboration is more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. Under this agreement, the only one performance obligation was to grant TJ103 license to CSPC. considering that the achievements of milestones are constrained such that the transaction price shall initially only include upfront payment and subsequently, once another milestone was achieved (that means when uncertainty associated with the variable consideration is subsequently resolved), the additional milestone payment shall be included in the total transaction price when it is no longer probable that a significant reversal of cumulative revenue would occur in future periods. As of December 31, 2018, the amount received of RMB14.2 million (net of VAT) was recorded as advance from customers in the consolidated balance sheet. In February 2019, an additional amount of RMB0.8 million (net of VAT) was received, and the license was also approved by China intellectual property office in May 2019. The first milestone was achieved in September 2019 and the amount of RMB15.0 million (net of VAT) was received according to the terms of the agreement. Accordingly, RMB30.0 million was recognized as revenue in the consolidated statements of comprehensive loss for the year ended December 31, 2019.

19. OTHER INCOME (EXPENSES), NET

The following table summarizes other income (expenses), net recognized for the years ended December 31, 2017, 2018 and 2019:

		Year Ended December 31			
		2017	2018	2019	
	Notes	RMB	RMB	RMB	US$ (Note 2.5)
Loss from conversion of 2017 Notes	14	—	(18,375)	—	—
Loss from conversion of Onshore Convertible Loans	14	—	(8,548)	—	—
Loss from issuance of 2018 Notes	14	—	(5,081)	—	—
Loss on termination agreement with Everest	18	—	—	(23,039)	(3,309)
Fair value change of short-term investments		—	—	703	101
Income from other financial assets		5,572	13,622	—	—
Net foreign exchange gains (losses)		(3,873)	742	1,619	233
Subsidy income		—	750	568	82
Fair value change of other financial assets		—	—	42	6
Others		(172)	110	(98)	(15)
		1,527	(16,780)	(20,205)	(2,902)

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20. NET LOSS PER SHARE

Basic and diluted net loss per share for each of the periods presented are calculated as follows:

	Year Ended December 31			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
	(in thousands, except for loss per shares)			
Numerator:				
Net loss attributable to I-Mab	(298,240)	(402,833)	(1,451,950)	(208,560)
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	—	—	(5,283)	(759)
Deemed dividend to Series B-1, B-2 and C preferred shareholders at modification of Series B-1, B-2 and C Preferred Shares	—	—	(27,768)	(3,989)
Net loss attributable to ordinary shareholders	(298,240)	(402,833)	(1,485,001)	(213,308)
Denominator:				
Weighted average number of ordinary shares outstanding - basic and diluted	5,742,669	6,529,092	7,381,230	7,381,230
Net loss per share - basic and diluted	(51.93)	(61.70)	(201.19)	(28.90)

For the years ended December 31, 2017, 2018 and 2019, the effects of all outstanding convertible preferred shares, restricted shares, warrants and certain stock options have been excluded from the computation of diluted loss per share for the years ended December 31, 2017, 2018 and 2019 as their effects would be anti-dilutive.

For the years ended December 31, 2017, 2018 and 2019, the Company also has certain dilutive potential stock options. These stock options which cannot be exercised until the Company completes its listing are not included in the computation of diluted earnings per shares as such contingent event had not taken place.

The potentially dilutive securities that have not been included in the calculation of diluted net loss per share as their inclusion would be anti-dilutive are as follows:

	Year Ended December 31		
	2017	2018	2019
Convertible preferred shares	14,811,182	64,389,968	92,238,119
Convertible promissory notes	673,738	—	—
Restricted shares	1,623,553	1,134,058	—
Stock options	not applicable	not applicable	11,388,776

21. EMPLOYEE BENEFITS

Full time employees of the Group in the PRC participate in a government mandated defined contribution plan, pursuant to which certain pension benefits, medical care, employee housing fund and other welfare benefits are provided to the employees. Chinese labor regulations require that the PRC subsidiaries of the Group make contributions to the government for these benefits based on certain percentage of the employees' salaries, up to a maximum amount specified by the government. The Group has no legal obligation for the benefits beyond the contribution made. The total amounts charged to the consolidated statements of comprehensive loss for such employee benefits amounted to approximately RMB5,120, RMB9,294 and RMB14,152 for the years ended December 31, 2017, 2018 and 2019, respectively.

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22. COMMITMENTS AND CONTINGENCIES

Contingencies

The Group is a party to or an assignee of license and collaboration agreements that may require it to make future payments relating to milestone fees and royalties on future sales of licensed products (Note 18).

The Group did not have significant capital and other commitments, long-term obligations, or guarantees as of December 31, 2018 and 2019.

23. RELATED PARTY BALANCES AND TRANSACTIONS

The table below sets forth the major related parties and their relationships with the Group as of December 31, 2018 and 2019:

Name of related parties	Relationship with the Group
Everest	Controlled by the ultimate controlling party of a principal shareholder of the Group
CMAB Biopharma (Suzhou) Inc.	Controlled by the ultimate controlling party of a principal shareholder of the Group
Tasly Pharmaceutical Group Co., Ltd.	Controlled by the ultimate controlling party of a principal shareholder of the Group

Details of related party balance as of December 31, 2018 and 2019 are as follows:

*Research and development funding received**

	As of December 31,		
	2018	2019	
	RMB	RMB	US$ (Note 2.5)
Everest	178,715	—	—

*Ordinary Shares to be issued to Everest**

	As of December 31,		
	2018	2019	
	RMB	RMB	US$ (Note 2.5)
Everest	—	258,119	37,076

*Note: Pleaserefer to Note 18 for further details.

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23. RELATED PARTY BALANCES AND TRANSACTIONS (CONTINUED)

Details of related party transactions for the years ended December 31, 2017, 2018 and 2019 are as follows:

Receipt of CRO services - recognized in research and development expenses

	For the year ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
CMAB Biopharma (Suzhou) Inc.	—	2,786	—	—
Tasly Pharmaceutical Group Co., Ltd.	752	—	5,590	803

Receipt of research and development funding

	For the year ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
Everest (Note 18)	—	178,715	53,148	7,634

24. CONCENTRATION OF CREDIT RISK

Financial instruments that are potentially subject to significant concentration of credit risk consist of cash and cash equivalents, restricted cash, short-term investments, other financial assets, contract assets, and other receivables. The carrying amounts of cash and cash equivalents, restricted cash, short-term investments, contract assets, and other financial assets represent the maximum amount of loss due to credit risk. As of December 31, 2018 and 2019, all of the Group's cash and cash equivalents, restricted cash and short-term investments were held by major financial institutions located in the PRC and international financial institutions outside of the PRC which management believes are of high credit quality and continually monitors the credit worthiness of these financial institutions. With respect to the contract assets, other receivables and other financial assets, the Group performs on-going credit evaluations of the financial condition of its customers and counterparties.

25. SUBSEQUENT EVENTS

The Group evaluated subsequent events through April 29, 2020.

(a) i) On January 17, 2020, the Company completed its IPO and became listed on the Nasdaq Global Market by issuing 7,407,400 American Depositary Shares ("ADSs") at the price of US$14.00 per ADS for a total gross proceeds of US$103.7 million. On February 10, 2020, the underwriters of the IPO have exercised their over-allotment option to purchase an additional 768,350 ADSs of the Company at the IPO price of US$14.00 per ADS. After giving effect to the exercise of the over-allotment option, the Company has issued and sold a total of 8,175,750 ADSs in the IPO, for total gross proceeds of US$114,460,500. Each ten ADSs represent twenty-three ordinary shares of the Company.

ii) On January 17, 2020, the Company also issued 6,078,571 ordinary shares to Everest (see Note 18 for details).

iii) Upon the completion of the IPO, the Company's then outstanding 30,227,056 Series A Preferred Shares, 23,288,783 Series B Preferred Shares, 3,714,580 Series B-1 Preferred Shares, 3,301,849 Series B-2 Preferred Shares, 31,046,360 Series C Preferred Shares and 3,857,143 Series C-1 Preferred Shares were converted into 30,227,056, 23,288,783, 3,714,580, 3,571,427, 34,420,469 and 4,537,814 ordinary shares, respectively.

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(All amounts in thousands, except for share and per share data, unless otherwise noted)

25. SUBSEQUENT EVENTS(CONTINUED)

iv) Upon the completion of the IPO and according to the amendments to 2017 Plan, the maximum aggregate number of shares which may be granted pursuant to all awards under 2017 Plan was changed to 9,609,084. Each of the Company's founders, namely Zheru Zhang, Lili Qian, Zhengyi Wang and Lei Fang surrendered 83,142 unvested stock options that granted to him or her under 2017 Plan before, totally 332,566 unvested options, for no consideration, and these stock options were cancelled immediately. Upon the completion of the IPO and according to the amendments to 2018 Plan, the maximum aggregate number of shares which may be granted pursuant to all awards under 2018 Plan was changed to 11,005,888. The director of the Company, Dr. Jingwu Zhang Zang surrendered 2,544,917 unvested options that granted to him under 2018 Plan, for no consideration, and these stock options were cancelled immediately.

(b) As of the date of these consolidated financial statements, I-Mab has not identified any significant impact on the Group's financial performance as a result of the COVID-19 outbreak. I-Mab will continue to assess potential impact of COVID-19 on its business. Currently, I-Mab expects the COVID-19 worldwide health crisis to have immaterial impact on its business as its operations in China are in conjunction with hospitals located in regions that were relatively less affected by COVID-19. However, as research hospitals and government agencies focus clinical resources on the pandemic, I-Mab believes there could be some delays in regulatory interactions and inspections, and patient recruitment and participation, particularly in the first quarter of 2020. Similarly, the worsening situation of COVID-19 in the U.S. may cause some delays in the on-going clinical trials in the U.S. On the other hand, I-Mab clinical trials in both the U.S. and China involve many clinical sites and hospitals located in many different regions. While the full scope and duration of the crisis is far from clear at this time, I-Mab is actively and diligently working to minimize delays and disruptions to its clinical trials. At the present time, the COVID-19 situation has improved in China, and I-Mab will continue to execute on its regulatory and clinical development goals in China and the U.S.

(c) In March 2020, I-Mab signed a strategic partnership with Kalbe Genexine Biologics for first right of negotiation for an exclusive license to potentially commercialize I-Mab's CD73 antibody, in ASEAN, MENA and Sri Lanka. The deal package is valued up to approximately US$340 million.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
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26. UNAUDITED PRO FORMA NET LOSS PER SHARE

The unaudited pro forma balance sheet information as of December 31, 2019 assumes 1) the automatic conversion of all of the outstanding convertible preferred shares into ordinary shares at a conversion ratio of 1:1 (except for 1-to-1.08 for Series B-2 convertible preferred shares, 1-to-1.11 for Series C convertible preferred shares and 1-to-1.18 for Series C-1 convertible preferred shares), as if the conversion had occurred as of December 31, 2019, 2) the issuance of 6,078,571 ordinary shares to Everest Medicines Limited ("Everest"), as if the conversion had occurred as of December 31, 2019, and 3) the Company's authorized share capital had been changed into US$80,000 divided into 800,000,000 ordinary shares of a par value of US$0.0001 each as of December 31, 2019.

The unaudited pro forma net loss per ordinary share is computed using the weighted-average number of ordinary shares outstanding and assumes the automatic conversion of all of the Group's outstanding mezzanine equity into ordinary shares upon the closing of the Group's Qualified Public Offering, as if it had occurred on January 1, 2019. The Group believes the unaudited pro forma net loss per share provides material information to investors, as the automatic conversion of the Group's outstanding mezzanine equity and the disclosure of pro forma net loss per ordinary share provides an indication of net loss per ordinary share that is comparable to what will be reported by the Group as a public company following the closing of the Qualified Public Offering.

The following table summarizes the unaudited pro forma net loss per share attributable to ordinary shareholders:

	For the year ended 2019	
	RMB	US$ (Note 2.5)
	(in thousands, except for loss per share)	
Numerator		
Net loss attributable to I-Mab	(1,451,950)	(208,560)
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	(5,283)	(759)
Deemed dividend to Series B-1, B-2 and C preferred shareholders at modification of Series B-1, B-2 and C Preferred Shares	(27,768)	(3,989)
Numerator for pro-forma basic and diluted net loss per share	(1,485,001)	(213,308)
Denominator		
Weighted average number of ordinary shares outstanding	7,381,230	7,381,230
Pro-forma effect of the conversion of Series A Preferred Shares	30,227,056	30,227,056
Pro-forma effect of the conversion of Series B Preferred Shares	30,574,790	30,574,790
Pro-forma effect of the conversion of Series C Preferred Shares	34,420,469	34,420,469
Pro-forma effect of the conversion of Series C-1 Preferred Shares	775,872	775,872
Denominator for pro-forma basic and diluted net loss per share	103,379,417	103,379,417
Pro-forma net loss per share:		
Basic	(14.36)	(2.06)
Diluted	(14.36)	(2.06)

The unaudited pro forma balance sheets and loss per share excluded the impacts of the Group's share-based awards that are subject to IPO conditions.

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27. RESTRICTED NET ASSETS

The Group's ability to pay dividends may depend on the Group receiving distributions of funds from its PRC subsidiary. Relevant PRC statutory laws and regulations permit payments of dividends by the Group's PRC subsidiary only out of its retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the consolidated financial statements prepared in accordance with U.S. GAAP differ from those reflected in the statutory financial statements of the Group's PRC subsidiary.

In accordance with the Company law of the PRC, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Group's PRC subsidiary was established as domestic invested enterprise and therefore is subject to the above mentioned restrictions on distributable profits.

For the years ended December 31, 2017, 2018 and 2019, no appropriation to statutory reserves was made because the PRC subsidiary had substantial losses during such periods.

As a result of these PRC laws and regulations subject to the limit discussed above that require annual appropriations of 10% of after-tax income to be set aside, prior to payment of dividends, as general reserve fund, the Group's PRC subsidiary is restricted in their ability to transfer a portion of their net assets to the Group.

Foreign exchange and other regulations in the PRC further restrict the Company's PRC subsidiaries from transferring funds to the Company in the form of dividends, loans and advances.

Since the Group has a consolidated shareholders' deficit, its net asset base for purposes of calculating the proportionate share of restricted net assets of consolidated subsidiaries should be zero. Therefore, the restrictions placed on the net assets of the Company's PRC subsidiaries with positive equity would result in the 25 percent threshold being exceeded and a corresponding requirement to provide parent company financial information (Note 28).

28. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY

The Company performed a test on the restricted net assets of consolidated subsidiaries in accordance with Securities and Exchange Commission Regulation S-X Rule4-08 (e)(3), "General Notes to Financial Statements" and concluded that it was applicable for the Company to disclose the financial statements for the parent company.

The subsidiaries did not pay any dividends to the Company for the years presented. For the purpose of presenting parent company only financial information, the Company records its investments in its subsidiaries under the equity method of accounting. Such investments are presented on the separate condensed balance sheets of the Company as "Investments (deficit) in subsidiaries" and the loss of the subsidiaries is presented as "share of losses of subsidiaries". Certain information and footnote disclosures generally included in financial statements prepared in accordance with U.S. GAAP have been condensed and omitted. The footnote disclosures contain supplemental information relating to the operations of the Company, as such, these statements should be read in conjunction with the notes to the consolidated financial statements of the Company.

The Company did not have significant capital and other commitments, long-term obligations, other long-term debt, or guarantees as of December 31, 2018 and 2019.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts in thousands, except for share and per share data, unless otherwise noted)

28. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY(CONTINUED)

The Company did not have significant capital and other commitments, long-term obligations, other long-term debt, or guarantees as of December 31, 2018 and 2019.

Balance sheets

	As of December 31,		
	2018	2019	
	RMB	RMB	US$ (Note 2.5)
Assets			
Current assets			
Cash and cash equivalents	603,234	719,269	103,317
Total current assets	603,234	719,269	103,317
Receivables due from subsidiaries	1,455,048	939,832	134,998
Other non-current assets	—	18,331	2,633
Total assets	**2,058,282**	**1,677,432**	**240,948**
Liabilities, mezzanine equity and shareholders' deficit			
Current liabilities			
Accruals and other payables	—	117,977	16,946
Ordinary shares to be issued to Everest	—	258,119	37,076
Warrant liabilities	5,618	—	—
Total current liabilities	5,618	376,096	54,022
Convertible promissory notes	67,026	68,199	9,796
Deficit in subsidiaries	25,384	163,655	23,507
Total liabilities	**98,028**	**607,950**	**87,325**
Mezzanine equity			
Series A convertible preferred shares (US$0.0001 par value, 30,227,056 shares authorized, issued and outstanding as of December 31, 2018 and 2019)	687,482	687,482	98,751
Series B convertible preferred shares (US$0.0001 par value, 30,305,212 shares authorized, issued and outstanding as of December 31, 2018 and 2019)	921,243	921,243	132,328
Series C convertible preferred shares (US$0.0001 par value, 31,046,360 shares authorized, issued and outstanding as of December 31, 2018 and 2019, respectively)	1,306,633	1,306,633	187,686
Series C-1 convertible preferred shares (US$0.0001 par value, nil and 3,857,143 shares authorized, issued and outstanding as of December 31, 2018 and 2019, respectively)	—	188,819	27,122
Total mezzanine equity	**2,915,358**	**3,104,177**	**445,887**
Shareholders' deficit			
Ordinary shares (US$0.0001 par value, 500,000,000 shares authorized as of December 31, 2018 and 2019, 8,363,719 shares authorized, issued and outstanding as of December 31, 2018 and 2019, respectively)	6	6	1
Treasury stock	(1)	—	—
Additional paid-in capital	—	389,379	55,931
Accumulated other comprehensive income	59,380	70,127	10,074
Accumulated deficit	(1,014,489)	(2,494,207)	(358,270)
Total shareholders' deficit	**(955,104)**	**(2,034,695)**	**(292,264)**
Total liabilities, mezzanine equity and shareholders' deficit	**2,058,282**	**1,677,432**	**240,948**

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts in thousands, except for share and per share data, unless otherwise noted)

28. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (CONTINUED)

Statements of comprehensive loss

	Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
Operating expenses				
Research and development expenses	(128,721)	(121,734)	(380,143)	(54,604)
Administrative expenses	—	(15,373)	(204,874)	(29,428)
Total operating expenses	**(128,721)**	**(137,107)**	**(585,017)**	**(84,032)**
Interest income (expenses), net	(3,892)	(7,467)	16,995	2,441
Other expenses	—	—	(23,492)	(3,374)
Share of losses of subsidiaries	(151,600)	(319,664)	(866,080)	(124,406)
Fair value change of warrants	(14,027)	61,405	5,644	811
Loss before income tax expense	**(298,240)**	**(402,833)**	**(1,451,950)**	**(208,560)**
Net loss attributable to I-MAB	**(298,240)**	**(402,833)**	**(1,451,950)**	**(208,560)**
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	—	—	(5,283)	(759)
Deemed dividend to Series B-1, B-2 and C preferred shareholders at modification of Series B-1, B-2 and C Preferred Shares	—	—	(27,768)	(3,989)
Net loss attributable to ordinary shareholders	**(298,240)**	**(402,833)**	**(1,485,001)**	**(213,308)**
Net loss attributable to I-MAB	**(298,240)**	**(402,833)**	**(1,451,950)**	**(208,560)**
Other comprehensive income:				
Foreign currency translation adjustments, net of nil tax	5,918	53,689	10,747	1,544
Total comprehensive loss	**(292,322)**	**(349,144)**	**(1,441,203)**	**(207,016)**

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts in thousands, except for share and per share data, unless otherwise noted)

28. CONDENSED FINANCIAL INFORMATION OF THE PARENT COMPANY (CONTINUED)

Statements of cash flows

	Year Ended December 31,			
	2017	2018	2019	
	RMB	RMB	RMB	US$ (Note 2.5)
Net cash (used in) generated from operating activities	(132,732)	40,232	(528,322)	(75,889)
Net cash (used in) generated from investing activities	(356,635)	(1,032,483)	449,592	64,580
Net cash generated from financing activities	475,224	1,498,669	183,536	26,365
Effect of exchange rate changes on cash and cash equivalents	4,697	62,587	11,229	1,612
Net (decrease) increase in cash and cash equivalents	(9,446)	569,005	116,035	16,668
Cash and cash equivalents at beginning of the year	43,675	34,229	603,234	86,649
Cash and cash equivalents at end of the year	34,229	603,234	719,269	103,317

Exhibit 2.5

Description of rights of American Depositary Shares
registered under Section 12 of the Securities Exchange Act of 1934 (the "Exchange Act")

This exhibit contains a description of the rights of the holders of American Depositary Shares ("ADSs"). Ordinary shares underlying the ADSs are held by Citibank, N.A., as depositary, and holders of ADSs will not be treated as holders of the ordinary shares.

Description of American Depositary Shares (Items 12.D.1 and 12.D.2 of Form 20-F)

Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. ADSs represent ownership interests in securities that are on deposit with the depositary. ADSs may be represented by certificates that are commonly known as "American Depositary Receipts" or "ADRs." The depositary has appointed a custodian to safekeep the securities on deposit, which is Citibank, N.A.—Hong Kong, located at 9/F, Citi Tower, One Bay East, 83 Hon Hai Road, Kwun Tong, Kowloon, Hong Kong.

We appointed Citibank as depositary pursuant to a deposit agreement. A copy of the deposit agreement is on file with the SEC under cover of a Registration Statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 and from the SEC's website (www.sec.gov). Please refer to Registration Number 333-234363 when retrieving such copy.

An ADS represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary may agree to change the ADS-to-ordinary shares ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners. The custodian, the depositary and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary, and the depositary (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as owner of ADSs and those of the depositary. As an ADS holder you appoint the depositary to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of the Cayman Islands, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADSs.

As an owner of ADSs you will be able to exercise the shareholders rights for the ordinary shares represented by your ADSs through the depositary only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.

The manner in which you own the ADSs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADSs) may affect your rights and obligations, and the manner in which, and extent to which, the depositary's services are made available to you. As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary in your name reflecting the registration of uncertificated ADSs directly on the books of the depositary (commonly referred to as the "direct registration system" or "DRS"). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary to the holders of the ADSs. The direct registration system includes automated transfers between the depositary and The Depository Trust Company ("DTC"), the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes you have opted to own the ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADSs and will own ADSs at the relevant time.

The registration of the ordinary shares in the name of the depositary or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares underlying my ADSs?

As a holder of ADSs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

Except as stated below, the depositary will deliver such distributions to ADR holders in proportion to their interests in the following manner:

Distributions of Cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of the Cayman Islands.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of Shares

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary shares ratio, in which case each ADS you hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary shares ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (*e.g.* , the U.S. securities laws) or if it is not operationally practicable. If the depositary does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of Rights

Whenever we intend to distribute rights to subscribe for additional ordinary shares, we will give prior notice to the depositary and we will assist the depositary in determining whether it is lawful and reasonably practicable to distribute rights to subscribe for additional ADSs to holders.

The depositary will establish procedures to distribute rights to subscribe for additional ADSs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). You may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of your rights. The depositary is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to subscribe for new ordinary shares other than in the form of ADSs.

The depositary will *not* distribute the rights to you if:

- We do not timely request that the rights be distributed to you or we request that the rights not be distributed to you; or
- We fail to deliver satisfactory documents to the depositary; or
- It is not reasonably practicable to distribute the rights.

The depositary will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary is unable to sell the rights, it will allow the rights to lapse.

Elective Distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary in determining whether such distribution is lawful and reasonably practicable.

The depositary will make the election available to you only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary will establish procedures to enable you to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to you, you will receive either cash or additional ADSs, depending on what a shareholder in the Cayman Islands would receive upon failing to make an election, as more fully described in the deposit agreement.

Other Distributions

Whenever we intend to distribute property other than cash, ordinary shares or rights to subscribe for additional ordinary shares, we will notify the depositary in advance and will indicate whether we wish such distribution to be made to you. If so, we will assist the depositary in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to you and if we provide to the depositary all of the documentation contemplated in the deposit agreement, the depositary will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary may sell all or a portion of the property received.

The depositary will *not* distribute the property to you and will sell the property if:

- We do not request that the property be distributed to you or if we request that the property not be distributed to you; or
- We do not deliver satisfactory documents to the depositary; or
- The depositary determines that all or a portion of the distribution to you is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary will convert into U.S. dollars upon the terms of the deposit agreement the redemption funds received in a currency other than U.S. dollars and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a pro rata basis, as the depositary may determine.

Deposit, Withdrawal and Cancellation

How does the depositary issue ADSs?

The depositary may create ADSs on your behalf if you or your broker deposit ordinary shares with the custodian. The depositary will deliver these ADSs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Your ability to deposit ordinary shares and receive ADSs may be limited by U.S. and Cayman Islands legal considerations applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary will only issue ADSs in a denomination of ten (10) ADSs or any whole multiple of ten (10) ADSs. No fractional ADSs will be issued and no fractional share will be accepted for deposit.

When you make a deposit of ordinary shares, you will be responsible for transferring good and valid title to the depositary. As such, you will be deemed to represent and warrant that:

- The ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained.
- All preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised.
- You are duly authorized to deposit the ordinary shares.
- The ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, “restricted securities” (as defined in the deposit agreement).
- The ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary may, at your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

How do ADR holders tranfer, combine and split up ADRs?

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and the ADSs evidenced thereby. For transfers of ADRs, you will have to surrender the ADRs to be transferred to the depositary and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;

- provide such proof of identity and genuineness of signatures as the depositary deems appropriate;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have your ADRs either combined or split up, you must surrender the ADRs in question to the depositary with your request to have them combined or split up, and you must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

How do ADR holders cancel an ADS and obtain deposited securities?

As a holder, you will be entitled to present your ADSs to the depositary for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. Your ability to withdraw the ordinary shares held in respect of the ADSs may be limited by U.S. and Cayman Islands law considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by your ADSs, you will be required to pay to the depositary the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. You assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If you hold ADSs registered in your name, the depositary may ask you to provide proof of identity and genuineness of any signature and such other documents as the depositary may deem appropriate before it will cancel your ADSs. The withdrawal of the ordinary shares represented by your ADSs may be delayed until the depositary receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary will only accept a number of ADSs for cancellation that represent a whole number of securities on deposit.

You will have the right to withdraw the securities represented by your ADSs at any time except for:

- Temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends.
- Obligations to pay fees, taxes and similar charges.
- Restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair your right to withdraw the securities represented by your ADSs except to comply with mandatory provisions of law.

Record Dates

The depositary may, after consultation with us if practicable, fix record dates (which, to the extent applicable, shall be as near as practicable to any corresponding record dates set by us) for the determination of the registered ADR holders who will be entitled (or obligated, as the case may be):

- to receive any distribution on or in respect of deposited securities,
- to give instructions for the exercise of voting rights at a meeting of holders of shares,
- to pay the fee assessed by the depositary for administration of the ADR program and for any expenses as provided for in the ADR, or
- to receive any notice or to act in respect of other matters

all subject to the provisions of the deposit agreement.

Voting Rights

How do you vote?

As a holder, you generally have the right under the deposit agreement to instruct the depositary to exercise the voting rights for the ordinary shares represented by your ADSs. The voting rights of holders of ordinary shares are described in “Description of Share Capital.”

At our request, the depositary will distribute to you any notice of shareholders’ meeting received from us together with information explaining how to instruct the depositary to exercise the voting rights of the securities represented by ADSs. In lieu of distributing such materials, the depositary may distribute to holders of ADSs instructions on how to retrieve such materials upon request.

If the depositary timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder’s ADSs as follows:

- *In the event of voting by show of hands* , the depositary will vote (or cause the custodian to vote) all ordinary shares held on deposit at that time in accordance with the voting instructions received from a majority of holders of ADSs who provide timely voting instructions.
- *In the event of voting by poll* , the depositary will vote (or cause the Custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders of ADSs.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated in the deposit agreement). Please note that the ability of the depositary to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure you that you will receive voting materials in time to enable you to return voting instructions to the depositary in a timely manner.

Reports and Other Communications

Will ADR holders be able to view our reports?

The depositary will make available for inspection by ADR holders at the offices of the depositary and the custodian the deposit agreement, the provisions of or governing deposited securities, and any written communications from us which are both received by the custodian or its nominee as a holder of deposited securities and made generally available to the holders of deposited securities.

Additionally, if we make any written communications generally available to holders of our shares, and we furnish copies thereof (or English translations or summaries) to the depositary, it will distribute the same to registered ADR holders.

Further, we are subject to periodic reporting and other informational requirements of the Exchange Act as applicable to foreign private issuers and, accordingly, file certain reports with the SEC. All information filed with the SEC can be obtained over the internet at the SEC's website at www.sec.gov.

Reclassifications, Recapitalizations and Mergers

The ordinary shares held on deposit for your ADSs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the Company.

If any such change were to occur, your ADSs would, to the extent permitted by law and the deposit agreement, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary may in such circumstances deliver new ADSs to you, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of your existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the ordinary shares. If the depositary may not lawfully distribute such property to you, the depositary may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to modify the deposit agreement at any time without your consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to your substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the ordinary shares represented by your ADSs (except as permitted by law).

How may the deposit agreement be terminated?

We have the right to direct the depositary to terminate the deposit agreement. Similarly, the depositary may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary must give notice to the holders at least 30 days before termination. Until termination, your rights under the deposit agreement will be unaffected.

After termination, the depositary will continue to collect distributions received (but will not distribute any such property until you request the cancellation of your ADSs) and may sell the securities held on deposit. After the sale, the depositary will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary will have no further obligations to holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with any termination of the deposit agreement, the depositary may make available to owners of ADSs a means to withdraw the ordinary shares represented by ADSs and to direct the depositary of such ordinary shares into an unsponsored American depositary share program established by the depositary. The ability to receive unsponsored American depositary shares upon termination of the deposit agreement would be subject to satisfaction of certain U.S. regulatory requirements applicable to the creation of unsponsored American depositary shares and the payment of applicable depositary fees.

Limitations on Obligations and Liability to ADR Holders

Limits on our obligations and the obligations of the depositary; limits on liability to ADR holders and holders of ADSs

The deposit agreement limits our obligations and the depositary's obligations to you. Please note the following:

- We and the depositary are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.

- The depositary disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to you on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- We and the depositary will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depositary disclaim any liability if we or the depositary are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our memorandum and articles of association, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.
- We and the depositary disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our memorandum and articles of association or in any provisions of or governing the securities on deposit.
- We and the depositary further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depositary also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to you.
- We and the depositary may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.
- We and the depositary also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.
- Nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary and you as ADS holder.

- Nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

Disclosure of Interest in ADSs

To the extent that the provisions of or governing any deposited securities may require disclosure of or impose limits on beneficial or other ownership of deposited securities, other shares and other securities and may provide for blocking transfer, voting or other rights to enforce such disclosure or limits, you agree to comply with all such disclosure requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof. We reserve the right to instruct you to deliver your ADSs for cancelation and withdrawal of the deposited securities so as to permit us to deal with you directly as a holder of shares and, by holding an ADS or an interest therein, you will be agreeing to comply with such instructions.

Books of Depositary

The depositary will maintain ADS holder records at its depositary office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement.

The depositary will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

Taxes

You will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs. We, the depositary and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary and to the custodian proof of taxpayer status and residence and such other information as the depositary and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

Foreign Currency Conversion

The depositary will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary may take the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practical.
- Distribute the foreign currency to holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable holders.

Governing Law/Waiver of Jury Trial

The deposit agreement, the ADRs and the ADSs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) are governed by the laws of the Cayman Islands.

As an owner of ADSs, you irrevocably agree that any legal action arising out of the Deposit Agreement, the ADSs or the ADRs, involving the Company or the Depositary, may only be instituted in a state or federal court in the city of New York.

AS A PARTY TO THE DEPOSIT AGREEMENT, YOU IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT OR THE ADRs AGAINST US AND/OR THE DEPOSITARY.

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ordinary shares, the ADSs or the deposit agreement, including any claim under U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law. However, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

Exhibit 2.6

Description of rights of ordinary shares
registered under Section 12 of the Securities Exchange Act of 1934 (the "Exchange Act")

This exhibit contains a description of the rights of the holders of ordinary shares. Ordinary shares underlying the ADSs are held by Citibank, N.A., as depositary.

Description of Ordinary Shares

The following is a summary of the material provisions of the sixth memorandum and articles of association of our company and of the Companies Law (2020 Revision), insofar as they relate to the material terms of our ordinary shares.

Objects of Our Company . Under our current memorandum and articles of association, the objects of our company are unrestricted and we have the full power and authority to carry out any object not prohibited the Companies Law or any other law of the Cayman Islands.

Ordinary Shares . Certificates representing the ordinary shares are issued in registered form and our ordinary shares are issued when registered in our register of members. We may not issue shares to bearers. Our shareholders who are non-residents of the Cayman Islands may freely hold and vote their shares.

Dividends . Our directors may from time to time declare dividends (including interim dividends) and other distributions on our shares in issue and authorize payment of the same out of the funds of our company lawfully available therefor. In addition, our company may declare dividends by ordinary resolution, but no dividend shall exceed the amount recommended by our directors. Our current memorandum and articles of association provide that dividends may be declared and paid out of the funds of our company lawfully available therefor. Under the laws of the Cayman Islands, our company may pay a dividend out of either profit or the credit standing in our share premium account; provided that in no circumstances may a dividend be paid out of the share premium account if this would result in our company being unable to pay its debts as they fall due in the ordinary course of business.

Voting Rights . Voting at any meeting of shareholders is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of such meeting or any one shareholder or shareholders collectively holding not less than 5% of the votes attaching to the shares present in person or by proxy.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast at a meeting, while a special resolution requires the affirmative vote of not less than two-thirds of the votes attaching to the ordinary shares cast at a meeting. A special resolution will be required for important matters such as a change of name or making changes to our current memorandum and articles of association.

Alternation of Share Capital

We may from time to time by ordinary resolution:

- increase our share capital by such sum, to be divided into shares of such classes and amount, as the resolution shall prescribe;
- consolidate and divide all or any of our share capital into shares of a larger amount than its existing shares;
- subdivide our shares, or any of them, into shares of an amount smaller than that fixed by the memorandum of association, provided that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced share shall be the same as it was in case of the share from which the reduced share is derived; and
- cancel any shares that, at the date of the passing of the resolution, have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the amount of the shares so cancelled.

We may by special resolution, subject to any confirmation or consent required by the Companies Law, reduce our share capital and any capital redemption reserve in any manner authorized by law.

General Meetings of Shareholders . As a Cayman Islands exempted company, we are not obliged by the Companies Law to call shareholders' annual general meetings. Our current memorandum and articles of association provide that we may (but are not obliged to) in each year hold a general meeting as our annual general meeting in which case we shall specify the meeting as such in the notices calling it, and the annual general meeting shall be held at such time and place as may be determined by our directors.

Shareholders' general meetings may be convened by our directors (acting by a resolution of our board). Advance notice of at least 14 calendar days is required for any general shareholders' meeting. A quorum required for any general meeting of shareholders consists of, at the time when the meeting proceeds to business, one or more of our shareholders holding shares which carry in aggregate (or representing by proxy) not less than one-third of all votes attaching to all of our shares in issue and entitled to vote at such general meeting.

The Companies Law does not provide shareholders with any right to requisition a general meeting, nor any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our current articles of association allow our shareholders holding in aggregate not less than one-tenth of all votes attaching to all issued and outstanding shares of our company that as at the date of the deposit carry the right to vote at general meetings of the company to requisition an extraordinary general meeting of our shareholders, in which case our board is obliged to convene an extraordinary general meeting and to put the resolutions so requisitioned to a vote at such meeting. However, our current memorandum and articles of association do not provide our shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such shareholders.

Transfer of Ordinary Shares . Subject to the restrictions set out below, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four; and
- a fee of such maximum sum as the Nasdaq Global Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our directors refuse to register a transfer, they shall, within three calendar months after the date on which the instrument of transfer was lodged with our company, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, on ten calendar days' notice being given by advertisement in such one or more newspapers, by electronic means or by any other means in accordance with the rules of the Nasdaq Global Market be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine; provided, however, that the registration of transfers shall not be suspended nor the register closed for more than 30 calendar days in any year.

Liquidation . On the winding up of our company, if the assets available for distribution amongst our shareholders shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus shall be distributed amongst our shareholders in proportion to the par value of the shares held by them at the commencement of the winding up, subject to a deduction from those shares in respect of which there are monies due, of all monies payable to our company for unpaid calls or otherwise. If our assets available for distribution are insufficient to repay the whole of the share capital, such assets will be distributed so that, as nearly as may be, the losses are borne by our shareholders in proportion to the par value of the shares held by them.

Calls on Shares and Forfeiture of Shares . Our board of directors may from time to time make calls upon shareholders in respect of any moneys unpaid on their shares in a notice served to such shareholders at least 14 calendar days prior to the specified time or times of payment. The shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption, Repurchase and Surrender of Shares . We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner as may be determined, before the issue of such shares, by our board of directors or by our shareholders by a special resolution. Our company may also repurchase any of our shares on such terms and in such manner as have been approved by our board of directors or by an ordinary resolution of our shareholders or are otherwise authorized by the articles of association. Under Cayman Islands law, any redemption or repurchase of shares by our company may be made out of profits of our company, out of our company's share premium account or out of the proceeds of a fresh issue of shares made for the purpose of the repurchase or, if so authorized by the articles of association and subject to provisions of the Companies Law, out of capital. Any premium payable on a redemption or repurchase over the par value of the shares to be repurchased or redeemed must be provided for out of profits of our company or from sums standing to the credit of the share premium account of our company or, if authorized by the articles of association and subject to the provisions of the Companies Law, out of capital. At no time may a company redeem or repurchase its shares unless they are fully paid. A company may not redeem or repurchase any of its shares if, as a result of the redemption or repurchase, there would no longer be any issued shares of the company other than shares held as treasury shares. In addition, our company may accept the surrender of any fully paid share for no consideration.

Variations of Rights of Shares . Whenever the capital of our company is divided into different classes the rights attached to any such class may, subject to any rights or restrictions for the time being attached to any class, only be varied with the consent in writing of the holders of all of the issued shares of that class or with the sanction of a special resolution passed at a separate meeting of the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued with preferred or other rights shall not, subject to any rights or restrictions for the time being attached to the shares of that class, be deemed to be varied by the creation, allotment or issue of further shares ranking *pari passu* with or subsequent to them or the redemption or purchase of any shares of any class by our company. The rights of the holders of shares shall not be deemed to be varied by the creation or issue of shares with preferred or other rights including, without limitation, the creation of shares with enhanced or weighted voting rights.

Issuance of Additional Shares . Our current memorandum and articles of association authorize our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine.

Our current memorandum and articles of association also authorize our board of directors to issue from time to time one or more series of preference shares and to determine, with respect to any series of preference shares, the terms and rights of that series, including:

- the designation of the series;

- the number of preferred shares to constitute such series;
- the dividend rights, dividend rates, conversion rights, voting rights; and
- the rights and terms of redemption and liquidation preferences.

Issuance of these shares may dilute the voting power of holders of ordinary shares.

Inspection of Books and Records . The notice of registered office is a matter of public record. A list of the names of the current directors and alternate directors (if applicable) are made available by the Registrar of Companies of the Cayman Islands for inspection by any person on payment of a fee. The register of mortgages is open to inspection by creditors and shareholders. Shareholders have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records. However, we intend to provide our shareholders with annual audited financial statements.

Anti-Takeover Provisions . Some provisions of our current memorandum and articles of association may discourage, delay or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that authorize our board of directors to issue preference shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preference shares.

However, under Cayman Islands law, our directors may only exercise the rights and powers granted to them under our current memorandum and articles of association for a proper purpose and for what they believe in good faith to be in the best interests of our company.

Exempted Company . We are an exempted company with limited liability incorporated under the Companies Law. The Companies Law distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;

- may register as a limited duration company; and
- may register as a segregated portfolio company.

“Limited liability” means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company.

Exhibit 4.12

THE SYMBOL "[Redacted]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

COLLABORATION AGREEMENT

between

ABL Bio

and

I-Mab

Dated July 26, 2018

This Collaboration Agreement (" **Agreement** ") is made and entered into as of the date first written above (the " **Effective Date** ") by and between ABL Bio having a business address at 16, Daewangpangyo-ro 712beon-gil, Bundang-gu, Seongnam-si, Gyeonggi-do, 13488, Republic of Korea (" **ABL Bio** ") and I - Mab, having a business address at P. O. Box 31119 Grand Pavilion, Hibiscus Way, 802 West Bay Road, Grand Cayman, KY1-1205 Cayman Islands (" **I-Mab** "). For purposes of this Agreement, ABL Bio and I-Mab are each referred to individually as a " **Party** " and together the " **Parties** ."

WHEREAS , ABL Bio has developed expertise in the area of bi-specific antibodies for cancer treatment and has developed proprietary intellectual property around the technology for BsAb (the " **BsAb Technology** " as further defined herein).

WHEREAS , I-Mab has developed three antibodies that it desires to incorporate into a bi-specific antibody using such BsAb Technology and has expertise in developing biologics.

WHEREAS , ABL Bio and I-Mab agreed to collaborate to enable the development and commercialization of [Redacted] (each as defined herein);

WHEREAS , ABL Bio and I-Mab entered into five Materials Transfer Agreements for the transfer of certain DNA and protein sequences of applicable antibodies from I-Mab to ABL Bio (the " **Materials Transfer Agreement** ").

NOW, THEREFORE , I-Mab and ABL Bio agree in this Collaboration Agreement (" **Agreement** ") as follows:

1. Definitions

1.1 " **Affiliates** " shall mean with respect to a Party, an entity that directly or indirectly through one (1) or more intermediaries, controls, is controlled by or is under common control with such Party. In this definition, "control" means: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors; and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such entities.

1.2 " **ABL Bio Parental Antibody** " shall mean the monoclonal antibody against [Redacted], controlled by ABL Bio as described in Appendix 1 .

1.3 " **ABL Bio Parental Antibody Patent Rights** " shall mean any and all Patent Rights Controlled by ABL Bio during the Term that claim or cover the composition, use or manufacture of the Parental Antibodies. Such Patent Rights are listed in Appendix 1 , as may be updated from time to time.

1.4 " **Business Day** " shall mean any day (other than Saturday or Sunday) when banks are open for business in both China and the Republic of Korea.

1.5 " **BsAb** " shall mean a bi-specific antibody molecule constructed by the combination of two Parental Antibodies using BsAb Technology, wherein one of the Parental Antibodies is [Redacted], and the other is [Redacted].

1.6 " **BsAb Improvements** " shall mean any and all improvements to the BsAb, whether patentable or not, that have been identified, discovered or made by or on behalf of either Party or its Affiliates during the Term. For avoidance of doubt, any and all improvements to BsAb Technology, ABL Bio Parental Antibody and I-Mab Parental Antibody that are specifically designed for BsAb should be deemed BsAb Improvements.

1.7 " **BsAb Technology** " shall mean the Know-How Controlled by ABL Bio during the Term that is reasonably necessary or useful for the practice of the bispecific antibody platform technology, which can cause one antibody to bind two different targeted antigens as described in Appendix 1 .

1.8 " **BsAb Technology Improvement(s)** " shall mean any and all data, results and other Know-How, inventions and developments that constitute improvements to the BsAb Technology, whether patentable or not, that have been identified, discovered or made by or on behalf of either Party or its Affiliates during the Term and are not specifically designed for BsAb. For the avoidance of doubt, Know-How and Patent Rights pertaining solely to the BsAb Technology itself (but not to Parental Antibody Technology) shall be deemed as BsAb Technology Improvement, and any and all improvements to the BsAb Technology that are specifically designed for BsAb should be deemed BsAb.

1.9 " **Ca** " shall mean the percentage value of costs sharing ascribed to ABL Bio in Appendix 5 .

1.10 " **Ci** " shall mean the percentage value of cost sharing ascribed to I-Mab in Appendix 5 .

1.11 " **Clinical Development** " shall mean the Research and Development after the fulfilment of Decision Point II.

1.12 " **Clinical Development Plan** " shall mean, subject to Section 3 , a plan for the Clinical Development activities to be performed by either Party under this Agreement that may be amended from time to time according to Section 6 .

1.13 " **Clinical Development Report** " shall mean, subject to Section 3 , the report provided by a Party to the other Party summarizing the Clinical Development activities it has performed during the past calendar quarter.

1.14 " **Clinical Study Completed** " shall mean upon the completion of submission and acceptance of a clinical study report (CSR) concerning the applicable clinical study phase.

1.15 " **Confidential Information** " shall mean all information and data, of a confidential or proprietary nature, which is obtained directly or indirectly by one Party (the " **Receiving Party** ") or its Affiliates, from the other Party (the " **Disclosing Party** ") or its Affiliates at any time before, on, or after the Effective Date, without regard to the form or manner in which such information is disclosed or obtained (including information disclosed orally or in documentary or electronic form or by way of model, or obtained by observation). The existence and terms of this Agreement are Confidential Information of both Parties. BsAb Technology, BsAb Technology Improvements, ABL Bio Parental Antibody Technology and ABL Bio Parental Antibody Improvements are the Confidential Information of ABL Bio, and ABL Bio is deemed as the Disclosing Party with respect to all BsAb Technology, BsAb Technology Improvements, ABL Bio Parental Antibody Technology and ABL Bio Parental Antibody Improvements. I-Mab Parental Antibody Technology and I-Mab Parental Antibody Improvements are the Confidential Information of I-Mab and I-Mab is deemed as the Disclosing Party with respect to all I-Mab Parental Antibody Technology and I-Mab Parental Antibody Improvements. BsAb Improvements are the Confidential Information of ABL Bio and I-Mab, and ABL Bio and I-Mab are deemed as the Disclosing Party with respect to all BsAb Improvements.

1.16 " **Commercially Reasonable Efforts** " shall mean the efforts, time, costs and resources invested that are comparable with the efforts, time, costs and resources a similarly situated pharmaceutical company would normally invest into a proprietary development candidate or pharmaceutical product of comparable nature, value and development stage.

1.17 " **Control"** or **"Controlled** " shall mean, with respect to an item or right, the possession, whether by ownership or license (in each case other than pursuant to this Agreement), by a Party of the item or right, or the ability of a Party to grant to the other Party access to or a license to or under each such item or right as provided in this Agreement without violating any agreement or other arrangement with any Third Party.

1.18 " **CRO** " or " **CMO** " shall mean a company or other business entity providing contract research services by performing research based on orders by customers.

1.19 " **Debar** ", " **Debarred** " or " **Debarment** " shall mean (a) being debarred, or being subject to a pending debarment, pursuant to section 306 of the FDCA, 21 U.S.C. § 335a or similar laws outside the United States, (b) being listed by any federal and/or state agencies, excluded, debarred, suspended or otherwise made ineligible to participate in federal or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f) or similar laws outside the United States), or being subject to any pending process by which any such listing, exclusion, debarment, suspension or other ineligibility could occur, (c) being disqualified by any government or regulatory agency from performing specific services, or being subject to a pending disqualification proceeding, or (d) being convicted of a criminal offense related to the provision of healthcare items or services or being subject to any pending criminal action related to the provision of healthcare items or services.

1.20 " **Decision Point** " shall mean any of Decision Point I, Decision Point II, Decision Point III and Decision Point IV.

1.21 " **Decision Point I** " shall mean immediately after the completion of final candidate selection via in vivo efficacy test according to study protocols approved by the JC.

1.22 " **Decision Point II** " shall mean immediately after the submission of IND Application for Phase I Clinical Study to the Food and Drug Administration in the U.S.

1.23 " **Decision Point III** " shall mean immediately after Phase I Clinical Study Completed in the U.S.

1.24 " **Decision Point IV** " shall mean immediately after Phase II Clinical Study Completed in the U.S.

1.25 " **Disclosing Party** " shall have the meaning as described in Section 1.15 .

1.26 " **Early Development** " shall mean the Research and Development prior to fulfilment of Decision Point I.

1.27 **"Early Development Plan** " shall mean a plan for the Early Development activities to be performed by I-Mab and ABL Bio under this Agreement as attached to this Agreement as Appendix 3 that may be amended by approval of the JC.

1.28 " **Early Development Report** " shall mean the report provided by a Party to the other Party summarizing the Early Development activities it has performed during the past calendar quarter.

1.29 " **I-Mab Parental Antibody** " shall mean the monoclonal antibodies against [Redacted] and [Redacted], respectively, controlled by I-Mab as described in Appendix 2 .

1.30 " **I-Mab Parental Antibody Patent Rights** " shall mean any and all Patent Rights Controlled by I-Mab during the Term that claim or cover the composition, use or manufacture of the Parental Antibodies. Such Patent Rights are listed in Appendix 2 , as may be updated from time to time.

1.31 " **Investigation New Drug"** or **"IND"** shall mean a drug that has not been approved for general use by the U.S. Food and Drug Administration or similar authority in the jurisdiction but is under investigation in clinical trials regarding its safety and effectiveness by clinical investigators and practicing physicians using patients.

1.32 " **IND Application** " shall mean an application for approval of a request for authorization by the U.S. Food and Drug Administration or similar authority in the jurisdiction to administer an IND to humans.

1.33 " **Joint Committee** " or " **JC** " shall have the meaning ascribed in Section 6.1 .

1.34 " **Know-How** " shall mean all biological materials and other tangible materials, inventions, practices, methods, protocols, formulations, knowledge, information, know-how, trade secrets, processes, assays, skills, experience, techniques and results of experimentation and testing, which shall include without limitation all biological, chemical, pharmacological, toxicological, clinical, assay, control and manufacturing data, ideas, concepts, drawings, methods of use or application and any other information, whether patentable or not.

1.35 " **Late Development** " shall mean the Research and Development activities after the fulfilment of Decision Point I prior to the fulfilment of Decision Point II.

1.36 " **Late Development Plan** " shall mean, subject to Section 3 , a plan for the Late Development activities to be performed by either Party under this Agreement as attached to this Agreement as Appendix 4 that may be amended from time to time according to Section 6 .

1.37 " **Late Development Report** " shall mean, subject to Section 3 , the report provided by a Party to the other Party summarizing the Late Development activities it has performed during the past calendar quarter.

1.38 " **Laws** " shall mean all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any governmental authority, including without limitation patent offices and any other local or national agency, authority court, tribunal, arbitrator, commission, inspectorate, official or other instrumentality of a government with application within a country.

1.39 " **Net Receipts** " shall mean (a) all payments the Parties received from their respective Out-Licensee under the Out-License Agreement, which shall include but not be limited to upfront payments, technology access fees, milestone payments, financial development funding, commissions, royalties, success payments as well as acquisition prices allocated to the Products, less (b) any portion of such amounts paid or payable by the Parties to their respective Out-Licensee under the Out-License Agreement that are reasonably allocable to the development, commercialization or manufacture of the Products in or for such portion of licensed territory thereunder and (c) taxes and other governmental charges occurred in connection with the Out-License Agreement.

1.40 " **Net Sales** " shall mean the aggregated gross amounts invoiced by the Parties or their respective Affiliates in respect of the gross sales of all Products under this Agreement by the Parties or their respective Affiliates to Third Parties at an arm's length open market price less deductions actually allowed in relation to or specifically allocated to the Products using generally accepted accounting standards for:

1.40.1 Ordinary and customary quantity, trade and/or cash discounts actually granted and logistics service provider fees paid and payable;

1.40.2 Amounts repaid or credited and allowances including cash or credit, given by reason of retroactive price reductions, or billing errors or rebates actually allowed or paid;

1.40.3 Amounts refunded or credited for the Products which were rejected, spoiled, damaged, outdated or returned;

1.40.4 Distribution, packing, handling, freight, shipment and insurance costs in transporting the Products to customers; and

1.40.5 Taxes and other governmental charges occurred in connection with the sale of Products.

1.41 " **Non-Royalty Income** " shall mean the portion of Net Receipts that is not Royalty Income.

1.42 " **Oa** " shall mean the percentage value of royalty and non-royalty sharing ascribed to ABL Bio in Appendix 5 .

1.43 " **Oi** " shall mean the percentage value of royalty and non-royalty sharing ascribed to I-Mab in Appendix 5 .

1.44 "Opt-In Notice" shall have the meaning ascribed in Section 3.2 .

1.45 " **Opt-In Party** " shall have the meaning ascribed in Section 4.3.2 .

1.46 " **Opt-Out Party** " shall have the meaning ascribed in Section 4.3.2 .

1.47 " **Out-Licensor** ", " **Out-License** " " **Out-Licensee** ", " **Out-License Agreement** " **and "Out-License Notice"** shall have the meanings ascribed in Section 3.3 and Section 4 .

1.48 " **Parental Antibody** " shall mean each of ABL Bio Parental Antibody and I-Mab Parental Antibody.

1.49 " **Parental Antibody Improvements** " shall mean any and all data, results and other Know-How, inventions and developments that constitute improvements to I-Mab Parental Antibody Technology or ABL Bio Parental Antibody Technology, whether patentable or not, that have been identified, discovered or made by or on behalf of either Party or its Affiliates during the Term and are not specifically designed for BsAb (" **I-Mab Parental Antibody Improvements** " and " **ABL Bio Parental Antibody Improvements** ", respectively). For the avoidance of doubt, Know-How and Patent Rights pertaining solely to the Parental Antibody itself (but not BsAb Technology) shall be deemed a Parental Antibody Improvement, and any and all improvements to Parental Antibody Technology that are specifically designed for BsAb should be deemed BsAb.

1.50 " **Parental Antibody Know-How** " shall mean the Know-How Controlled by I-Mab or ABL Bio during the Term that is reasonably necessary or useful for the practice of the inventions claimed by I-Mab or ABL Bio under its Parental Antibody Patent Rights (" **I-Mab Parental Antibody Know-How** " and " **ABL Bio Parental Antibody Know-How** ", respectively).

1.51 " **Parental Antibody Technology** " shall mean the Parental Antibody Patent Rights and the Parental Antibody Know-How (" **I-Mab Parental Antibody Technology** " and " **ABL Bio Parental Antibody Technology** ", respectively).

1.52 " **Patent Rights** " shall mean all patents and patent applications including without limitation continuations, continuations-in-part, divisions, patents of addition, utility patents, reissues, renewals, re-examinations, requests for continued examination, registrations, patents of importation or patent term extensions thereof including Supplemental Protection Certificates (" **SPCs** ").

1.53 [Redacted].

1.54 [Redacted]

1.55 [Redacted]

1.56 " **Product** " shall mean a finished pharmaceutical formulation packaged and ready for sale containing the BsAb.

1.57 " **Product Family** " shall mean all Products containing the BsAb.

1.58 " **Project Lead** " or " **PL** " shall have the meaning ascribed in Section 2.3 .

1.59 " **Receiving Party** " shall have the meaning ascribed in Section 1.15 .

1.60 " **Research and Development** " shall mean any research and development performed by I-Mab or ABL Bio pursuant to the Research and Development Plan.

1.61 " **Research and Development Plan** " shall mean the Early Development Plan, the Late Development Plan, and Clinical Development Plan.

1.62 " **Royalty Income** " shall mean royalty payments, received by either Party or its Affiliates from a Third Party under the terms and conditions of an Out-License Agreement, which, for the purpose of clarification, shall include payments calculated on the basis of Net Sales generated in connection with such Out-License Agreement.

1.63 " **Term** " shall mean the period commencing on the Effective Date ending upon fulfilment of the last payment obligation of either Party to the other Party hereunder.

1.64 " **Territory** " shall mean the following: [Redacted]

1.65 " **Third Party** " shall mean any other entity than a Party and its Affiliates.

1.66 In this Agreement unless it is inconsistent with the context, a reference to a statutory provision includes a reference to: (i) a statutory amendment, modification, substitution, consolidation or re-enactment (whether before or after Effective Date); (ii) statutory instruments or subordinate legislation or orders made under the statutory provision; and (iii) statutory provisions of which the statutory provision is an amendment, modification, substitution, consolidation or re-enactment. Unless the context of this Agreement otherwise requires, (i) words of one gender includes the other gender; (ii) words using the singular or plural number also include the plural or singular number respectively; (iii) the terms "hereof", "herein", "hereby" and derivative or similar words refer to this entire Agreement; and (iv) the terms "Article", "Section" and "Appendix" refer to the specified Article, Section and Appendix of this Agreement. When this Agreement refers to a number of days, unless otherwise specified (e.g. Business Days), such number shall refer to calendar days. When this Agreement refers to a number of years and/or months, unless otherwise specified, such number shall refer to calendar years and/or months.

2. Early Development

2.1 The Parties have agreed to share activities according to the Early Development Plan attached hereto as Appendix 3 up to Decision Point I. Such Early Development Plan provides the planned activities of each Party and shall be updated, if required, by mutual agreement between the Parties.

2.2 All Early Development shall be performed according to the Early Development Plan by each Party (and/or its Affiliate or permitted CRO) as assigned to it therein. In principle, the Parties agreed to share the cost and responsibility for Early Development in the Rest of the World equally with Commercially Reasonable Efforts. However, for the purpose of administrative convenience, the Parties agree to share the costs for Early Development as follows:

2.2.1 Each Party is responsible to bear their respective costs for any and all in-house work to be performed by each Party until the production of selected candidates prior to *in vivo* proof of concept experiments in accordance with the roles assigned to the Party as outlined in the Early Development Plan and Exhibit A of the Materials Transfer Agreement.

2.2.2 Any and all the costs associated with the subsequent *in vivo* experiments, including without limitation *in vivo* experiments performed by I-Mab and the permitted CRO, will be split 50%:50% between the Parties

(a) Within thirty (30) days after the end of each calendar quarter, all parties (excluding I-Mab but including all permitted CROs) shall submit to ABL Bio a reasonably detailed report setting forth the cost and expense (including both in house and external costs and expenses) incurred by such party to perform the *in vivo* experiments activities.

(b) ABL Bio shall, within thirty (30) days after the receipt of such reports, prepare a consolidated report, subject to approval by the other Party;

(c) A Party which has borne and expended more than its share of the *in vivo* experiments costs shall submit to the other Party an invoice for such exceeded amount so that the total cost can be borne by the Parties (50%:50%). The other Party shall pay such invoice within sixty (60) days after receipt. Each Party shall keep detailed books and records of the development cost incurred by such Party to *in vivo* experiments activities and shall make such books and records available to the other Party for inspection and audit upon reasonable advance notice.

2.3 Project Lead . Promptly after the Effective Date, the Parties will appoint a Project Lead (the " **PL** ") for each project to facilitate the communication of the Early Development activities. Each Party shall appoint its respective PL within thirty (30) days after the Effective Date, and may substitute its PL, in its sole discretion, effective upon written notice to the other Party of such change. Each Party's PL shall be a project manager and will have appropriate expertise and ongoing familiarity with the Research and Development Plans. The PLs shall keep each other informed of all details of the activities under the Early Development Plan and the Late Development Plan, subject to Section 3 . The PL responsibilities shall include (i) scheduling meetings, including the JC; (ii) setting the agenda for such meetings with solicited input from other members, including the JC.

2.4 Each Party shall provide the other Party with disclosure of any invention made by that Party during the Research and Development comprising BsAb Technology Improvements, BsAb Improvements, and Parental Antibody Improvements.

3. Late Development, Clinical Development and Options

3.1 At Decision Point I and, in the event the JC decides to develop and commercialize any Product in the Rest of the World, at each Decision Point after Decision Point I, if one Party owns more than 50% of the intellectual property rights for a particular project as determined in accordance with Appendix 5 , such Party shall be the Lead Party; if neither party owns more than 50% of the intellectual property rights for the project, the JC shall select a Party as the Lead Party within seven (7) Business Days after the completion of Decision Point I. [Redacted] the Lead Party shall be determined by the JC within seven (7) Business Days after Decision Point I. Decisions regarding Late Development, Clinical Development and entering into Out-License Agreement will be made in the following manner: in ABL Bio's Territory by ABL Bio, in I-Mab's Territory by I-Mab, and in the Rest of the World, by the Lead Party.

3.2 The Parties agree to co-develop each of the Products containing [Redacted] up to Decision Point II and share the cost and responsibilities equally with Commercially Reasonable Efforts in accordance with the Late Development Plan attached hereto as Appendix 4 . No later than seven (7) Business Days following each Decision Point II, III or IV, either Party can notify the other Party that it intends to share the costs of the next development work with the other Party in the Rest of the World (" **Opt-In Notice** "). After an Opt-In Notice from a Party, such Party shall automatically become the Lead Party if the other Party has not given a similar notice. For the avoidance of doubt, if one Party stops development work or sharing the costs of development work, the other Party who continues development work or bears the cost of such development work shall automatically become the Lead Party.

3.3 ABL Bio in ABL Bio's Territory, and I-Mab in I-Mab's Territory, has the right to pursue indirect development and commercialization of the Products via an Out-License Agreement (" **Out-License Agreement** ") with any Third Party (" **Out-Licensee** "). The Party who enters into an Out-License Agreement in its Territory shall make a commercially reasonable effort to obtain the consent of such Out-Licensee to disclose relevant information (excluding financial terms) regarding such Out-License Agreement with the other Party after the execution. In the Rest of the World, either Party may pursue out-license opportunities, but the final decision to enter into an Out-License Agreement with any Out-Licensee to indirectly develop and commercialize the Product (" **Out-License** ") in any country in the Rest of the World should be made by the Lead Party (a Party entering into an Out-License Agreement hereinafter referred to as " **Out-Licensor** "). Out-Licensor shall notify the other Party of the decision (" **Out-License Notice** ") and, subject to consent of the Out-Licensee, provide the other Party with a complete copy of each Out-License Agreement within thirty (30) days of the execution of such agreement, which shall not be unreasonably withheld or delayed.

3.4 At Decision Point I and, if both Parties decide to co-develop the Products in the Rest of the World, at each Decision Point after Decision Point I, according to Section 3.1 , the Lead Party shall, within ninety (90) days of such decision, convene a JC meeting for and agree to an amended Late Development Plan, the Clinical Development Plan, and the budget.

3.4.1 The PLs shall continue their responsibilities according to Sections 6.4 and 2.3 during the Late Development and the Clinical Development;

3.4.2 The JC shall discuss and approve any further changes to the Late Development Plan and the Clinical Development Plan in case of co-development and the budget proposed by the Parties;

3.4.3 All Late Development and Clinical Development shall be performed according to the Late Development Plan and Clinical Development Plan by each Party (and/or its Affiliate or permitted CMO/CRO) as assigned to it therein. Each Party shall use Commercially Reasonable Efforts to perform the Late Development and Clinical Development activities assigned to it and shall provide Late Development Report and Clinical Development Report to the other Party. Subject to the terms of this Agreement, the Lead Party may enter into a service agreement or collaboration agreement, without the other Party's prior written consent, with (i) its Affiliate and (ii) any Third Party acting solely as contract manufacturer, contract research organization, distributor or wholesaler of the Party or its Affiliates. A Party who enters into a service agreement or a collaboration agreement with its Affiliate or a Third Party shall, subject to consent of such Affiliate or Third Party, provide the other Party with a complete copy of such an Agreement within thirty (30) days of the execution of such agreement, which shall not be unreasonably withheld or delayed.

3.4.4 the Parties shall share the Late Development and Clinical Development cost as follows.

(a) Within fifteen (15) Business Days after the end of each calendar quarter, the other Party (*i.e.* , the party that is not the Lead Party) shall submit to the Lead Party a reasonably detailed report, together with evidence, setting forth the cost and expense (including both in house cost and expense at an FTE rate of [Redacted] and external cost and expense) in such calendar quarter incurred by such Party to perform the Late Development or Clinical Development activities assigned to it under the Late Development Plan or Clinical Development Plan.

(b) If there is any question in the report prepared by the other Party, the Lead Party may request the other Party to supplement within fifteen (15) Business Days after receiving the detailed report from the other Party. Otherwise, the Lead Party shall prepare a consolidated report (summary of the cost and expense incurred by both the Lead Party and the other Party) within fifteen (15) Business Days after receiving the detailed report from the other Party, subject to approval by the other Party. The other Party should give the Lead Party a written notice within fifteen (15) Business Days if there is any question in such consolidated report.

(c) Upon receipt of such written notice within the required time, the Lead Party may provide a revised consolidated report to the other Party. If the Lead Party does not receive such a written notice within the required time, the Lead Party shall invoice the other Party according to the Development Costs Sharing (Ca: Ci) as specified in Appendix 5 . The other Party shall pay such invoice within sixty (60) days after the invoice date.

(d) The total cost and expense, unless specifically approved by the JC, shall not exceed [Redacted] of the amount set forth in the budget for such Late Development activities in the Late Development Plan or Clinical Development activities in the Clinical Development Plan.

(e) Each Party shall keep detailed books and records of the development cost incurred by such Party to perform Late Development or Clinical Development activities and shall make such books and records available to the other Party for inspection and audit upon reasonable advance notice.

3.5 Immediately after the execution of this Agreement, neither Party shall develop independently from the other Party or with any Third Party a bispecific antibody that uses the same pair of antibodies as the BsAb under this Agreement for bispecific antibody development, even if the latter bispecific antibody contains a different sequence than what was contained in the particular BsAb. In the event that both Parties agree, by signing an amendment at any time, that such a bispecific antibody that uses such pair of antibodies under this Agreement has no drug developability, such bispecific antibody that uses such pair of antibodies should not be limited by this Section 3.5 .

3.6 Each Party should share the clinical data generated during its development work with the other Party without additional charge. Each Party should provide reasonable technical assistance regarding relevant documents, material, and technical transfer as reasonably requested by the other Party in accordance with, and at the FTE rate set forth in Section 3.4.4 .

4. Out-License Income Sharing and Royalty Incoming Sharing

4.1 Out-License Right. The final decision to enter an Out-License Agreement with a Third Party in the Rest of the World should be made by the Lead Party. All other Out-License Agreements shall require the prior written consent of the other Party, which shall not be unreasonably withheld, delayed or conditioned. A Party who enters an Out-License Agreement or Sublicense Agreement with a Third Party shall provide the other Party with a complete copy of each Out-License Agreement within thirty (30) days of the execution of such agreement.

4.2 Party's Territory .

4.2.1 When either Party or its Affiliate Out-Licenses the Products in the Party's Territory, such Party shall not pay the other Party royalties or out-licensing incoming sharing on Net Sales of all Products in the Party's Territory.

4.3 Rest of the World .

In the event the JC decides to develop and commercialize the Products at any Decision Point in the Rest of the World, income sharing shall be done in the following manner.

4.3.1 **Non-Royalty Income Sharing** . After any Decision Point if both Parties decide to participate in the development of a Product in any country in the Rest of the World and execute an Out-License Agreement for the country, ABL Bio shall be entitled to a share (Oa) of the Non-Royalty Income, and I-Mab shall be entitled to a share of (Oi) of the Non-Royalty Income as specified in Appendix 5 ;

4.3.2 **Non-Royalty Income Sharing Adjustment in case of Opt-Out** . After any Decision Point except Decision Point I, if a Party (" **Opt-Out Party** ") decides not to participate in the development of the Product(s) in the Rest of the World and the other Party (" **Opt-In Party** ") executes an Out-License Agreement in the Rest of the World, the Opt-In Party shall pay to the Opt-Out Party a percentage of the Out-License income, which percentage shall equal to [Redacted] where,

(a) [Redacted]

4.3.3 **Royalty Income Sharing** . After any Decision Point if both Parties decide to participate in the development of a Product in any country in the Rest of the World and execute an Out-License Agreement for the country, ABL Bio shall be entitled to a share (Oa) of the Royalty Income, and I-Mab shall be entitled to a share of (Oi) of the Royalty Income as specified in Appendix 5 .

4.3.4 **Royalty Income Sharing Adjustment in case of Opt-Out** . After any Decision Point except Decision Point I, if a Party decides not to participate in the development of the Product(s) in the Rest of the World and the other Party executes an Out-License Agreement in the Rest of the World, the Opt-In Party shall pay to the Opt-Out Party a minimal percentage of the Royalty Income as follows: when I-Mab or its Affiliate out-licenses the Products in the Rest of the World, I-Mab shall pay ABL Bio a percentage of the royalties, which percentage shall be [Redacted]; when ABL Bio or its Affiliate Out-Licenses the Products in the Rest of the World, ABL Bio shall pay I-Mab a percentage of the royalties, which percentage shall be [Redacted] as specified in Appendix 5 .

Example: [Redacted].

5. Payments

5.1 The payments under Section 4 above are expressly stated as exclusive of Value Added Tax or equivalent sales tax applicable (" **VAT** "). If VAT is or may become lawfully payable or chargeable in respect of a payment, then the Party receiving such Payment will promptly provide a valid VAT invoice to the Party making such Payment. If the VAT charged to and paid by the Party making such Payment is subsequently refunded by any relevant fiscal authority having oversight of either Party, then such refund shall be promptly forwarded to the Party who paid for the VAT with a valid VAT credit note. At the request of the other Party, either Party shall give the other Party the assistance as may be required by the relevant tax authority, to claim exemption from or reduction of the VAT.

5.2 If any withholding tax applies to any amount due to either Party under this Agreement, such amount of withholding tax due will be deducted from the amount to be paid to either Party and paid to the appropriate tax authorities in a timely manner. At the request of the other Party, either Party shall give the other Party the assistance as may be required by the relevant tax authority, to claim exemption from or reduction of such withholding tax imposed on the amount. The other Party will provide either Party written evidence of its payment of any such withholding tax.

5.3 Parties and their respective Affiliates shall keep complete and accurate books and records used in the determination of all Net Sales, payments and deliveries of the Products to Third Parties for [Redacted]. Either Party shall, not more than once a calendar year, have the right to appoint an independent certified public accountant or like person (the " **Auditor** ") reasonably acceptable to the other Party, to perform an audit at the other Party's site upon at least ten (10) Business Days' prior written notice and within normal business hours. The other Party shall provide all books and records necessary for the Auditor to determine Net Sales, payments and deliveries under this Agreement. The cost of such audit shall not be borne by the other Party, except for the event that the audit results determine a shortfall of reported Net Sales greater than [Redacted].

5.4 The other Party shall adhere to the payment terms described in Section 4. An interest of [Redacted] shall accrue on the total amount of late payment from the day when the corresponding payment becomes due and payable.

5.5 The Party shall make all the payments to the other party under this Agreement in US Dollar (USD), including, but not limited to, Net Sales and Net Receipts in currencies other than USD shall be converted into USD using the average of the respective exchange rate as published by Bloomberg for the respective quarter. All the payments will be made without deduction of exchange, collection or other charges.

6. Contract Governance

6.1 Joint Committee. Promptly after the Effective Date the Parties will establish a joint committee to facilitate the performance and oversight of the Research and Development Plan (the " **JC** "). The JC will be comprised of an equal number of representatives from either Party, at least two (2) named representatives of I-Mab and at least two (2) named representatives of ABL Bio. Each Party shall appoint its respective representatives to the JC within thirty (30) days after the Effective Date, and may substitute one or more of its representatives, in its sole discretion, effective upon notice to the other Party of such change. Each Party shall have a JC representative who is a senior employee (Vice President level or above), and each JC representative will have appropriate expertise and ongoing familiarity with the Research and Development Plans. Additional representatives may from time to time, by mutual consent of the Parties, be invited to attend JC meetings, subject to such representatives' written agreement to comply with the requirements of Section 8. All proceedings for the JC shall take place in English. Each Party shall bear its own expenses relating to attendance at such meetings by its representatives.

6.2 Meetings. The JC shall meet in accordance with a schedule established by agreement of the Parties, but no less frequently than once per calendar quarter, with the location for such meetings alternating between I-Mab and ABL Bio facilities (or such other locations as are determined by the JC). Alternatively, the JC may meet by means of teleconference, videoconference or other similar communications equipment, but at least one meeting per year shall be conducted in person. Each Party shall nominate a chairperson (each, a " **JC Chairperson** ") with equal voting rights on each decision.

6.3 JC Responsibilities. The JC shall (i) monitor progress under the Research and Development Plans, review relevant data and share information on progress of the Research and Development with the Parties, (ii) review and approve any proposed updates to the Early Development Plan and, subject to Section 3, the Late Development Plan and Clinical Development Plan, (iii) discuss and consult regarding any technical or scientific difficulties encountered under a Research and Development Plan, (iv) perform such other activities as the Parties agree in writing shall be the responsibility of the JC, (v) decide which Product to develop and commercialize, (vi) review and approve amended Research and Development Plan and the budget, and (vii) select a Party as the Lead Party of each project in the Rest of the World within seven (7) Business Days after the completion of Decision Point I. For avoid of the doubt, the Lead Party may be changed at any Decision Point by vote in JC or the consent of the Parties.

6.4 The PL shall be responsible for (i) scheduling meetings at least once per calendar quarter, but more frequently as the JC determines it necessary; (ii) setting agenda for meetings with solicited input from other members; (iii) confirming and delivering minutes to the JC for review and final approval; and (iv) conducting effective meetings, including ensuring that objectives for each meeting are set and achieved. Each Party will provide the members of the JC with written copies of all materials they intend to present at a JC meeting. In the absence of a PL, the tasks assigned to the PL in this Section 6.4 shall be assigned to the JC Chairperson.

6.5 All decisions of the JC shall be made by consensus, with each Party having collectively one (1) vote in all decisions. If after reasonable discussion and good faith consideration of both Party's views on a particular matter before the JC, the JC is still unable after a period of ten (10) days to reach a unanimous decision on such matter, then either Party may, by written notice to the other, have such matter referred to the CEOs of the Parties for resolution. If the CEOs are able to resolve such matter within the thirty (30) day period, then: (a) with respect to the Early Development Plan, the status quo (including the existing budget) shall persist until the Parties reach agreement with respect to any amendment thereto; and (b) I-Mab in I-Mab's Territory, ABL Bio in ABL Bio's Territory, and the developing Party(ies) in the Rest of the World shall have the right to approve amendments to the Late Development Plan and Clinical Development Plan.

7. Diligence and Reports

7.1 Each Party agrees to maintain proper records (the " **Records** ") in respect of its performance of the Research and Development, including the procedures, techniques and methodologies used, the progress made, and any inventions conceived and/or reduced to practice or otherwise made as part of the Research and Development. In order to file, prosecute and defend and Patent Rights claiming any BsAb Improvement, BsAb Technology Improvement, or Parental Antibody Improvement, each Party shall upon request of the other Party, which shall not be unreasonably made, (a) make the Records available to the other Party or its designee for inspection; and (b) provide copies of the Records or any part(s) thereof to the other Party or its designee. As part of keeping the Records, each Party shall ensure that all of its personnel and all of its agents that are involved in the Research and Development will keep accurate laboratory notebooks, that: (i) shall be duly signed, dated and witnessed; and (ii) shall be created and maintained in accordance with its standard operating procedures that would be sufficient to allow for said laboratory notebooks to be used in any proceedings before the relevant governmental authorities in the relevant Territory, in order to establish the date of invention for any inventions in according with the patent Laws applicable in the relevant Territory.

7.2 Each calendar quarter until expiration of the royalty payment or income sharing obligation under Section 4 , each Party shall provide to the other Party reports as follows:

7.2.1 Each Party shall provide to the other Party an Early Development Report within thirty (30) days after the end of each calendar quarter during Early Development including all the results obtained in the past calendar quarter (including without limitation all raw data).

7.2.2 Regardless of whether a Party participates in Late Development or Clinical Development, each Party shall provide to the other Party a Late Development Report or Clinical Development Report within thirty (30) days after the end of each calendar quarter during Late Development or Clinical Development including all the results obtained in the past calendar quarter (including without limitation all raw data).

7.2.3 Upon and after the launching of the Product or Product Family, I-Mab and ABL Bio shall provide a biannual report to each other providing a high-level overview of all material commercial activities in the respective territories for the Product within thirty (30) days after the end of each six-month period.

8. Confidentiality Obligations

8.1 In consideration of disclosure of Confidential Information by the Disclosing Party, the Receiving Party undertakes:

8.1.1 to keep the Confidential Information secret and confidential at all times;

8.1.2 not to disclose or permit the disclosure of any Confidential Information of the Disclosing Party, in whole, in part, or in summary, to any person, except as expressly permitted by this Agreement;

8.1.3 not to use the Confidential Information of the Disclosing Party or permit it to be used, in whole or in part, for any purpose other than the performance of its obligations or exercise of its rights under this Agreement;

8.1.4 to take all proper and reasonable measures to ensure the confidentiality of the Confidential Information of the Disclosing Party, including but not limited to applying the same security measures and degree of care to such Confidential Information as the Receiving Party applies to its own confidential information; and

8.1.5 to inform the Disclosing Party immediately if it becomes aware of the possession, use or knowledge of any of the Confidential Information of the Disclosing Party by an unauthorised person, and to provide any assistance in relation to such unauthorised possession, use or knowledge that the Disclosing Party may reasonably require.

8.2 Exceptions to Confidentiality Obligations

8.2.1 The Receiving Party's obligations of confidentiality and non-use under this Agreement shall not apply to any Confidential Information of the Disclosing Party that the Receiving Party can prove by means of reasonable written evidence:

(a) was known to the Receiving Party on a non-confidential basis prior to disclosure by the Disclosing Party; or

(b) is or becomes publicly known other than as a result of breach of this Agreement by the Receiving Party or by anyone to whom the Receiving Party disclosed the Confidential Information of the Disclosing Party; or

(c) is received by the Receiving Party without restriction on disclosure or use from a Third Party lawfully entitled to make the disclosure without such restrictions; or

(d) is developed by any of the Receiving Party's or its Affiliate's directors, employees, consultants, advisors or agents (collectively, " **Representatives** ") who have not had any direct or indirect access to, or use or knowledge of, the Confidential Information of the Disclosing Party;

except that the above exceptions do not extend to circumstances where the Confidential Information is (i) specific, does not fall within the above exceptions, and is embraced by more general information which does fall within the above exceptions or (ii) a combination of information in the public domain separated across multiple sources.

8.2.2 The Receiving Party will not be in breach of its obligations under this Agreement to the extent that it is required to disclose Confidential Information of the Disclosing Party by law (provided, in the case of a disclosure under any freedom of information legislation, that the exemptions under that legislation do not apply) or order of a court or other public body that has jurisdiction over it, provided that, before making such a disclosure, the Receiving Party shall, to the extent it is legally permitted to do so:

(a) inform the Disclosing Party of the proposed disclosure as soon as possible, and if possible before the court or other public body orders the disclosure;

(b) take into account reasonable requests of the Disclosing Party in relation to such disclosure;

(c) ask the court or other public body to treat such Confidential Information as confidential; and

(d) permit the Disclosing Party to make representations to the court or other public body in respect of the disclosure and/or confidential treatment of such Confidential Information.

8.3 Disclosure to Representatives

8.3.1 The Receiving Party shall permit access to the Confidential Information of the Disclosing Party only to those of its representatives who:

(a) reasonably require such access for performing its obligations or exercising its rights under this Agreement;

(b) have been informed of the confidential nature of such Confidential Information, the Disclosing Party's interest in such Confidential Information, and the provisions of this Agreement, and have been instructed to comply with this Agreement; and

(c) have entered into legally binding confidentiality obligations to the Receiving Party on terms that are no less onerous than those set out in this Agreement, and which extend to such Confidential Information.

8.3.2 The Receiving Party shall ensure that all those representatives who have access to the Confidential Information of the Disclosing Party comply with the provisions of this Agreement, and the Receiving Party shall be liable to the Disclosing Party for any breach of this Agreement by the Receiving Party's Representatives.

8.4 Upon expiration or termination of this Agreement,

8.4.1 At the Disclosing Party's written request, the Receiving Party shall;

(a) immediately return to the Disclosing Party (or, if the Disclosing Party so requests, destroy or erase) all Confidential Information of the Disclosing Party that the Receiving Party has received under this Agreement including any copies made and permanently delete all electronic copies of any such Confidential Information from the Receiving Party's computer systems;

(b) provide to the Disclosing Party a certificate, signed by an officer of the Receiving Party, confirming that the obligations in this Section 8.4 have been complied with; and

(c) make no further use of any such Confidential Information.

The Receiving Party may, however, keep one copy of the Confidential Information of the Disclosing Party in its legal advisor's files solely for the purpose of enabling it to comply with the provisions of this Agreement.

8.5 As between the parties, except as otherwise expressly set forth in this Agreement:

8.5.1 the Confidential Information of the Disclosing Party is proprietary to the Disclosing Party and the Disclosing Party reserves all rights in such Confidential Information;

8.5.2 the Disclosing Party is the sole owner of all property rights in tangible records of the Confidential Information of the Disclosing Party; and

8.5.3 the Disclosing Party is and shall remain the sole owner of all intellectual property rights in the Confidential Information of the Disclosing Party.

8.6 No rights in respect of the Confidential Information of the Disclosing Party are granted to the Receiving Party, other than to use it in accordance with the terms of this Agreement, and no obligations are imposed on the Disclosing Party other than those expressly stated in this Agreement. In particular, nothing in this Agreement shall be construed or implied as obliging the Disclosing Party to disclose any specific type of information under this agreement, whether Confidential Information or not.

8.7 The Receiving Party agrees that any breach of its obligations of confidentiality and non-use under this Agreement will cause irreparable harm to the Disclosing Party; therefore, the Disclosing Party shall have, in addition to any remedies available at law, the right to obtain equitable relief to enforce this Agreement.

8.8 The confidentiality obligations under this Section shall, notwithstanding any termination of discussions between the Parties, continue in force for a period of [Redacted] after the expiration or termination of this Agreement. Notwithstanding the foregoing, the non-disclosure and non-use obligations imposed by this Agreement with respect to trade secrets included in the Confidential Information of a Party will continue for as long as such Party continues to treat such Confidential Information as a trade secret.

8.9 The Parties agree to make a joint press release according to Appendix 6 of this Agreement. Regarding any other information not expressly contained in such joint press release, except for disclosure required by applicable laws, neither Party shall make, or permit any person to make, any public announcement concerning this Agreement without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed).

9. Representation and Warranties

9.1 Each Party represents and warrants to the other Party that as of the Effective Date:

9.1.1 Such Party (i) is a company duly organized, validly existing and in good standing under the Laws of the jurisdiction of its organization; (ii) has the requisite corporate power and authority and the legal right to conduct its business as now conducted and hereafter contemplated to be conducted; and (iii) has or will obtain all necessary licenses, permits, consents, or approvals from or by, and has made or will make all necessary notices to, all governmental authorities having jurisdiction over such Party, required for the performance of this Agreement.

9.1.2 The execution, delivery and performance of this Agreement by such Party (i) are within the corporate power of such Party; (ii) have been duly authorized by all necessary or proper corporate action; (iii) do not conflict with any provision of the organizational documents of such Party; (iv) will not, to the best of such Party's knowledge, violate any Laws or any order or decree of any court or governmental authority; and (v) will not violate or conflict with any terms of any indenture, mortgage, deed of trust, lease, agreement or other instrument to which such Party is a party, or by which such Party is bound;

9.1.3 This Agreement has been duly executed and delivered by such Party and constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, subject to bankruptcy, insolvency, reorganization, arrangement, winding-up, moratorium, and similar laws of general application affecting the enforcement of creditors' rights generally, and subject to general equitable principles, including the fact that the availability of equitable remedies, such as injunctive relief or specific performance, is in the discretion of the court.

9.2 Each Party represents, warrants and covenants that neither it nor any of its Affiliates has been Debarred or is subject to Debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the Research and Development, any person or entity who has been Debarred. Each Party agrees to inform the other Party in writing immediately if it or any person or entity who is performing Research and Development under this Agreement is Debarred, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to such Party's knowledge, is threatened, relating to the Debarment of such Party or any person or entity used in any capacity by such Party or any of its Affiliates in connection with the Research and Development.

9.3 ABL Bio represents and warrants to I-Mab that as of the Effective Date, ABL Bio is the lawful owner of all right, title and interest in and to the BsAb Technology, the ABL Bio Parental Antibody Patent Rights and ABL Bio Parental Antibody Know-How. As of the Effective Date, ABL Bio has no knowledge of any claim made against it (x) asserting the invalidity, misuse, unregisterability or unenforceability of any of the BsAb Technology and the ABL Bio Parental Antibody Patent Rights or (y) challenging ABL Bio's Control of BsAb Technology, ABL Bio Parental Antibody Patent Rights or ABL Bio Parental Antibody Know-How or making any adverse claim of ownership of BsAb Technology, ABL Bio Parental Antibody Patent Rights or ABL Bio Parental Antibody Know-How.

9.4 I-Mab represents and warrants to ABL Bio that as of the Effective Date, I-Mab is the lawful owner of all right, title and interest in and to the I-Mab Parental Antibody Patent Rights and I-Mab Parental Antibody Know-How. As of the Effective Date, I-Mab has no knowledge of any claim made against it (x) asserting the invalidity, misuse, unregisterability or unenforceability of any of the I-Mab Parental Antibody Patent Rights or (y) challenging I-Mab's Control of I-Mab Parental Antibody Patent Rights or I-Mab Parental Antibody Know-How or making any adverse claim of ownership of the I-Mab Parental Antibody Patent Rights or I-Mab Parental Antibody Know-How.

9.5 THE EXPRESS REPRESENTATIONS AND WARRANTIES OF THE PARTIES STATED IN THIS SECTION 9 ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS.

10. Indemnification

10.1 Subject to the other provisions of this Section, ABL Bio shall defend, indemnify and hold harmless I-Mab, its Affiliates, and each of their officers, directors, shareholders, employees, successors and assigns from and against all Third Parties claims, suites, losses, liabilities, damages, costs, fees and expenses (including reasonable attorney's fee), to the extent arising out of (i) ABL Bio's negligence or willful misconduct in performing any of its obligations under this Agreement, or (ii) breach by ABL Bio of any of its representations, warranties, covenants or agreements under this Agreement, except in each case to the extent such claims arise from a matter for which I-Mab is obligated to indemnify ABL Bio under Section 10.2 .

10.2 Subject to the other provisions of this Section, I-Mab shall defend, indemnify and hold harmless ABL Bio, its Affiliates, and each of their officers, directors, shareholders, employees, successors and assigns from and against all Third Parties claims, suites, losses, liabilities, damages, costs, fees and expenses (including reasonable attorney's fee), to the extent arising out of (i) I-Mab's negligence or willful misconduct in performing any of its obligations under this Agreement, or (ii) breach by I-Mab of any of its representations, warranties, covenants or agreements under this Agreement, except in each case to the extent such claims arise from a matter for which ABL Bio is obligated to indemnify I-Mab under Section 10.1 .

10.3 Each Party (" **Indemnified Party** ") will promptly notify the other Party (" **Indemnifying Party** ") in writing if it becomes aware of a claim (actual or potential) by any Third Party or any proceeding (including any investigation by a governmental authority) (" **Third Party Claim** ") for which indemnification may be sought and will give such related information as the Indemnifying Party shall reasonably request.

10.4 To be eligible to be indemnified hereunder, the Indemnified Party will provide the Indemnifying Party with prompt notice of the claim giving rise to the indemnification obligation pursuant to this Section 10.4 and the exclusive ability to defend (with the reasonable cooperation of the Indemnified Party) or settle any such claim; provided , however , that the Indemnifying Party will not enter into any settlement for damages other than monetary damages without the Indemnified Party's written consent, such consent not to be unreasonably withheld. The Indemnified Party has the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the Indemnifying Party. If the Parties cannot agree as to the application of Sections 10.1 and 10.2 to any particular Third Party Claim, the Parties may conduct separate defenses of such Third Party Claim. Each Party reserves the right to claim indemnity from the other in accordance with Sections 10.1 and 10.2 above upon resolution of the underlying claim, notwithstanding the provisions of this Section 10.4 requiring the Indemnified Party to tender to the Indemnifying Party the exclusive ability to defend such claim or suit.

10.5 NEITHER PARTY WILL BE LIABLE UNDER ANY LEGAL THEORY (WHETHER TORT, CONTRACT OR OTHERWISE) FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, INCLUDING LOST PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF A MATERIAL BREACH OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS IN SECTION 8. NOTHING IN THIS SECTION 10.5 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY.

11. Intellectual Property Rights, BsAb Technology and BsAb Improvements, Parental Antibody Technology and Parental Antibody Improvements.

11.1 Each Party shall have and retain sole and exclusive title to their respective intellectual property rights. For avoidance of doubt, as between the Parties, ABL Bio shall own and retain all rights to the BsAb Technology (including BsAb Technology Improvements) and ABL Bio Parental Antibody Technology (including ABL Bio Parental Antibody Improvements), and I-Mab shall retain all rights to I-Mab Parental Antibody Technology (including I-Mab Parental Antibody Improvements). ABL Bio grants I-Mab right to exploit (including right to grant sub-license for the purpose of Out-License) the intellectual property rights in the BsAb Technology (including BsAb Technology Improvements) and ABL Bio Parental Antibody Technology (including ABL Bio Parental Antibody Improvements) within the scope of this Agreement, and I-Mab grants ABL Bio right to exploit (including right to grant sub-license for the purpose of Out-License) the intellectual property rights in I-Mab Parental Antibody Technology (including I-Mab Parental Antibody Improvements) within the scope of this Agreement.

11.2 All BsAb Improvements shall be (i) jointly owned by ABL Bio and I-Mab (Oa: Oi) in the Rest of World as specified in Appendix 5 ; (ii) owned solely by ABL Bio in ABL Bio's Territory; and (iii) owned solely by I-Mab in I-Mab's Territory. The Parties will coordinate the preparation, filing, prosecution and maintenance of any patents covering any BsAb Improvement. All costs and expenses in relation to the prosecution, settlement and compensation shall be (i) shared by ABL Bio and I-Mab (Oa: Oi) in the Rest of World as specified in Appendix 5 ; (ii) solely born by ABL Bio in ABL Bio's Territory; and (iii) solely born by I-Mab in I-Mab's Territory.

11.3 As between the Parties, all BsAb Technology (including BsAb Technology Improvements) and ABL Bio Parental Antibody (including ABL Bio Parental Antibody Improvements) shall be solely owned by ABL Bio. As between the Parties, ABL Bio has the sole right for the preparation, filing, and maintenance of any patents covering any BsAb Technology (including BsAb Technology Improvements) and ABL Bio Parental Antibody (including ABL Bio Parental Antibody Improvements). All costs and expenses incurred relation to the preparation, filing, and maintenance shall be solely born by ABL Bio.

11.4 All I-Mab Parental Antibody (including I-Mab Parental Antibody Improvements) shall be solely owned by I-Mab. I-Mab has the sole right for the preparation, filing, and maintenance of any patents covering I-Mab Parental Antibody (including I-Mab Parental Antibody Improvements). All costs and expenses incurred relation to the preparation, filing, and maintenance shall be solely born by I-Mab.

11.5 During and after the Term, I-Mab will, and will cause its Affiliates and representatives to, (i) cooperate fully in obtaining patent and other proprietary protection for any patentable or protectable BsAb Technology Improvements and ABL Bio Parental Antibody Improvements, all in the name of ABL Bio and at ABL Bio's cost and expense; and (ii) execute and deliver all requested applications, assignments and other documents, and take such other measures as ABL Bio reasonably requests, in order to perfect and enforce ABL Bio's rights in BsAb Technology Improvements and ABL Bio Parental Antibody Improvements. I-Mab appoints ABL Bio as its attorney to execute and deliver any such documents on behalf of I-Mab and its Affiliates and representatives in the event I-Mab, its Affiliates or its representatives fail to do so.

11.6 During and after the Term, ABL Bio will, and will cause its Affiliates and representatives to, (i) cooperate fully in obtaining patents and other proprietary protections for any patentable or protectable I-Mab Parental Antibody Improvements, all in the name of I-Mab and at I-Mab's cost and expense; and (ii) execute and deliver all requested applications, assignments and other documents, and take such other measures as I-Mab reasonably requests, in order to perfect and enforce I-Mab's rights in I-Mab Parental Antibody Improvements. ABL Bio appoints I-Mab as its attorney to execute and deliver any such documents on behalf of ABL Bio and its Affiliates and representatives in the event ABL Bio, its Affiliates or its representatives fail to do so.

11.7 Each Party shall be responsible for the maintenance of its own intellectual property rights during the Term of this Agreement.

11.8 In the event of the institution of any suit by a Third Party against a Party or its Affiliates for Patent Right infringements involving the registration, development, manufacture, use, sale, distribution, or marketing of the Products, the Party being sued shall promptly inform the other Party in writing and shall take appropriate action to defend such suit at its own expense; provided however that, if such Third Party action affects the BsAb Technology's or ABL Bio Parental Antibody Technology's freedom to operation, then ABL Bio shall have the first right, but not the obligation, to take over and control the defense of such action; and if such Third Party action affects I-Mab Parental Antibody Technology's freedom to operation, then I-Mab shall have the first right, but not the obligation, to take over and control the defense of such action. The cost and expense sharing are pursuant to Sections 11.2 , 11.3 , and 11.4 . ABL Bio and I-Mab shall provide reasonable assistance to one another and reasonably cooperate in any such litigation at the other Party's request without expense to the requesting Party.

11.9 In the event I-Mab becomes aware of actual or threatened infringement or validity attacks of BsAb Technology, ABL Bio Parental Antibody Patent Rights or ABL Bio Parental Antibody Know-How in I-Mab's Territory, I-Mab shall promptly notify ABL Bio in writing of such actual or threatened activity or validity attacks. ABL Bio shall have the first right, but not the obligation, to bring an action against any infringement of BsAb Technology, ABL Bio Parental Antibody Patent Rights or ABL Bio Parental Antibody Know-How. If ABL Bio elects to institute the enforcement action, it shall have full control over such enforcement action, including settlement thereof. In any event, at ABL Bio's request, I-Mab shall provide reasonable assistance and cooperation to ABL Bio in connection with any such proceeding, provided, however that all reasonable third-party out of pocket costs shall be borne by ABL Bio and reimbursable to I-Mab upon written request. ABL Bio shall bear all of its costs and expenses of such enforcement actions and shall be entitled to retain all monetary and non-monetary recoveries or settlements obtained as a result. In the event ABL Bio elects not to institute the enforcement action in accordance with this Section 11.9 , and I-Mab reasonably believes such infringement has a significant negative impact on the rights granted to its hereunder, I-Mab shall, upon reasonable advance notice to ABL Bio, be entitled to institute enforcement actions to enjoin such infringement; provided, however, that (a) I-Mab shall keep ABL Bio informed of any such proceedings in a timely manner, and (b) the settlement of any such proceedings instituted by I-Mab shall be subject to ABL Bio's prior written approval, which shall not be unreasonably withheld or delayed. ABL Bio shall use its best and good faith efforts to assist and cooperate with I-Mab and provide I-Mab with such assistance and information as may be reasonably requested by I-Mab in respect of any such action; provided, however, that all reasonable third-party out of pocket costs with respect to such enforcement action shall be borne by I-Mab and reimbursable to ABL Bio. I-Mab shall bear all of its costs and expenses of such enforcement actions and shall be entitled to retain all monetary and non-monetary recoveries or settlements obtained as a result.

11.10 In the event ABL Bio becomes aware of actual or threatened infringement or validity attacks of I-Mab Parental Antibody Patent Right or I-Mab Parental Antibody Know-How in ABL Bio's Territory, ABL Bio shall promptly notify I-Mab in writing of such actual or threatened activity or validity attacks. I-Mab shall have the first right, but not the obligation, to bring an action against any infringement of I-Mab Parental Antibody Patent Right or I-Mab Parental Antibody Know-How. If I-Mab elects to institute the enforcement action, it shall have full control over such enforcement action, including settlement thereof. In any event, at I-Mab's request, ABL Bio shall provide reasonable assistance and cooperation to I-Mab in connection with any such proceeding , provided, however that all reasonable third-party out of pocket costs shall be borne by I-Mab and reimbursable to ABL Bio upon written request. I-Mab shall bear all of its costs and expenses of such enforcement actions and shall be entitled to retain all monetary and non-monetary recoveries or settlements obtained as a result. In the event that I-Mab elects not to institute the enforcement action in accordance with this Section 11.10 , and ABL Bio reasonably believes such infringement has a material negative impact on the rights granted to it hereunder, ABL Bio shall, upon reasonable advance notice to I-Mab, be entitled to institute enforcement actions to enjoin such infringement in its own right upon reasonable advance notice to I-Mab; provided, however, that (a) ABL Bio shall keep I-Mab informed of any such proceedings in a timely manner, and (b) the settlement of any such proceedings instituted by ABL Bio shall be subject to I-Mab's prior written approval, which shall not be unreasonably withheld or delayed. I-Mab shall use its best and good faith efforts to assist and cooperate with ABL Bio and provide ABL Bio with such assistance and information as may be reasonably requested by ABL Bio in respect of any such action; provided, however, that all reasonable third-party out of pocket costs with respect to such enforcement action shall be borne by ABL Bio and reimbursable to I-Mab. ABL Bio shall bear all of its costs and expenses of such enforcement actions and shall be entitled to retain all monetary and non-monetary recoveries or settlements obtained as a result.

11.11 The Parties shall keep another informed of the status of their respective activities regarding any litigation or settlement thereof concerning the Products.

11.12 The Parties shall coordinate with each other for the assign, transfer, license or grant any of its rights in BsAb Improvements in the Rest of the World. Neither party shall assign, transfer, license or grant any of its rights in BsAb Improvements in the Rest of the World to a third party without the consent of the other Party, such consent shall not be unreasonably withheld.

12. Termination

12.1 This Agreement shall continue for the Term, if not terminated earlier as described in this Section 12 .

12.2 Either Party (the " **Non-Breaching Party** ") may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in its entirety in the event the other Party (the " **Breaching Party** ") has materially breached or defaulted in the performance of any of its obligations hereunder and such default has continued for sixty (60) days after written notice thereof was provided to the Breaching Party by the Non-Breaching Party. Any such termination will become effective at the end of such 60-day period unless the Breaching Party has cured any such breach or default prior to the expiration of such 60-day period. Notwithstanding the foregoing, in the event and to the extent that any such breach is a payment breach, the applicable notice and cure period as provided above will be ten (10) Business Days.

12.3 In the event that:

12.3.1 I-Mab or any of its Affiliates (the " **ABL Bio Challenging Party** ") (i) commence or participate in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise assert in writing any claim, challenging or denying the validity of any of the BsAb Technology or ABL Bio Parental Antibody Patent Rights (each a " **ABL Bio Technology Challenge** ") or (ii) actively assist any other person or entity in bringing or prosecuting any ABL Bio Technology Challenge, then ABL Bio has the right to terminate this Agreement immediately by giving notice to the ABL Bio Challenging Party (and, if the ABL Bio Challenging Party is not I-Mab, to give such notice to I-Mab as well).

12.3.2 ABL Bio or any of its Affiliates (the " **I-Mab Challenging Party** ") (i) commence or participate in any action or proceeding (including any patent opposition or re-examination proceeding), or otherwise assert in writing any claim, challenging or denying the validity of any of the I-Mab Parental Antibody Patent Rights, or any claim thereof (each, a " **I-Mab Patent Challenge** ") or (ii) actively assist any other person or entity in bringing or prosecuting any I-Mab Patent Challenge, then I-Mab has the right to terminate this Agreement immediately by giving notice to the I-Mab Challenging Party (and, if the I-Mab Challenging Party is not ABL Bio, to give such notice to ABL Bio as well).

12.4 In the event that there is an early termination of this Agreement in accordance with Sections 12.2 or 12.3 after completion of Late Development and either Party continues the further development and commercialization of the Products in any Territory, the Party continuing the development and commercialization of the Product shall continue to be obliged to pay to the other Party the royalty and the Out-License income sharing as described under Section 4 of this Agreement, provided that such rights have accrued hereunder prior to the effective date of such termination.

12.5 The following provisions will survive any expiration or termination of this Agreement for the period of time specified therein, or if not specified, then they will survive indefinitely: Sections 1 , 8 , 10 , and 13 , and Sections 5.3 , 7.1 , 11 , 12.4, 12,5 and 12.6 . Termination of this Agreement will not relieve the Parties of any liability and/or payment obligation that accrued hereunder prior to the effective date of such termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement. The remedies provided in this are not exclusive of any other remedies a Party may have in law or equity.

12.6 The Parties acknowledge and agree that in the event insurmountable technical difficulties and risk factors (" **Risk** ") occurs to a Party and such Risk is not resolved by the Party within 90 days thereafter despite all reasonable efforts, the Party shall be entitled to terminate this Agreement by sending a written notice to the other Party. After termination of this Agreement in accordance with this Section 12.6 , the losses incurred to the Parties shall be borne by the Parties respectively, and the terminating Party will no longer have the right to continue developing any Product.

13. Miscellaneous

13.1 All disputes which arise in connection with this Agreement and its interpretation shall be settled in amicable way between the Parties. If the dispute cannot be settled in friendly way, it will be settled by arbitration to be held in New York in conformity with the rules of International Chamber of Commerce (ICC). Such arbitration will be held in the English language. The decision of the arbitrator will be final and binding on the Parties.

13.2 This Agreement shall be construed, and the respective rights of the Parties determined, according to the Laws of the State of New York, without regard to its choice of law principles.

13.3 In the event that any legal proceeding is brought to enforce or interpret any of the provisions of this Agreement, the prevailing Party shall be entitled to recover its reasonable attorney fees, court costs and expenses of litigation whether or not the action or proceeding results in a final judgment.

13.4 This Agreement may not be assigned or transferred by either Party, in whole or in part, whether voluntarily or by operation of law, without the prior written consent of the other Party; provided that either Party my assign this Agreement, in whole or in part, to any of its Affiliates if such Party guarantees the performance of this Agreement by such Affiliate; and provided further that ABL Bio and/or I-Mab may assign this Agreement to a successor to all or substantially all of its assets or business to which this Agreement relates, whether by merger, sale of stock, sale of assets or other similar transaction. Any assignment in violation of this provision is void and without effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their permitted successors, legal representatives and assigns.

13.5 All notices must be in writing in English and sent to the address for the recipient set forth in this Agreement or at such other address as the recipient may specify in writing under this procedure.

If to ABL Bio:	ABL Bio
	16, Daewangpangyo-ro 712beon-gil, Bundang-gu,
	Seongnam-si, Gyeonggi-do, 13488, Republic of Korea
	Attention: [Redacted]
	Email: [Redacted]
	Fax: [Redacted]
with a copy to:	Attention: [Redacted]
	Email: [Redacted]
If to I-Mab:	I-MAB Biopharma Co., Ltd.
	Suite 802, West Tower, OmniVision Tech Park, 88 Shangke Rd.,
	Pudong New District, Shanghai, China 201210
	Attention: Lei Fang
	Email: lei.fang@i-mabbiopharma.com
	Fax: +86 21 6057 8000
with a copy to:	Attention: Tina Wang
	Email: tina.wang@i-mabbiopharma.com

13.6 All notices must be given (a) by personal delivery, with receipt acknowledged; or (b) by prepaid certified or registered mail, return receipt requested; or (c) by prepaid recognized express delivery service. Notices will be effective upon receipt or at a later date stated in the notice. If any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, that provision shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect and enforceable.

13.7 The headings used in this Agreement have been inserted for convenience of reference only and not define or limit the provisions hereof.

13.8 No waiver of any term or condition of this Agreement shall be effective unless set forth in this Agreement, all rights and remedies available to a Party, whether under this Agreement or afforded by Law or otherwise, will be cumulative and not in the alternative to any other righty or remedies that may be available to such Party.

13.9 This Agreement (including the exhibits and schedules hereto) constitutes the entire agreement between the Parties hereto with respect to the subject matter hereof and supersedes all previous agreements and understandings between the Parties with respect to such subject matter, whether written or oral, including, but not limited to all proposals, negotiation, conversations, letters of intent, memoranda of understanding or discussions, between the Parties relating to the subject matter of this Agreement and all past dealing or industry custom.

13.10 This Agreement may be altered, amended, or changed only by a writing making specific reference to this Agreement and the clause to be modified, which amendment is signed duly by authorized representatives of ABL Bio and I-Mab.

13.11 Nothing in this Agreement shall be deemed to constitute the grant of any license or other right in either Party, to or in respect of any product, trademark, confidential information, trade secret or other data or any other intellectual property of the other Party except as expressly set forth herein.

13.12 None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including, but not limited to, any creditor of either Party.

13.13 This Agreement shall be deemed to have been drafted jointly by both Parties; and ambiguities, if any, shall not be construed against either Party, irrespective of which Party may have actually drafted the ambiguous provision.

13.14 This Agreement may be executed in counterparts, each of which, when executed, shall be deemed an original and all of which together shall constitute one and the same document.

[REMAINDER OF THE PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF , I-Mab and ABL Bio, by their duly authorized officers, have executed this Collaboration Agreement as of the Effective Date.

ABL Bio

Signed by: /s/ Sang Hoon Lee

Name: Sang Hoon Lee

Title: CEO

I-Mab

Signed by: /s/ Jingwu Zhang Zang

Name: Jingwu Zhang Zang

Title: CEO

EXHIBIT 8.1

List of Principal Subsidiaries of I-MAB

Subsidiaries	Place of Incorporation
I-Mab Biopharma Hong Kong Limited	Hong Kong
I-Mab Biopharma US Ltd.	United States
I-Mab Bio-tech (Tianjin) Co., Ltd.	People's Republic of China
I-Mab Biopharma (Shanghai) Co., Ltd.	People's Republic of China

EXHIBIT 12.1

Certification by the Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Joan Huaqiong Shen, certify that:

1. I have reviewed this annual report on Form 20-F of I-Mab;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [intentionally omitted]

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 29, 2020

By: /s/ Joan Huaqiong Shen
Name: Joan Huaqiong Shen
Title: Director and Chief Executive Officer

EXHIBIT 12.2

Certification by the Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Jielun Zhu, certify that:

1. I have reviewed this annual report on Form 20-F of I-Mab;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) [intentionally omitted]

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent function):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: April 29, 2020

By: /s/ Jielun Zhu
Name: Jielun Zhu
Title: Director and Chief Financial Officer

EXHIBIT 13.1

Certification by the Principal Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of I-Mab (the "Company") on Form 20-F for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joan Huaqiong Shen, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 29, 2020

By: /s/ Joan Huaqiong Shen
Name: Joan Huaqiong Shen
Title: Director and Chief Executive Officer

EXHIBIT 13.2

Certification by the Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of I-Mab (the "Company") on Form 20-F for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jielun Zhu, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 29, 2020

By: /s/ Jielun Zhu
Name: Jielun Zhu
Title: Director and Chief Financial Officer

EXHIBIT 15.1

April 29, 2020
I-MAB
Suite 802, West Tower, OmniVision
88 Shangke Road
Pudong District, Shanghai
People's Republic of China

Dear Sir/Madam:

We hereby consent to the reference of our name under the headings "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China" and "Item 10. Additional Information—E. Taxation—PRC Taxation" in I-Mab's Annual Report on Form 20-F for the year ended December 31, 2019 (the " **Annual Report** "), which will be filed with the Securities and Exchange Commission (the " **SEC** ") on the date hereof. We also consent to the filing of this consent letter with the SEC as an exhibit to the Annual Report.

In giving such consent, we do not thereby admit that we come within the category of persons whose consent is required under Section 7 of the Securities Act of 1933, or under the Securities Exchange Act of 1934, in each case, as amended, or the regulations promulgated thereunder.

Very truly yours,

/s/ JunHe LLP
JunHe LLP