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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, 2020.

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) American depositary shares representing twenty-three (23) ordinary shares	**IMAB**	The Nasdaq Stock Market LLC (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:

164,888,519 ordinary shares outstanding, par value of US$0.0001 per share, including 4,036,868 ordinary shares issued upon the exercising or vesting of awards granted under our share incentive plans, as of December 31, 2020.

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. ☒

†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. ☐

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 pandemic 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 RMB6.5250 to US$1.00, the exchange rate in effect as of December 31, 2020 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 comprehensive income (loss) data for the years ended December 31, 2018, 2019 and 2020, selected consolidated balance sheet data as of December 31, 2019 and 2020 and selected consolidated statements of cash flow data for the years ended December 31, 2018, 2019 and 2020 have been derived from our audited consolidated financial statements included elsewhere in this annual report. The selected consolidated statements of comprehensive loss data for the year ended December 31, 2017, selected consolidated balance sheet data as of December 31, 2017 and 2018 and selected consolidated statements of cash flow data for the year ended 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	2020	
	RMB	RMB	RMB	RMB	US$
	(in thousands, except for share and per share data)				
Selected Consolidated Statements of Comprehensive Income (Loss) Data:					
Revenues					
Licensing and collaboration revenue	11,556	53,781	30,000	1,542,668	236,424
Expenses					
Research and development expenses[(1)]	(267,075)	(426,028)	(840,415)	(984,689)	(150,910)
Administrative expenses[(1)]	(25,436)	(66,391)	(654,553)	(402,409)	(61,672)
Income (loss) from operations	(280,955)	(438,638)	(1,464,968)	155,570	23,842
Interest income	858	4,597	30,570	24,228	3,713
Interest expense	(5,643)	(11,695)	(2,991)	(957)	(147)
Other income (expenses), net	1,527	(16,780)	(20,205)	412,892	63,278
Equity in loss of an affiliate[(1)]	—	—	—	(108,587)	(16,642)
Fair value change of warrants	(14,027)	61,405	5,644	—	—
Income (loss) before income tax expense	(298,240)	(401,111)	(1,451,950)	483,146	74,044
Income tax expense	—	(1,722)	—	(12,231)	(1,874)
Net income (loss) attributable to I-Mab	(298,240)	(402,833)	(1,451,950)	470,915	72,170
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	—	—	(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)	—	—
Net income (loss) attributable to ordinary shareholders	(298,240)	(402,833)	(1,485,001)	470,915	72,170
Other comprehensive income (loss)					
Foreign currency translation adjustments, net of nil tax	5,918	53,689	10,747	(120,920)	(18,531)
Total comprehensive income (loss) attributable to I-Mab	(292,322)	(349,144)	(1,441,203)	349,995	53,639
Net income (loss) attributable to ordinary share-holders	**(298,240)**	**(402,833)**	**(1,485,001)**	**470,915**	**72,170**

Weighted-average number of ordinary shares used in calculating net income (loss) per share					
Basic	5,742,669	6,529,092	7,381,230	134,158,824	134,158,824
Diluted	5,742,669	6,529,092	7,381,230	157,231,652	157,231,652
Net income (loss) per share attributable to ordinary shareholders					
Basic	(51.93)	(61.70)	(201.19)	3.51	0.54
Diluted	(51.93)	(61.70)	(201.19)	3.00	0.46
Net income (loss) per ADS attributable to ordinary shareholders					
Basic	(119.44)	(141.91)	(462.74)	8.07	1.24
Diluted	(119.44)	(141.91)	(462.74)	6.90	1.06

Note:

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

	For the Year Ended December 31,				
	2017	2018	2019	2020	
	RMB	RMB	RMB	RMB	US$
	(in thousands)				
Research and development expenses	2,112	1,056	470	284,431	43,591
Administrative expenses	4,927	2,464	514,733	209,033	32,036
Equity in loss of an affiliate	—	—	—	32,707	5,013
Total	**7,039**	**3,520**	**515,203**	**526,171**	**80,640**

The following table presents our selected consolidated statements of balance sheet data as of December 31, 2017, 2018, 2019 and 2020:

	As of December 31,				
	2017	2018	2019	2020	
	RMB	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	4,758,778	729,315
Restricted cash	104,783	92,653	55,810	—	—
Accounts receivable	—	—	—	130,498	20,000
Contract assets	—	11,000	—	227,391	34,849
Short-term investments	—	—	32,000	31,530	4,832
Prepayments and other receivables	12,633	88,972	136,036	195,467	29,957
Other financial assets	266,245	255,958	—	—	—
Total current assets	691,591	2,036,861	1,361,319	5,343,664	818,953
Property, equipment and software	22,336	27,659	30,069	25,272	3,873
Operating lease right-of-use assets	—	—	16,435	14,997	2,298
Intangible assets	148,844	148,844	148,844	120,444	18,459
Goodwill	162,574	162,574	162,574	162,574	24,916
Investment accounted for using the equity method	—	—	—	664,832	101,890
Other non-current assets	—	—	18,331	2,010	308
Total assets	**1,025,345**	**2,375,938**	**1,737,572**	**6,333,793**	**970,697**
Total liabilities	**309,151**	**415,684**	**668,090**	**706,648**	**108,298**
Total mezzanine equity	**1,015,989**	**2,915,358**	**3,104,177**	**—**	**—**
Shareholders' deficit					
Ordinary shares (US$0.0001 par value, 500,000,000 shares authorized as of December 31, 2019 and 800,000,000 shares authorized as of December 31, 2020, respectively; 8,363,719 shares issued and outstanding as of December 31, 2019 and 164,888,519 shares issued and outstanding as of December 31, 2020, respectively)	6	6	6	114	17
Treasury stock	(1)	(1)	—	—	—
Additional paid-in capital	52,369	—	389,379	7,701,116	1,180,249
Accumulated other comprehensive income (loss)	5,691	59,380	70,127	(50,793)	(7,784)
Accumulated deficit	(357,860)	(1,014,489)	(2,494,207)	(2,023,292)	(310,083)
Total shareholders' equity/(deficit)	**(299,795)**	**(955,104)**	**(2,034,695)**	**5,627,145**	**862,399**
Total liabilities, mezzanine equity and shareholders' equity/(deficit)	**1,025,345**	**2,375,938**	**1,737,572**	**6,333,793**	**970,697**

The following table presents our selected consolidated statements of cash flow data for the years ended December 31, 2017, 2018, 2019 and 2020:

	For the Year Ended December 31,				
	2017	2018	2019	2020	
		RMB	RMB	RMB	US$
			(in thousands)		
Selected Consolidated Statements of Cash Flow Data:					
Net cash (used in) generated from operating activities	(252,157)	(280,705)	(867,982)	433,558	66,446
Net cash (used in) generated from investing activities	(157,665)	9,500	212,462	(201,901)	(30,943)
Net cash generated from financing activities	758,585	1,479,669	152,709	3,440,481	527,277
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(132)	59,754	15,163	(106,643)	(16,344)
Net increase (decrease) in cash, cash equivalents and restricted cash	348,631	1,268,218	(487,648)	3,565,495	546,436
Cash, cash equivalents and restricted cash, beginning of the year	64,082	412,713	1,680,931	1,193,283	182,879
Cash, cash equivalents and restricted cash, end of the year	412,713	1,680,931	1,193,283	4,758,778	729,315

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 the past and we may not be able to maintain profitability in the future.

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 had incurred net losses of RMB402.8 million and RMB1,452.0 million in 2018 and 2019, respectively, and had net income of RMB470.9 million (US$72.2 million) in 2020. 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 cannot assure you that we will be able to continue to generate net profits in the future. Our ability to achieve and maintain profitability depends in large part on our ability to out-license some of our commercialization rights and execute our product commercialization strategies as our business further grows in scale. Accordingly, we intend to continue to invest for the foreseeable future in 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 continue to 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 in the past. 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 RMB280.7 million and RMB868.0 million in net cash to finance our operations in 2018 and 2019, respectively, and generated RMB433.6 million (US$66.4 million) in net cash from our operations in 2020.

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.

COVID-19 has spread globally and the World Health Organization (WHO) has declared it a pandemic. While still evolving, the COVID-19 pandemic 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, our initial public offering and private placement, 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 annual report, we have obtained IND approvals from the NMPA for eight of our drug candidates, felzartamab, olamkicept, efineptakin alfa, lemzoparlimab, uliledlimab, plonmarlimab, eftansomatropin alfa and TJ210. In addition, we have obtained IND approvals from the FDA for six of our drug candidates, lemzoparlimab, uliledlimab, plonmarlimab, TJ210, TJ-L14B and TJ-CD4B; from the Taiwan Food and Drug Administration (the "TFDA") for two of our drug candidates, felzartamab and olamkicept; and from the Korea Ministry of Food and Drug Safety (the "MFDS") for olamkicept. 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 olamkicept in South Korea and Greater China, for efineptakin alfa and eftansomatropin alfa in China, for felzartamab in Greater China, for TJ210 in the United States, for lemzoparlimab, plonmarlimab and uliledlimab in China and the United States.

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 this annual report, we have obtained IND approvals from the NMPA for eight of our drug candidates, felzartamab, olamkicept, efineptakin alfa, lemzoparlimab, ulilediimab, plonmarlimab, eftansomatropin alfa and TJ210. In addition, we have obtained IND approvals from the FDA for six of our drug candidates, lemzoparlimab, ulilediimab, plonmarlimab, TJ210, TJ-L14B and TJ-CD4B; from the TFDA for two of our drug candidates, felzartamab and olamkicept; and from the MFDS for olamkicept. 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 this annual report, we have no existing manufacturing infrastructure or capabilities. We intend to build a comprehensive biologics manufacturing facility in Hangzhou, China (the “Hangzhou Facility”) as part of our strategic plan to become a fully integrated biopharma company. We have taken concrete steps to execute this plan. These steps include detailed operational planning for the facility, actions taken to secure an appropriate site, and negotiations with external financing providers. The Hangzhou Facility targets to have a pilot capacity of 2 production lines (1 line configured with 2 x 2,000L and another line with 1 x 2,000L) by 2022 and commercially progressive capacity up to 8 x 4,000L to begin operation by the end of 2023. Construction is expected to commence in April 2021 and ready for use by the end of 2023. However, the investment for building this new biologics manufacturing facility that is compliant with cGMP regulations will 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 felzartamab in Greater China. Another example is our collaboration with AbbVie. In September 2020, we granted AbbVie a global license, excluding Mainland China, Hong Kong and Macau, to develop and commercialize lemzoparlimab (as well as certain other compounds directed against CD47), and we will retain all rights to develop and commercialize lemzoparlimab in Mainland China, Hong Kong and Macau.

The effectiveness of the contract with AbbVie is subject to our performance of certain contractual obligations and regulatory approval; such approval may not be obtained or may be delayed, which could result in a detrimental effect on our collaboration. For a more detailed discussion, please see "Item 4. Information on the Company—B. Business—Our Global Strategic Collaborations—Global Strategic Partnership with AbbVie." 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, 2020, our owned patent portfolio consists of 22 issued patents and 241 patent applications primarily in connection with the drug candidates in our Global Portfolio, including 18 Patent Cooperation Treaty ("PCT") patent applications, 18 U.S. patent applications, 16 PRC patent applications and 211 patent applications in other jurisdictions. In addition, as of December 31, 2020, we in-licensed the Greater China and Korea rights relating to 24 issued patents and 31 pending patent applications primarily in connection with felzartamab, eftansomatropin alfa, olamkicept, enoblituzumab and efineptakin alfa. 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 do 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.

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, administrative fines and criminal liabilities. 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 year 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.

Our business, financial condition and results of operations could be adversely affected by the COVID-19 pandemic. The global pandemic of COVID-19, the disease caused by a novel strain of coronavirus, has created significant business disruption which could materially and adversely affect our business and operations. The pandemic has resulted in governments implementing numerous measures to contain COVID-19, such as travel bans and restrictions, quarantines, shelter-in-place, temporary shutdown of factories, business limitations, or total lock-down orders. These containment measures are subject to change and may be further tightened. This pandemic has led to temporary closure of our offices in the first quarter of 2020, causing cancellation of physical participation in meetings, restrictions on employee travels, and a significant portion of our employees working from home, which resulted in lower work efficiency and productivity, and the disruption to our business operations and clinical trials.

The pandemic of COVID-19 and the resulting government measures may materially and adversely impact our planned and ongoing clinical trials and development. Clinical site initiation, including recruiting clinical site investigators and clinical site staff, and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. The diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators and hospitals serving as our clinical trial sites, or other staff supporting the conduct of our clinical trials may significantly disrupt our research activities. Hospitals have also had reduced patient flow in general during the pandemic period. As a result, the expected timeline for data readouts of our clinical trials and potential submission and filings will likely be negatively impacted, which would adversely affect and delay our ability to obtain certain regulatory approvals, increase our operating expenses and have a material adverse effect on our financial condition. Furthermore, we could face the interruption of key clinical activities such as trial site data monitoring, which may impact the integrity of clinical data. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may be impeded, which would also materially and adversely impact our clinical trial operations. As a result of disruptions caused by the COVID-19 pandemic, we may require additional capital to continue our research activities, which we may be unable to secure on favorable terms, if at all. In addition, we believe that our business partners, such as our licensing partners, CROs, CMOs or suppliers, have also experienced and may continue to experience similar or more severe disruptions to their business operations. Any disruption to the business operations of us and our business partners could materially and adversely affect the development of our drug candidates, our business, financial condition and results of operations. 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 “Risk Factors” section. See also “Item 5. Operating and Financial Review and Prospects—A. Operating Results—Impact of the COVID-19 Pandemic” for a detailed description of the impact of the COVID-19 pandemic on our business.

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 pandemic has also resulted in temporary closure of many corporate offices, retail stores, manufacturing facilities and factories. 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 pandemic 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 pandemic, 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 pandemic, including new information concerning the global severity of and actions taken to contain the pandemic, 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 pandemic 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.

If we fail to implement and maintain an effective system of internal controls over financial reporting, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud.

We are a public company in the United States subject to the Sarbanes-Oxley Act of 2002. Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we include a report of management on our internal control over financial reporting in our annual report on Form 20-F. 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, as 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. Our management, with the participation of our chief executive officer and principal financial officer, evaluated the effectiveness of our internal control over financial reporting and concluded that our internal control over financial reporting was effective as of December 31, 2020. See also “Item 15. Controls and Procedures” for a detailed description of management’s report on internal control over financial reporting and remediation of the material weaknesses in internal control over financial reporting reported in 2019.

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 ADSs may be delisted under the Holding Foreign Companies Accountable Act if the PCAOB is unable to inspect auditors who are located in China. The delisting of our ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment. Additionally, the inability of the PCAOB to conduct inspections deprives our investors with the benefits of such inspections.

The Holding Foreign Companies Accountable Act, or the HFCA Act, was enacted on December 18, 2020. The HFCA Act states if the SEC determines that we have filed audit reports issued by a registered public accounting firm that has not been subject to inspection by the PCAOB for three consecutive years beginning in 2021, the SEC shall prohibit our shares or ADSs from being traded on a national securities exchange or in the over the counter trading market in the U.S.

Our auditor, the independent registered public accounting firm that issues the audit report included elsewhere in this annual report as an auditor of companies that are traded publicly in the United States and a firm registered with the PCAOB, is subject to laws in the United States pursuant to which the PCAOB conducts regular inspections to assess its compliance with the applicable professional standards. Since our auditor is located in China, a jurisdiction where the PCAOB has been unable to conduct inspections without the approval of the Chinese authorities, our auditor is currently not inspected by the PCAOB.

On March 24, 2021, the SEC adopted interim final rules relating to the implementation of certain disclosure and documentation requirements of the HFCA Act. We will be required to comply with these rules if the SEC identifies us as having a “non-inspection” year under a process to be subsequently established by the SEC. The SEC is assessing how to implement other requirements of the HFCA Act, including the listing and trading prohibition requirements described above.

The SEC may propose additional rules or guidance that could impact us if our auditor is not subject to PCAOB inspection. For example, on August 6, 2020, the President’s Working Group on Financial Markets, or the PWG, issued the *Report on Protecting United States Investors from Significant Risks from Chinese Companies* to the then President of the United States. This report recommended the SEC implement five recommendations to address companies from jurisdictions that do not provide the PCAOB with sufficient access to fulfil its statutory mandate. Some of the concepts of these recommendations were implemented with the enactment of the HFCA Act. However, some of the recommendations were more stringent than the HFCA Act. For example, if a company was not subject to PCAOB inspection, the report recommended that the transition period before a company would be delisted would end on January 1, 2022.

The SEC has announced that the SEC staff is preparing a consolidated proposal for the rules regarding the implementation of the HFCA Act and to address the recommendations in the PWG report. It is unclear when the SEC will complete its rulemaking and when such rules will become effective and what, if any, of the PWG recommendations will be adopted. The implications of this possible regulation in addition the requirements of the HFCA Act are uncertain. Such uncertainty could cause the market price of our ADSs to be materially and adversely affected, and our securities could be delisted or prohibited from being traded “over-the-counter” earlier than would be required by the HFCA Act. If our securities are unable to be listed on another securities exchange by then, such a delisting would substantially impair your ability to sell or purchase our ADSs when you wish to do so, and the risk and uncertainty associated with a potential delisting would have a negative impact on the price of our ADSs.

The PCAOB’s inability to conduct inspections in China prevents it from fully evaluating the 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 the 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.

In May 2013, the 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 the PCAOB in the PRC or by the CSRC or the PRC Ministry of Finance in the United States. The PCAOB continues to be in discussions with the CSRC and the PRC Ministry of Finance to permit joint inspections in the PRC of audit firms that are registered with the PCAOB and audit Chinese companies that trade on U.S. exchanges.

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 a publicly-listed company, 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. Any regulatory inquiries or investigations or other actions against our 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, 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.

It may be difficult for overseas regulators to conduct investigation or collect evidence within China.

Shareholder claims or regulatory investigation that are common in the United States generally are difficult to pursue as a matter of law or practicality in China. For example, in China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigations initiated outside China. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such cooperation with the securities regulatory authorities in the Unities States may not be efficient in the absence of mutual and practical cooperation mechanism. Furthermore, according to Article 177 of the PRC Securities Law, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the PRC territory. While detailed interpretation of or implementation rules under Article 177 have yet to be promulgated, the inability for an overseas securities regulator to directly conduct investigation or evidence collection activities within China may further increase the difficulties you face in protecting your interests. See also "—Risks Related to Our ADSs— 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." for risks associated with investing in us as a Cayman Islands company.

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 international trade policies and rising political tensions, particularly between the U.S. and 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. While the "Phase One" agreement was signed between the United States and China on trade matters, it remains unclear what additional actions, if any, will be taken by the U.S. or other governments with respect to international trade, tax policy related to international commerce, or other trade matters. The situation is further complicated by the political tensions between the United States and China that escalated during the COVID-19 pandemic and in the wake of the PRC National People's Congress' decision on Hong Kong national security legislation, sanctions imposed by the U.S. Department of Treasury on certain officials of the Hong Kong Special Administrative Region and the central government of the PRC and the executive orders issued by the then U.S. President in August 2020 that prohibit certain transactions with certain China-based companies and their respective subsidiaries. Rising trade and political tensions could reduce levels of trades, investments, technological exchanges and other economic activities between China and other countries, which would have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies.

While we have not started commercialization of drug candidates, any rising trade and political tensions or 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. In particular, if any new tariffs, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, especially, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade and political tension, such changes could have an adverse effect on our business, financial condition and results of operations. In addition, our results of operations could be adversely affected if any such tensions or unfavorable government trade policies harm the Chinese economy or the global economy in general.

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"), the 2019 Share Incentive Plan (the "2019 Plan") and the 2020 Share Incentive Plan (the "2020 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 28, 2021, the awards that had been granted to our directors, officers, employees and consultants and remained outstanding included (i) options to purchase an aggregate of 7,115,955 ordinary shares, 9,948,512 ordinary shares, 72,000 ordinary shares and 1,052,025 ordinary shares under the 2017 Plan, the 2018 Plan, the 2019 Plan and the 2020 Plan, respectively, excluding options that were forfeited, cancelled, or exercised after the relevant grant date; and (ii) restricted share units to receive an aggregate of 5,106,141 ordinary shares under the 2020 Plan, excluding restricted share units that were forfeited, cancelled, or vested after the relevant grant date. See "Item 6. Directors, Senior Management and Employees—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 foreign-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.

General 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$65.94 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;
- any share repurchase program;
- 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.

We cannot guarantee that any share repurchase program will be fully consummated or that any share repurchase program will enhance long-term shareholder value, and share repurchases could increase the volatility of the price of our ADSs and could diminish our cash reserves.

On July 15, 2020, we announced that our board of directors has authorized a share repurchase program, pursuant to which we were authorized to repurchase our own ordinary shares, in the form of ADSs, with an aggregate value of up to US$20.0 million during a twelve-month period effective upon and from the date on which a formal stock repurchase plan engagement agreement is signed with a qualified broker-dealer(s). From July 15, 2020 to the date of this annual report, we did not repurchase any ADSs. Our share repurchase program could affect the price of our ADSs and increase volatility and may be suspended or terminated at any time.

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 substantial amounts of our ADSs in the public market, or the perception that these sales could occur, could adversely affect the market price of our ADSs and could materially impair our ability to raise capital through equity offerings in the future. As of March 31, 2021, we had 166,532,087 ordinary shares issued and outstanding (excluding 2,982,401 ordinary shares issued to our depositary bank for bulk issuance of ADSs reserved for future issuances upon the exercising or vesting of awards granted under our share incentive plans). Among these shares, 73,412,688 ordinary shares are in the form of ADSs (including 2,982,401 ordinary shares issued to our depositary bank for bulk issuance of ADSs reserved for future issuances upon the exercising or vesting of awards granted under our share incentive plans), which are freely transferable without restriction or additional registration under the Securities Act. On December 14, 2020, the SEC declared effective a registration statement on Form F-1, under which the selling shareholders identified therein may offer, from time to time, up to 25,123,751 ordinary shares, including ordinary shares represented by ADSs of our company. On March 23, 2021, the SEC declared effective a post-effective amendment to this registration statement on Form F-1 that terminates the effectiveness of this registration statement and removes from registration all securities registered but not sold under this registration statement. On March 19, 2021, we filed a prospectus supplement as part of a registration statement on Form F-3 (Registration No. 333-252793), under which the selling shareholders identified therein may offer, from time to time, up to 19,050,555 ordinary shares, including ordinary shares represented by ADSs of our company. Remaining ordinary shares issued and outstanding will be available for sale in the public market 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. 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, or sales of securities held by our significant shareholders or any other shareholder or the availability of these securities for future sale could cause the price of our ADSs to 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 Act, Cap. 22 (Act 3 of 1961, as consolidated and revised) of the Cayman Islands (the "Companies Act"), which we refer to as the Companies Act, 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.

We retain broad discretion in the use of the net proceeds from our initial public offering.

We retain broad discretion in the application of the net proceeds from our initial public offering and could spend the proceeds in ways that do not produce income or increase our ADS price. We have not determined a specific use for a portion of the net proceeds of our initial public offering, and our management will have considerable discretion in deciding how to apply these proceeds. You will not have the opportunity to assess whether the net proceeds from our initial public offering are being used appropriately. You must rely on the judgment of our management regarding the application of the net proceeds of our initial public offering. We cannot assure you that the net proceeds from our initial public offering will be used in a manner that would improve our results of operations or increase our ADS price, nor that these net proceeds will be placed only in investments that generate income or appreciate in value.

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 are 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 Act 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. We follow home country practice with respect to adoption of the 2020 Plan. 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 classified as 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 value of our assets (generally determined on the basis of quarterly average) during such year produce or are held for the production of passive income. We do not believe that we were a PFIC for the taxable year ended December 31, 2020. Although we do not believe we were a PFIC for the taxable year ended December 31, 2020, no assurance can be given with respect to our PFIC status 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. Furthermore, prior to the commercialization of any of our drug candidates, interest and other passive income could constitute more than 75% of gross income for any taxable year. 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.

If we are a PFIC in any taxable year, a U.S. Holder (as defined in "Item 10. Additional Information—E. 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 ceased 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 to 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 established 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 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.

In 2020, we have taken concrete steps to execute our plan to build a comprehensive biologics manufacturing facility in Hangzhou, China (the "Hangzhou Facility") as part of our strategic plan to become a fully integrated biopharma company. The Hangzhou Facility targets to have a pilot capacity of 2 production lines (1 line configured with 2 x 2,000L and another line with 1 x 2,000L) by 2022 and commercially progressive capacity up to 8 x 4,000L to begin operation by the end of 2023. Construction is expected to commence in April 2021 and ready for use by the end of 2023. The project will be financed by a combination of internal and external sources. A group of domestic investors in China have agreed to invest a total of US$120 million (in RMB equivalent) in cash. Upon closing, we, through our wholly owned subsidiary and parties acting in concert, will remain the majority shareholder of I-Mab Biopharma (Hangzhou) Limited ("I-Mab Hangzhou"), the entity holding the Hangzhou Facility, and retain a managing role and take full control to build and operate the manufacturing facility.

In September 2020, we, through I-Mab Biopharma Co., Ltd. and I-Mab Biopharma US Limited, each a wholly-owned subsidiary of our company, entered into a broad global collaboration with AbbVie Ireland Unlimited Company ("AbbVie"), a leading global, research-based biopharmaceutical company. Pursuant to this collaboration, we grant AbbVie a global license, excluding Mainland China, Hong Kong and Macau, to develop and commercialize lemzoparlimab. We retain the rights to develop and commercialize lemzoparlimab (as well as certain other compounds directed against CD47) in Mainland China, Hong Kong and Macau. AbbVie will conduct further global clinical trials (which we may elect to co-fund) to evaluate lemzoparlimab in multiple cancers. This deal also allows for potential collaboration on future CD47-related therapeutic agents, including CD47-based bispecific antibodies and combination therapies with lemzoparlimab and AbbVie's venetoclax (Venclexta®). Each party will have the opportunity, subject to rights of first negotiation to further licenses, to explore certain of each other's related CD47-antibody programs in their respective territories. In addition, we and AbbVie will share manufacturing responsibilities, with AbbVie being the primary manufacturer for supply outside of Mainland China, Hong Kong and Macau and us being the primary manufacturer for supply in Mainland China, Hong Kong and Macau. We believe that this collaboration will accelerate the establishment of our commercial production operations in China. Pursuant to this collaboration, AbbVie has paid us an upfront payment of US$180 million and milestone payment of US$20 million. We will also be eligible to receive up to US$1.74 billion in further success-based development, regulatory and sales milestone payments for lemzoparlimab, of which US$840 million are based on clinical development and regulatory approval milestones, with the remainder based on commercial milestones. Upon commercialization of lemzoparlimab, AbbVie will also pay tiered royalties from low-to-mid teen percentages on global net sales outside of Mainland China, Hong Kong and Macau. In addition, AbbVie has a license and right of first negotiation to further develop and commercialize two additional lemzoparlimab-based bispecific antibodies discovered and currently being developed by us and we cannot commercialize products containing these two additional lemzoparlimab-based bispecific antibodies outside of Mainland China, Hong Kong and Macau even if AbbVie does not exercise its right of first negotiation or we are unable to come to financial terms on such products. The potential value of each such license is minimum US$500 million in upfront and milestone payments, for a combined total of no less than US$1 billion.

In September 2020, we entered into definitive subscription agreements (collectively, the "Subscription Agreements," and each, a "Subscription Agreement") with a consortium of institutional investors, pursuant to which we agree to issue and sell to these investors (i) a total of 29,133,502 ordinary shares of our company for an aggregate purchase price of approximately US$418 million (equivalent to a price of US$33 per ADS); and (ii) warrants (the "Investor Warrants") to subscribe for up to 5,341,267 ordinary shares of our company at an exercise price of US$45 per ADS, subject to the closing conditions set forth in the Subscription Agreements. On September 11, 2020, we issued 20,421,378 ordinary shares to these investors pursuant to the Subscription Agreements. The Subscription Agreement with the Hillhouse Entities contemplates two closings. The first closing occurred in September 2020 and the second closing occurred in December 2020. The closings of the Subscription Agreements with investors other than the Hillhouse Entities have occurred in September 2020.

On December 14, 2020, the SEC declared effective a registration statement on Form F-1, under which the selling shareholders identified therein may offer, from time to time, up to 25,123,751 ordinary shares, including ordinary shares represented by ADSs of our company. On March 23, 2021, the SEC declared effective a post-effective amendment to this registration statement on Form F-1 that terminates the effectiveness of this registration statement and removes from registration all securities registered but not sold under this registration statement. On March 19, 2021, we filed a prospectus supplement as part of a registration statement on Form F-3 (Registration No. 333-252793), under which the selling shareholders identified therein may offer, from time to time, up to 19,050,555 ordinary shares, including ordinary shares represented by ADSs of our company. We will not receive any of the proceeds from the sale of the ordinary shares or ADSs by the selling shareholders under this registration statement.

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

Executive Summary

Our company has made tremendous progress on multiple fronts since our initial public offering in January 2020. The major progress is highlighted in the three areas of significant business value as summarized below.

Firstly, we have made remarkable progress in rapidly advancing our innovative pipeline and achieved a series of critical clinical milestones. Since IPO in January 2020, we have achieved nineteen significant clinical milestones. As a result, our pipeline today has progressed to include three registrational trials with the first NDA planned in 2021 and more than ten Phase 1 and 2 clinical programs in both the U.S. and China. In particular, critical advancements have been made with the core assets of near-term value realization, which include two late-stage assets, i.e. felzartamab and eftansomatropin alfa, that are progressing towards NDA and two representative homegrown clinical assets, i.e. lemzoparlimab and ulilediimab, that are now among the global front-runners. Our internally developed assets of the global portfolio have begun to demonstrate their innovative potential and value through the U.S.-initiated clinical trials. We have set our goals to deliver a new series of key clinical milestones in 2021 to transform the pipeline in its readiness for near-term product launches in China as well as its validated clinical differentiation as exemplified by lemzoparlimab.

- **Late-stage assets advancing towards NDA**. Both felzartamab and eftansomatropin alfa are in registrational clinical trials with NDA planned for felzartamab in 2021 and for eftansomatropin alfa in 2023. Both plonmarlimab and efineptakin alfa are now in Phase 2/3 clinical trials in the U.S. or China, respectively. Additional Phase 2 studies are expected in 2021.
- **Clinical validation and global partnership of internally developed innovative assets**. Since our IPO in 2020, we have made critical progress on the two core clinical assets developed internally, i.e. lemzoparlimab and ulilediimab, and demonstrated drug safety, clinical activity or clinical differentiation in clinical trials in the U.S. In particular, we will accelerate our clinical development plan for lemzoparlimab to achieve an early product registration in China and globally in collaboration with AbbVie. Our new monoclonal antibody TJ210 in collaboration with MorphoSys is now being evaluated in a Phase 1 clinical trial in the U.S.

- **Bi-specific antibody panel moving to clinical trial**. Our novel bi-specific antibodies are now progressing towards clinical trials in the U.S. Our two lead assets, TJ-L14B and TJ-CD4B, have been granted IND approval by the U.S. FDA to start clinical development. Other bi-specific antibodies, including TJ-C4GM and TJ-L1C4, are being developed to enable IND.

Secondly, revolving around our globally competitive and rapidly progressing pipeline, we forged a string of collaborations in 2020. Our global partnership with AbbVie on lemzoparlimab represents the largest biotech out-licensing deal from China. These global and regional deals have started to not only generate a significant revenue stream for the Company but also provide timely validation for our innovative assets that are being evaluated in clinical trials. Moving forward, we will continue to explore global partnership opportunities through an out-licensing approach as part of the strategy for our global portfolio and an in-licensing approach as part of the strategy to selectively enrich our China portfolio. Our ongoing business development activities are focused on creating value in the following three specific areas:

- **Landmark global partnerships with industry leaders.** Our strategy for the global portfolio is to partner with global pharmaceutical companies for the global rights (excluding China) upon clinical validation. This approach is best demonstrated by our global partnership with AbbVie on lemzoparlimab (also known as TJC4). In September 2020, we entered into a broad global strategic collaboration with AbbVie for the development and commercialization of lemzoparlimab. This deal is valued at US$1.94 billion and was the largest cross-border out-licensing deal from China. We will continue to seek similar partnership opportunities with global pharma companies for other innovative assets of the global portfolio that are either novel or highly differentiated.
- **Selective in-licensing opportunities to enrich our emerging product portfolio**. In-licensing of innovative late-stage assets or globally marketed products remains a part of our pipeline strategy going forward and will become more selective as our pipeline grows and advances. The in-licensing approach aims to fill specific gaps in our rapidly growing pipeline towards commercialization. In addition, we set forth to seek in-licensing of specific clinical assets as combination partners for our selected clinical assets in development for better treatment efficacy.

- **New wave of novel drug molecules to sustain our pipeline through partnerships**. We have been engaging in active negotiations with global and regional biotech companies with transformational technology platforms, such as mRNA technology, cell-penetrating antibody technology and tumor-focused delivery technology. We strive to build a new wave of novel drug molecules created through a combination of our proprietary antibody sequences with our partners' transformational technologies. In March 2021, we entered into two new collaborations with Complix, an EU-based biotech company, and Affinity, a Shanghai-based biotech company, respectively, allowing us to access cutting edge technology platforms to create next generation novel and highly differentiated drug candidates, including Cell Penetrating Alphabodies (CPAB) for otherwise intractable intra-cellular drug targets and masked antibodies for targeted tumor-site activation, respectively. These new/third-wave of novel drug molecules will complement our existing clinical programs and sustain our leading position in immuno-oncology with a globally competitive pipeline that has evolved in the past, through the first-wave comprised of highly differentiated monoclonal antibodies such as TJC4, TJD5, TJM2 and TJ210 and the second-wave of innovative bi-specific antibodies such as TJ-CD4B and TJ-L14B.

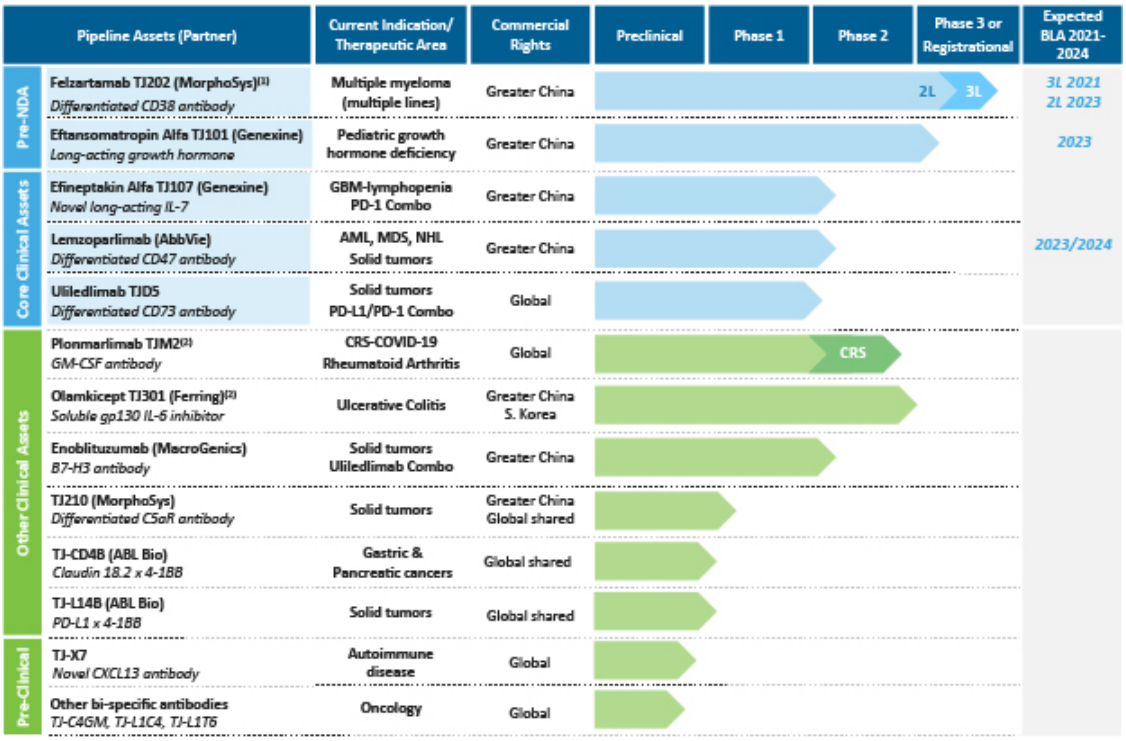
Thirdly, we have embarked on a transforming journey and moving from currently a clinical stage biotech to a fully integrated biopharma within the next 3 to 4 years, following our successful listing and subsequent capital market performance. This progress is being accelerated by our strong progress in our pipeline development towards NDA. To this goal, we have been expanding our global R&D and corporate footprint, connecting five hubs in China (Shanghai, Beijing and Hong Kong) and the U.S. (Maryland and San Diego). More importantly, we have begun to construct our manufacturing facility in Hangzhou, China and build our commercialization capability under the leadership of Mr. Ivan Yifei Zhu, our Chief Commercial Officer, who will drive upcoming product launches, starting in 2022.

- **Expanded global R&D and corporate footprint**. Since our IPO in 2020, we have taken steps to expand our geographic reach and R&D footprint to accelerate our transformation to a fully integrated global biopharma company. We opened our Hong Kong office as a regional hub for capital markets and investor relations activities, further benefiting from the Greater Bay Area economic development initiative in the region. We are in the process of establishing a new R&D facility in San Diego, CA, in the U.S. for translational medicine and biomarker research, CMC formulation and global alliance management. These new sites are designed to complement our existing facilities in Shanghai, Beijing and Gaithersburg, MD, by leveraging geographic advantages to enhance our development capability and efficiency.
- **Manufacturing facility**. Since our IPO in 2020, we have taken concrete steps to execute our plan to build a comprehensive biologics manufacturing facility in Hangzhou, China (the "Hangzhou Facility"). The Hangzhou Facility aims to have a pilot capacity of 2 production lines (1 line configured with 2 x 2,000L and another line with 1 x 2,000L) by 2022 and commercially progressive capacity up to 8 x 4,000L to become operational by the end of 2023. The project has been financed by a combination of internal and external sources. A group of domestic investors in China committed to investing a total of US$120 million (in RMB equivalent) in cash. Upon closing, we, through our wholly owned subsidiary and parties acting in concert, will remain the majority shareholder of I-Mab Biopharma (Hangzhou) Limited ("I-Mab Hangzhou"), the entity holding the Hangzhou Facility. We will retain a managing role and take full control of building and operating the manufacturing facility. This manufacturing facility, when operational, will secure our CMC and manufacturing needs for all clinical trials in the U.S. and China as well as the sustained production of our commercial products in a well-controlled and highly cost-effective manner.
- **Commercialization strategy and capability**. In August 2020, we appointed Mr. Ivan Yifei Zhu as our Chief Commercial Officer, to prepare for market launch of our initial series of products in China. Our commercialization strategy is aimed at securing a leading position in the hematologic oncology therapeutic area in China, as we begin the launch of felzartamab (TJ202) for multiple myeloma, lemzoparlimab (TJC4) for various leukemia indications and a late-stage asset/product to be in-licensed for lymphoma indications. With this product portfolio focused on hematologic oncology, we will be uniquely positioned to offer a near-complete therapeutic coverage of the major hematologic oncology indications, i.e. myeloma, leukemia and lymphoma, while working towards achieving a near-cure therapeutic goal through combination with other internal or in-licensed products with proven advantages in treatment efficacy. Our commercialization strategy and plans take consideration of the accessibility of our products by building alliances with the stakeholders on the value chain, the affordability by cooperating with government authorities, charity organizations, insurance companies and the availability by educating doctors, pharmacists and patients.

Our Drug Pipeline

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 biopharmaceutical 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 15 clinical and pre-clinical stage assets through our internal research and development efforts as well as in-licensing arrangements with global pharmaceutical and biotech companies.

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



Notes:

(1) Felzartamab (TJ202) has two ongoing registrational trials, a monotherapy trial (3L) and a combination therapy trial (2L) in relapsed or refractory multiple myeloma in Greater China.

(2) Plonmarlimab (TJM2, excluding cytokine release syndrome indications) and Olamkicept (TJ301) are managed by I-Mab Biopharma (Hangzhou) Limited.

Pre-NDA Assets

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

Summary

Felzartamab is a fully human, highly differentiated monoclonal antibody directed against CD38. In November 2017, we obtained an exclusive license from MorphoSys to develop felzartamab in Greater China. The development of felzartamab is driven by a fast-to-market strategy. Felzartamab, if approved, is positioned as a potential highly differentiated CD38 antibody therapy for multiple myeloma ("MM"), either as a monotherapy or as a combination therapy with other anti-cancer agents. It also has great potentials for other indications than MM, such as autoimmune diseases.

We aim to demonstrate the advantages of felzartamab, including its short infusion time, low infusion related reaction ("IRR"), in addition to its comparable treatment efficacy, in our ongoing clinical trials in China for an NDA approval. We are conducting two parallel registrational trials with felzartamab as a third-line (3L) monotherapy and as a second-line (2L) combination therapy with lenalidomide, both in patients with multiple myeloma in Greater China. Completion of patient enrollment of the 2L registrational study for MM is anticipated in Q3 2021. We expect to submit an NDA for felzartamab as a 3L monotherapy for MM to the NMPA in Q4 2021.

In addition, a new IND application with pre-clinical data and trial design for combination therapy of felzartamab with lemzoparlimab as a potential first-line (1L) treatment for MM will be submitted in Q2 2021 and the study is expected to be initiated in the second half of 2021. Pre-clinical studies conducted by us and reported by others suggest that felzartamab may work with lemzoparlimab to achieve potentially better efficacy.

Furthermore, as pathogenic CD38-positive B cells and plasma cells are strongly implicated in the pathogenesis and disease progression of antibody-mediated autoimmune diseases, such as systemic lupus erythematosus ("SLE"), we and MorphoSys have been working together to explore the potential therapeutic role of felzartamab in selected antibody-mediated autoimmune indications, e.g. SLE by I-Mab and autoimmune kidney disease by MorphoSys. We previously submitted an IND application to the NMPA and expect to initiate a Phase 1b trial in patients with SLE in the second half of 2021.

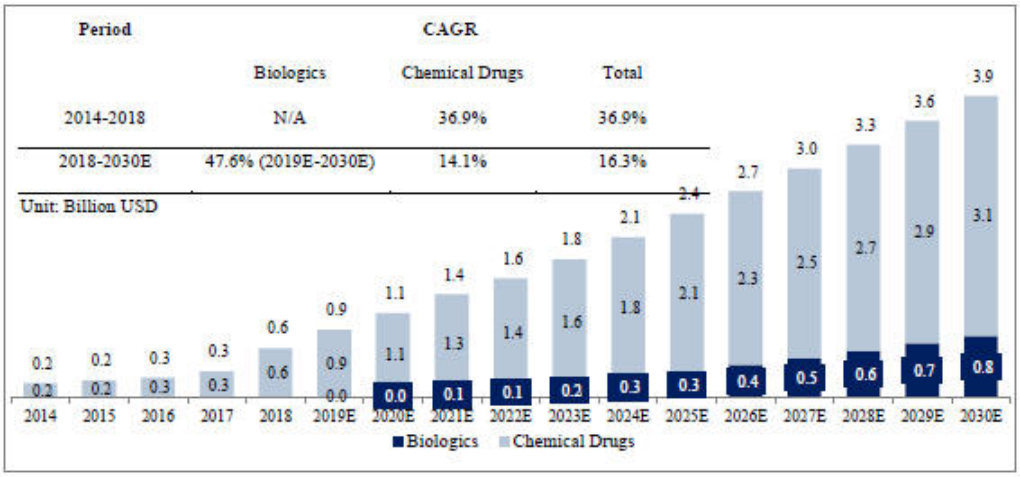
Multiple Myeloma Drug Market and Competitive Landscape

Multiple myeloma ("MM") is a type of blood cancer that starts in the bone marrow and is characterized by the excessive proliferation of malignant plasma cells that accumulate in the bone marrow, where they displace and suppress healthy blood progenitor cell populations. The prognosis factors for MM include host factors, tumor characteristics and response to treatment. There is a consensus that disease prognosis in MM is significantly impacted by treatment response and micro-residual disease ("MRD") level.

In China, MM is the second most common hematologic malignancy, accounting for approximately 10% of the malignant tumors in the blood system. MM is primarily a disease of the elderly. The incidence rate of MM in China is about 1.5 per 100,000 in 2020 and is increasing year by year due to the rapidly growing 65-year or older population. According to a report by Frost & Sullivan, new cases of MM reached approximately 21,770 in 2020 and are expected to increase to approximately 28,290 in 2030, representing a compound annual growth rate ("CAGR") of 2.7%.

The following diagram illustrates the market size of all MM therapeutics in terms of sales revenue in China market. (*Source: Frost & Sullivan Report*)

China Market for MM Therapeutics (2014-2030E)



The treatment options currently approved in China are listed as follows: (1) Small molecule drugs. Two or three approved drugs known as doublets or triplets are currently being used. Proteasome inhibitors, immunomodulators or CD38 antibody combination therapy is recommended as the first-line treatment for relapsed or refractory MM according to 2020 version of the treatment guideline. In 2019, Velcade (bortezomib), Revlimid (lenalidomide) and dexamethasone (VRD triplet) were included in the National Reimbursement Drug List in China; and (2) CD38 antibody therapy. Daratumumab (from Johnson & Johnson) received conditional NDA approval for a third-line treatment in July 2019 and is currently on the market in China. The current intravenous infusion of daratumumab can take up to six hours to be administered and cause a high infusion reaction rate ("IRR"). In clinical trials, approximately half of all patients experience an infusion reaction. Symptoms include fever, chills, nausea, bronchospasm, hypoxia, dyspnea, hypertension, laryngeal edema and pulmonary edema. Subcutaneous injection of daratumumab, which requires an injection device, is not yet approved in China.

CD38 Antibody Products Approved or to be Approved in China

Product (1)	Company	Global Status	Greater China Status
Daratumumab	Johnson & Johnson	Approved	3L approved
Felzartamab (2)	**I-Mab**	**N/A**	**3L NDA submission expected in Q4 2021. 2L registrational trial on-going**
Isatuximab	Sanofi	Approved	Phase 3
TAK-079	Takeda	Phase 1/2	N/A

Notes:

(1) Product candidates that are prior to clinical Phase 2 are not included in this table.
(2) In November 2017, we and MorphoSys entered into an exclusive regional licensing agreement to develop and commercialize MOR202, which we refer to as felzartamab (TJ202), in Greater China (including Taiwan, Hong Kong and Macao). Felzartamab is currently undergoing two registrational clinical trials in relapsed/refractory multiple myeloma in Greater China. We aim to submit an NDA to the NMPA for felzartamab as a monotherapy in 2021.

As aforementioned, CD38 antibody therapy represents a novel mechanism of action among the current therapeutic classes for MM. We believe that there is rapidly increasing clinical adoption of CD38 antibody therapy in China. The natural evolution of epidemiology driven by the aging population in China will lay a solid foundation for the growth of the overall MM market, while the adoption of multiple combination therapies and new drug classes will further expand the progression-free survival ("PFS") and overall survival ("OS") of MM patients. Currently, clinical outcome for r/r MM patients who had received multiple lines of interventions remain unsatisfactory. MM is still an incurable disease and the extension of PFS and OS remains a major unmet medical need. CD38 antibody therapy has demonstrated synergetic cellular and molecular effects in eliminating CD38+ tumor cells with proven clinical efficacy in terms of significantly prolonged PFS and OS compared to the baseline survival status of other treatment options.

Systemic Lupus Erythematosus (SLE) Drug Market and Competitive Landscape

Systemic lupus erythematosus ("SLE") is a chronic, multi-system and incurable autoimmune disease that can potentially lead to serious organ failure and even death. Patients with SLE have aberrant auto-antibodies in a form of so-called immune-complexes in their blood, which deposit in the kidneys and cause tissue damage. Common symptoms of SLE include painful and swollen joints, unexplained fever, chest pain, hair loss, mouth ulcers, swollen lymph nodes, extreme fatigue, and red rashes appearing most commonly on the face. These symptoms vary widely among different patients and fluctuate unpredictably over time with disease development. More importantly, at the advanced disease stages, patients can develop renal damage and renal failure.

In China, the estimated prevalence of SLE was 50-100 cases per 100,000 persons, which was much higher than that of 10-35 per 100,000 people in European and North American countries, according to researchers at Peking University First Hospital (L Mu et al., Lupus, 2018). SLE prevalence in China is projected to reach 1.11 million in 2030.

Patients with mild SLE are often given non-steroidal anti-inflammatory drugs, while more severe patients require treatments with corticosteroids and/or immunosuppressants. Approved by the FDA in 2011 and by the China NMPA in July 2019, Benlysta (belimumab), a B-lymphocyte stimulator (BLyS)-specific inhibitor developed by GSK, is the world's first biologic approved to treat SLE. In March 2021, RemeGen announced that its telitacicept, a TACI-Fc fusion protein targeting both BLyS and A PRoliferation-Inducing Ligand (APRIL), has been granted conditional marketing approval by the China NMPA for the treatment of patients with SLE. However, there remains a significant unmet medical need beyond the currently approved treatment options in China and the rest of the world. As dysregulated CD38-positive B cells and plasma cells and the resulting autoimmune 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 provide a more efficacious treatment option, which is supported by pre-clinical studied reported so far. Felzartamab has the potential to offer such a disease-modifying treatment option. In addition, as described below, the advantages of felzartamab include convenience of use and a lower IRR, making it a more favorable treatment agent in long-term clinical management of SLE if approved.

Clinical Advantages of Felzartamab

Felzartamab, if approved, is a potentially highly differentiated CD38 monoclonal antibody drug and will be the second CD38 antibody therapy for MM to launch in China. A Phase 2a trial of felzartamab in MM revealed treatment effects comparable to those 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, felzartamab required only a short infusion time of 30 minutes (as subsequent infusions) to 2 hours (as initial infusion), 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 felzartamab, compared to 48% for the currently marketed CD38 antibody. The advantages of felzartamab associated with infusion may be attributed to its lack of antibody CDC activity and show potential for 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, felzartamab 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 felzartamab treatments. As felzartamab is being considered for long-term treatment management of autoimmune diseases, we believe such clinical differentiation is advantageous.

For autoimmune diseases, felzartamab has an advantage over other B cell-targeting therapies such as CD20 antibodies, as it specifically targets pathogenic $CD38^{high}$ B cells and plasma cells involved in autoimmune diseases while CD20 antibodies target a wide range of B lineage cells, including those involved in normal immune functions and regulatory functions, but not CD38+ plasma cells producing pathogenic antibodies.

Mechanism of Action

Felzartamab 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.

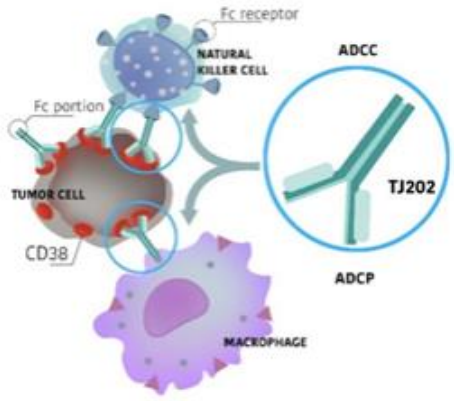


Figure: Felzartamab kills CD38-bearing tumor cells by inducing ADCC and ADCP.

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 felzartamab 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 felzartamab 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. Felzartamab 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. Felzartamab was well tolerated in patients with relapsed or refractory multiple myeloma (r/r MM), as a single agent and in combination with DEX, or with POM/DEX, or with LEN/DEX. The MTD of felzartamab was not reached. In the 56 patients from three groups receiving combination regimens, grade 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.

Felzartamab 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 felzartamab combination therapies. No responses were observed for the monotherapy groups which were primarily serving for dose escalation. Felzartamab 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.

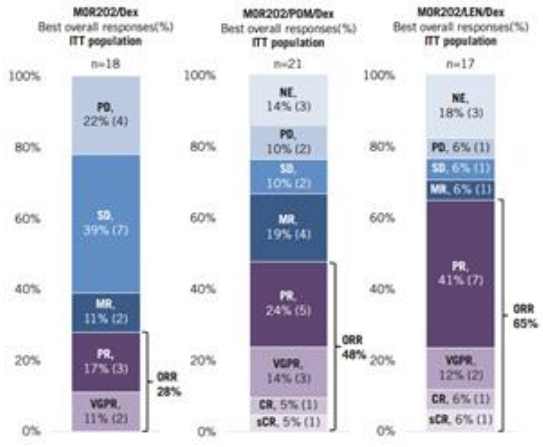


Figure: Best overall response and ORR. Patients were treated with felzartamab in combination with low dose of DEX (40 mg for 75 years old and younger, or 20 mg for older than 75 years old), POM (4 mg) /Dex or LEN (25 mg)/Dex. Dex: dexamethasone; POM: pomalidomide; LEN: lenalidomide; ITT: intent to treat; 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 • <5% plasma cells in bone marrow[b]
VGPR	• Serum and urine M-protein detectable by immunofixation but not electrophoresis or • ³90% reduction in serum M-protein plus urine M-protein level <100 mg/24 hours
PR	• ³50% reduction of serum M-protein and reduction in 24-hour urinary M-protein by ³90% or to <200 mg/24 hours • If the serum and urine M-protein were unmeasurable, a ³50% decrease in the difference between levels of involved and uninvolved free-light-chains instead of the M-protein criteria • In addition to the above-listed criteria, if present at baseline, a ³50% 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)

RESPONSE SUBCATEGORY	CRITERIA [A]
SD [f]	• Not meeting criteria for CR, VGPR, PR, MR, or PD
PD	NOTE: Required any 1 or more of the following: Increase of ³25% from nadir in • Serum M-component and/or (absolute increase ³0.5 g/dL)[g] • Urine M-component and/or (absolute increase ³200 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 % ³10%[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 <1:2.
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 ³1 g/dL were sufficient to define relapse if starting M-component was ³5 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 felzartamab 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 felzartamab in reducing M protein levels.

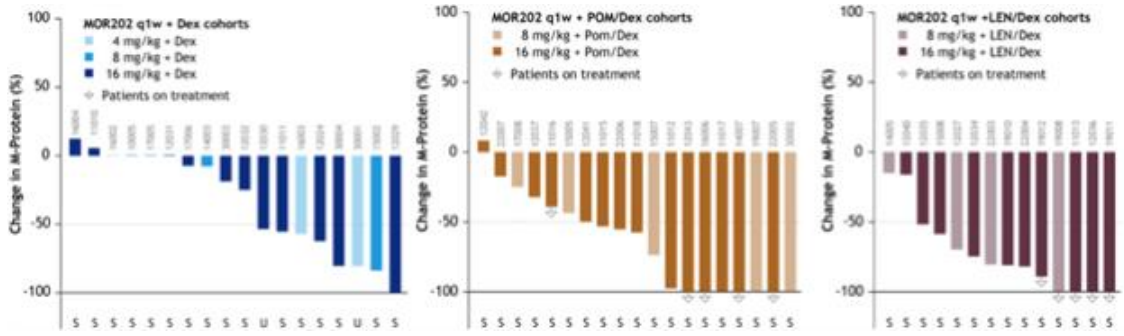


Figure: The relative change in M protein levels from baseline to post-baseline nadir. Patients were treated with felzartamab in combination with low doses of DEX, POM/DEX or LEN/DEX. S: serum sample; U: urine sample. (Source: MorphoSys)

Pharmacokinetics ("PK"). The PK of felzartamab 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 (³4 mg/kg) was at approximately two weeks. Pharmacokinetics of felzartamab were generally consistent across different individuals and dosing days and not affected by the co-medications.

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

Clinical Development Plan and Current Development Status

Immediately after the agreement with MorphoSys, we formulated a robust clinical development strategy with the aim to achieve an NDA submission in 2021. We are currently on track for two on-going registrational clinical trials. One is a single-arm registrational trial with felzartamab and DEX as a 3L therapy for MM patients in Greater China using ORR as the primary endpoint (NCT03860038). We have now successfully enrolled all patients (N=113) and moved into follow-up stage as of January 2021. Data from this study are expected to be the major package supporting NDA filing in 2021 for conditional approval. The other is a parallel registrational trial combining felzartamab with LEN and DEX as a 2L combination therapy in MM patients (NCT03952091). We plan to enroll 291 patients in this study and the patient enrollment is well on-track. As of February 2021, 155 patients have been randomized and treated in the trial. In addition to our original clinical development plan for felzartamab as 2L and 3L treatment for MM, we will initiate a combination clinical trial of felzartamab with lemzoparlimab in the second half of 2021 to explore the potential as a first-line (1L) treatment for MM based on the pre-clinical data generated in house and reported by others.

In parallel, the preparation of the initial NDA submission for 3L r/r MM therapy is ongoing, including CMC process characterization and process validation being conducted at our CDMO. Additionally, we expect to receive IND approval and start a Phase 1b clinical trial in patients with SLE in the second half of 2021.

Summary of Expected Milestones

The major milestones are: (1) the submission of initial NDA (3L r/r MM) in Q4 2021; (2) completion of patient enrollment of 2L registrational trial by Q3 2021 and follow up of the patients for median PFS as the primary endpoint defined in the study protocol; (3) the IND submission of a combination trial with lemzoparlimab in Q2 2021 and the study is expected to initiate in the second half of 2021; and (4) the initiation of Phase 1b SLE trial in the second half of 2021.

Commercialization Strategy in China

Through years of research and clinical development, we have established long-term relationships with key opinion leaders and have cultivated an extensive clinical network in the field of hematologic oncology in China. In August 2020, the appointment of Mr. Ivan Yifei Zhu as our Chief Commercial Officer has strengthened our commercial leadership to expand our commercialization team and prepare for launch readiness of felzartamab.

We believe that the CD38 antibody market in China will undergo a significant increase within the next five to ten years. The China market for CD38 antibody is expected to reach US$542 million in 2027, benchmarking the forecast of global CD38 market from DataMonitor. The market experienced an initial period of market build-up and cultivation from 2019 to 2021 with daratumumab launched as the first CD38 antibody in China in 2019. Going forward, we will witness rapidly improved clinical awareness and increased adoption to CD38 antibody therapy from 2021 to 2027, which represents a phase of rapid market expansion for CD38 antibody products. Upon the expected market launch of felzartamab in 2022, we expect to capture the market opportunity provided by this phase of market expansion in the period of 2022-2027, as CD38 antibody therapy will become a mainstream treatment option.

Within the next many years, daratumumab and felzartamab will be the two leading CD38 antibody products on the China market. Assuming that daratumumab remains in the China market with the current pricing and market access strategy as a non-NRDL product, we would be able to rapidly build up our position for a significant market share for felzartamab through our unique advantages in the following aspects. (1) *Cost of the product*. We are able to leverage our local manufacturing capability in Hangzhou to reduce the cost of goods to be more competitive and flexible in pricing; (2) *To be listed in NRDL*. We are more competitive with flexible pricing to be included in NRDL and are not constrained by global pricing; (3) *Product advantages*. We have been building clinical experience in the convenient use of felzartamab with major clinical sites and network through our on-going clinical trials. The clinical advantages of felzartamab are widely noted and acknowledged by physicians; and (4) *Commercial focus in hematologic oncology*. Felzartamab is part of our focused commercial strategy for hematologic oncology in China with felzartamab for MM as 2L and 3L therapies and potentially more efficacious combination therapy with lemzoparlimab, and lemzoparlimab for leukemia, e.g. AML and MDS. In addition, we are in the process of potentially in-licensing a global product for lymphoma. With this focused commercialization strategy by leveraging the highly competitive and efficacious hematologic oncology products, we strive to build a leading market position in the hematologic oncology in China.

In 2020, we established our core commercialization capability, including market access and medical affairs teams, to prepare for the near-term product launch and have begun to discuss the inclusion of felzartamab in NRDL with national experts as a necessary step to follow the market launch of felzartamab. Plans are being prepared to expand market penetration of felzartamab through the following strategies: (1) increasing accessibility of felzartamab by building alliances with stakeholders on the value chain; (2) ensuring affordability by cooperating with government authorities, charity organizations, insurance companies and research institutions; and (3) improving availability by educating doctors, pharmacists and patients and establishing standardized treatment procedures for patients.

Upon obtaining NDA approval of felzartamab as 3L treatment for MM, we expect to rapidly build our market position in the period of 2022-2027, starting with the promotion and marketing of felzartamab. Our commercial strategy is to focus on a network of 200-250 top-tier hospitals in the first-tier cities in China to capture approximately 70-80% of national sales while maintaining a premium price based on the product advantages of felzartamab. Following the expected market launch of felzartamab as 2L therapy with Revlimid and the multi-year inclusion of felzartamab (2L and 3L) in NRDL, we aim to reach more than 50% of the national market share for CD38 antibody therapy in China around 2026-2027. We believe that felzartamab will remain as a competitive product even after 2027 when one or two additional global competitors may enter the market because we would have established deep market penetration as the only local product included in NRDL with continued competitiveness through further reduced manufacturing cost.

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

Summary

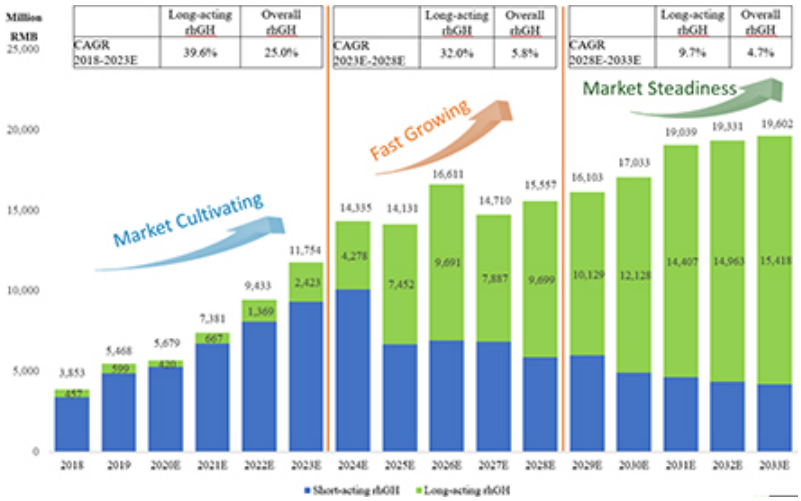
Eftansomatropin alfa is a potential highly differentiated long-acting recombinant human growth hormone (“rhGH”) being developed as a more convenient and effective therapy for growth hormone deficiency (“GHD”), for which there is substantial unmet medical need in China. Eftansomatropin alfa is the only rhGH in its proprietary fusion protein format. Eftansomatropin alfa has met the pre-set safety endpoints in three multi-regional clinical trials conducted in Europe and Asia and the preliminary efficacy endpoints in pre-pubertal patients with growth hormone deficient (“PGHD”) in a Phase 2 clinical trial conducted in Europe. In contrast to marketed short-acting rhGH products, such as Genotropin, eftansomatropin alfa showed similar treatment efficacy in a more convenient weekly (vs. daily) regimen. Furthermore, eftansomatropin alfa does not carry the safety concerns typically associated with pegylated hGH drugs, especially for PGHD. We own all rights of eftansomatropin alfa in China and are positioning the investigational drug as a highly differentiated growth hormone replacement therapy, highlighting its advantages over a daily regimen and safety profile (natural protein-based vs. pegylated long-acting hGH) for the rapidly growing GH market in China. With an approved IND by the NMPA in September 2020, we initiated a registrational Phase 3 trial of eftansomatropin alfa in patients with PGHD, and the patient enrollment is on track as of April 2021. This registrational clinical trial involves 165 patients and is expected to complete patient enrollment by early 2022 to support an NDA submission in late 2022.

Growth Hormone Deficiency Drug Market in China

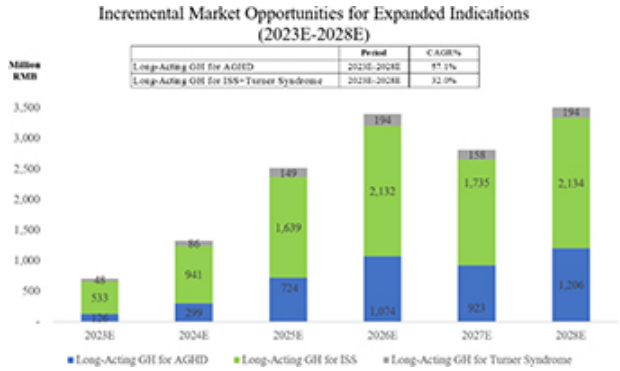
GHD is a pituitary disorder that occurs when the production of growth hormone, normally secreted by the pituitary gland, is disrupted. Since growth hormone plays a critical role in stimulating body growth and development and is involved in the production of muscle protein and the breakdown of fats, a decrease in growth hormone affects numerous physiological processes, including short stature in children and other physical ailments in both children (“PGHD”) and adults (“AGHD”). Both globally and in China, the widely adopted treatment for PGHD is patient-specific growth hormone replacement therapy, which is given in a calculated weight-based dosing regimen.

Deficiency in growth hormone can be induced by different pathological status, therefore rhGH has an extensive range of clinical application, including ordinary deficiency of growth hormone, idiopathic short stature ("ISS"), Turner Syndrome, etc. We believe that the clinical application of rhGH will cover children and juveniles of different age groups, forming a wide population base to support the substantial market growth in the mid-to-long term. Due to the long duration of treatment usually calculated in years and the dominating route of administration applied by the patients, long-acting rhGH will be more attractive in the available treatment options. As the patients, caregivers and physicians raise their expectations to the quality of life, we believe the long-acting rhGH will witness its booming with the improvement of affordability and drug availability.

According to the Frost & Sullivan Report, only 5.7% of all PGHD patients projected in China received primarily daily injections of growth hormone replacement therapy in 2020, therefore, the China PGHD patients' clinical needs are largely untapped. The PGHD market in China is forecasted to grow to RMB19.6 billion (US$3.0 billion) by 2033, representing an estimated CAGR of 11.5% from the year 2018 to 2033. According to a report by Pharmacodia, the overall PGHD market will evolve in three stages: (1) market cultivation for long-acting rhGH from 2018 to 2023, during which short-acting agents still dominate the market; (2) fast growing stage for long-acting rhGH from 2023 to 2028, during which there is an expected progressive migration of short-acting rhGH to long-acting rhGH; and (3) steady status for long-acting rhGH to take the majority of the overall market share of rhGH from 2028 to 2033, due to multiple years of clinical/patient education, affordability and increasing demand. As a result, the long-acting rhGH market is forecasted to grow much faster than the overall rhGH market, representing an estimated CAGR of 20.3% from the year 2023 to 2033. The following figure illustrates the growing rhGH market in China. (*Source: Pharmacodia Report*)



In addition to PGHD, rhGH can be applied to treat other clinical conditions driven by GH deficiency, including AGHD, Idiopathic Short Stature (ISS) and Turner Syndrome. The following figure illustrates the forecasted market opportunities for AGHD, ISS and Turner Syndrome in China, respectively. *(Source: Pharmacodia Report)*



Competitive Landscape in China

Currently, short-acting (daily) recombinant human growth hormone ("rhGH") is commonly used for the long-term treatment of children and adults with inadequate endogenous growth hormone secretion. In China, the daily rhGH market is dominated by domestic companies including GeneScience Pharmaceuticals, Shanghai United Cell Biotechnology and Anhui Anke Biotechnology. Novo Nordisk launched their daily rhGH, Norditropin, in March 2018.

There is only one pegylated long-acting (weekly) rhGH (Jintrolong) for PGHD in China, which has been marketed by GeneScience since 2014. Other companies currently developing long-acting rhGH in China include Novo Nordisk, Anhui Anke Biotechnology, Xiamen Amoytop Biotech, Evive Biotech and Visen Pharmaceuticals. Eftansomatropin alfa is the only Fc-based long-acting rhGH in China. As 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, eftansomatropin alfa is considered to be clinically advantageous.

The following table illustrates the competitive landscape of long-acting growth hormone products approved and to be approved in China. (*Source: Pharmacodia Report*)

Long-acting rhGH Products Marketed and Under Development in China

Format	Product [1]	Company	China Status
PEGylated GH	Jintrolong®	GeneScience	Approved
Fusion Protein	**Eftansomatropin[2]**	**I-Mab**	**Registrational Phase 3**
TransCon hGH	Lonapegsomatropin	Ascendis/Visen	Phase 3
PEGylated GH	PEG-rhGH	Anhui Anke	Phase 3

Notes:

(1) Long-acting growth hormone products prior to clinical Phase 2 are not included in this table.
(2) In December 2017, Genexine, Inc. (KOSDAQ: 095700) granted us exclusive rights to develop and commercialize GX-H9, which we refer to as eftansomatropin alfa (TJ101), in Greater China.

Advantages of eftansomatropin alfa

We believe that eftansomatropin alfa has the following advantages: (1) when compared to the daily regimen of rhGH, eftansomatropin alfa is proven to be a more convenient therapy with better patient compliance due to its weekly dosing frequency (potentially twice-monthly administration), while maintaining similar efficacy; and (2) eftansomatropin alfa has no 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, eftansomatropin alfa 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 eftansomatropin alfa's growth-promoting activity. Eftansomatropin alfa is based on Genexine's patented hyFc technology. The hyFc part consists of a portion of human immunoglobulin D ("IgD") and G4 ("IgG4"). The former contains a flexible hinge, and the latter is responsible for half-life extension through neonatal Fc receptor ("FcRn")-mediated recycling. Additionally, eftansomatropin alfa's increased molecular weight (103 kilodalton) is expected to reduce renal clearance.

Figure: Schematic presentation of the structure of eftansomatropin alfa. 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 eftansomatropin alfa, 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, eftansomatropin alfa was shown to be well-tolerated, and clinical efficacy endpoint achieved by weekly or twice-monthly eftansomatropin alfa administration was comparable to that of daily administration of Genotropin.

Phase 1 Clinical Trial

The first-in-human trial of eftansomatropin alfa 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. Eftansomatropin alfa was shown to be well-tolerated at all dose levels studied (0.2–1.6 mg/kg). Eftansomatropin alfa 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 eftansomatropin alfa 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. Eftansomatropin alfa 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 eftansomatropin alfa, 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 eftansomatropin alfa (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 eftansomatropin alfa was consistent with known properties of marketed products. The AE incidence rate was generally similar across the eftansomatropin alfa 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 eftansomatropin alfa 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 eftansomatropin alfa) 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 eftansomatropin alfa) 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 in 13 out of 40 subjects (32.5%) in the eftansomatropin alfa cohorts. Pain was the most prominent and common symptom that was observed in 10 subjects. 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 eftansomatropin alfa or Genotropin.

Pharmacokinetics. Half-life of eftansomatropin alfa 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 eftansomatropin alfa. 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 eftansomatropin alfa 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 eftansomatropin alfa 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.

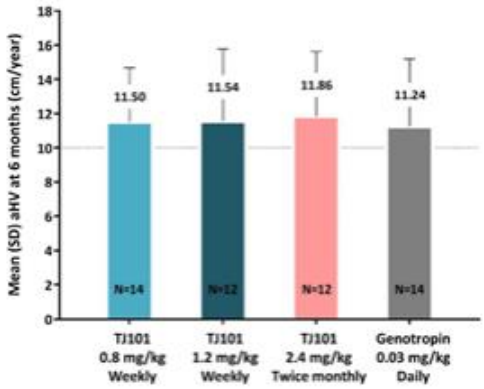


Figure: The aHV at six months indicated comparable growth rates between all doses of eftansomatropin alfa (both weekly and twice-monthly treatment) and the active comparator, Genotropin. (Source: Genexine)

In an extension study in which all patients were put on eftansomatropin alfa, greater than two-digit growth velocity remained until 12 months in all eftansomatropin alfa cohorts, while the Genotropin cohort showed 9.14 cm/ year at 12 months. Moreover, no remarkable slow-down of the growth velocity was observed in the second year in either patients who received eftansomatropin alfa throughout, or in subjects who switched from Genotropin cohort.

Pharmacodynamics. The growth-promoting effect of eftansomatropin alfa 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 eftansomatropin alfa 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 and Expected Milestones

In September 2020, the NMPA approved our IND application for a registrational Phase 3 trial of eftansomatropin alfa in PGHD in China. This Phase 3 trial ("TALLER") is a multi-center, randomized, open-label, active-controlled clinical study designed to assess the safety, efficacy and pharmacokinetics of eftansomatropin alfa in PGHD. This trial will enroll 165 patients across multiple centers in China. The primary objective is to demonstrate non-inferiority of 1.2 mg/kg/week of eftansomatropin alfa administered SC, compared to the active control Norditropin, a daily rhGH marketed in China. The first patient was dosed in the TALLER study in February 2021. The top-line clinical data are expected to become available in Q2 2023 to support NDA submission.

Commercialization Strategy in China

As described earlier in this section, the growth hormone market in China will continue to grow rapidly, primarily driven by the potential expansion of applicable patient population, the affordability, the improved awareness of short stature, the availability of more convenient weekly administration of rhGH and the improved injection devices. In particular, the market growth of long-acting rhGH such as eftansomatropin alfa will outpace the growth of overall rhGH market, progressively shifting the market dominance from short-acting rhGH to long-acting rhGH within the next 5-8 years. In addition, we have plans to initiate new clinical studies to expand the treatment application of eftansomatropin alfa to other selected indications such as AGHD, Idiopathic Short Stature (ISS) and Turner Syndrome.

While advancing the current registrational clinical trial, we have begun to prepare for market launch of eftansomatropin alfa. Our plan is to co-promote eftansomatropin alfa by partnering with a China domestic big pharma group who has extensive commercial capability and sales network for pediatric drug products. We are currently in negotiation with selected potential commercial partners. Such partnership will leverage the existing well-established commercial capabilities, including medical marketing, patient education and community outreach programs, and commercial channels of our potential partner to rapidly build a market position and penetration for eftansomatropin alfa in the rhGH market in China. In addition, we are in the process of developing a more convenient injection device in an attempt to improve patient adherence and product competitiveness. The expected market launch of eftansomatropin alfa falls nicely within the predicted time window of the fast-growing stage for long-acting rhGH (2023-2028) as described earlier. Together with the commercial strategy mentioned above and the demonstrated product advantages of eftansomatropin alfa, we aim to rapidly build a strong market position for eftansomatropin alfa to become a top three player in the long-acting rhGH market space in China by 2028. It is estimated that annual sales of the top two or three long-acting rhGH players collectively account for US$1.0 billion (RMB6.3 billion) in 2028, which represents approximately 65% of the overall long-acting rhGH market in China.

Core Assets

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

Summary

Lemzoparlimab is a fully human CD47 monoclonal antibody discovered and developed internally by us 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-generation clinical stage CD47 antibodies were found in clinical trials to bind to RBCs and caused significant hematologic adverse effects, such as severe hemolytic anemia, which has hampered the development of these CD47 antibodies as a potential cancer therapy.

We developed lemzoparlimab by design to embed a unique property or differentiation through a different antibody binding epitope, to minimize binding to RBCs while retaining superb anti-tumor activities. This key differentiation is achieved by incorporating a RBC counter-screen step in the antibody screen champagne in order to select rare antibody clones that bind to CD47 with high affinity but do not to RBCs. Lemzoparlimab was selected as a result and 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). In addition, the topline results of the completed Phase 1a dose escalation monotherapy trial in the United States (NCT03934814) have demonstrated the differentiated profile of lemzoparlimab in drug safety and favorable pharmacokinetics in cancer patients. The key findings include: (1) *Safety advantage*. lemzoparlimab was well tolerated up to 30 mg/kg on a weekly basis without priming dosing strategy, with no dose-limiting toxicity and no clinical or laboratory evidence of hemolytic anemia observed throughout; (2) *PK and receptor occupancy*. The PK profile appeared to be linear at mid to high dose levels following a single dose with no significant "sink effect". Maximal receptor occupancy was achieved at 30 mg/kg; and (3) *Clinical activity*. One confirmed partial response (PR) was observed in the 30 mg/kg monotherapy cohort (N=3), and this patient had failed prior treatments with checkpoint inhibitors. Three stable disease cases were also reported. The overall pre-clinical and clinical data generated so far have provided strong evidence supporting lemzoparlimab as a highly differentiated CD47 antibody with the clinical advantages described above.

In September 2020, to facilitate and accelerate the global development and commercialization of lemzoparlimab, we granted AbbVie a global license valued at US$1.94 billion, including an upfront payment of US$180 million and the first milestone payment of US$20 million based on the phase 1 clinical results. We retain the rights to develop and commercialize lemzoparlimab in Mainland China, Hong Kong and Macau. We believe that this global partnership with AbbVie will greatly facilitate the clinical development, manufacturing and commercialization of lemzoparlimab globally and in China.

Therapeutic Indications

We plan to evaluate the therapeutic role of lemzoparlimab in a variety of solid tumors, such as NSCLC, ovarian cancer and SCCHN, and hematological malignancies such as AML, MDS and non-Hodgkin's lymphoma ("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 therapies. 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. Lemzoparlimab 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 Gilead/Forty-Seven, Inc., Surface Oncology and Arch Oncology. The most advanced asset, magrolimab, originally developed by Forty-Seven, Inc., is in Phase 3 clinical studies for multiple cancer indications. However, almost all clinical trials with CD47 antibodies 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 precautions.

Advantages of Lemzoparlimab

Lemzoparlimab has similar sub-nanomolar binding affinity as other CD47 antibodies and exhibits comparable anti-tumor activity. The key advantage of lemzoparlimab 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 lemzoparlimab is, at least in part, due to its unique epitope interaction as revealed by crystallography, which is different from those recognized by other CD47 antibodies currently in clinical development based on publicly available information. The differentiation of lemzoparlimab is highlighted in a series of pre-clinical studies summarized as the following: (1) lemzoparlimab displays only minimal RBC-binding even at high antibody concentrations by flow cytometry; (2) lemzoparlimab does not induce RBC agglutination even in a high concentration range; and (3) most importantly, lemzoparlimab 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, lemzoparlimab has a potentially better clinical safety profile and may be used in a broader patient population 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*	No DLT, No priming dose No hemolytic anemia

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

Mechanism of Action

Lemzoparlimab blocks the interaction between CD47 expressed on cancer cells and SIRPα expressed on macrophages, leading to increased phagocytosis of cancer cells by macrophages. Blockade of CD47 by lemzoparlimab 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.

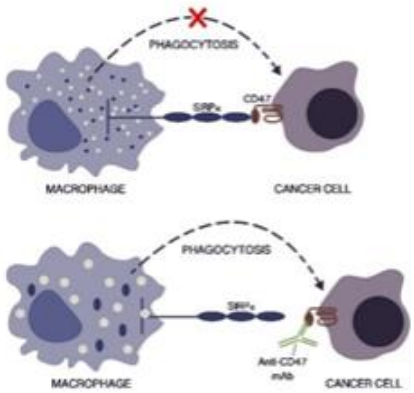


Figure: *Targeting the CD47/SIRPα myeloid-specific immune checkpoint. CD47 is highly expressed on many different types of cancers. SIRPα is an inhibitory receptor expressed on macrophages and other myeloid immune cells. When CD47 binds to SIRPα, it causes the inhibition of phagocytosis. CD47 antibodies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

Summary of Pre-clinical Results

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

Lemzoparlimab 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, lemzoparlimab (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, lemzoparlimab 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).

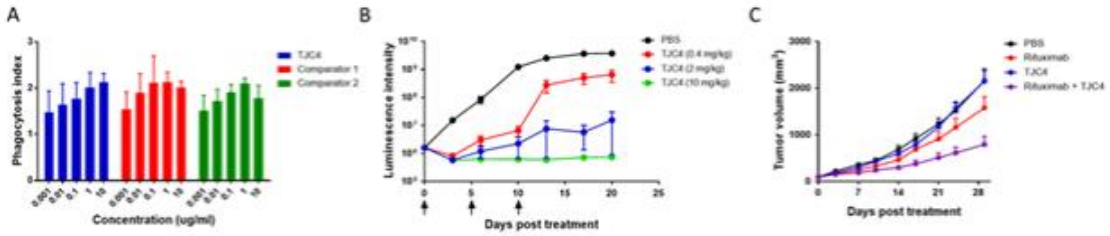


Figure: *In vitro and in vivo anti-tumor activity of lemzoparlimab (TJC4). (A) In vitro phagocytosis of Raji cells by primary human macrophages in the presence of different doses of lemzoparlimab or comparator CD47 antibodies. (B) In vivo anti-tumor activity of lemzoparlimab mono-treatment in Raji xenograft model. (C) In vivo anti-tumor activity of lemzoparlimab (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

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

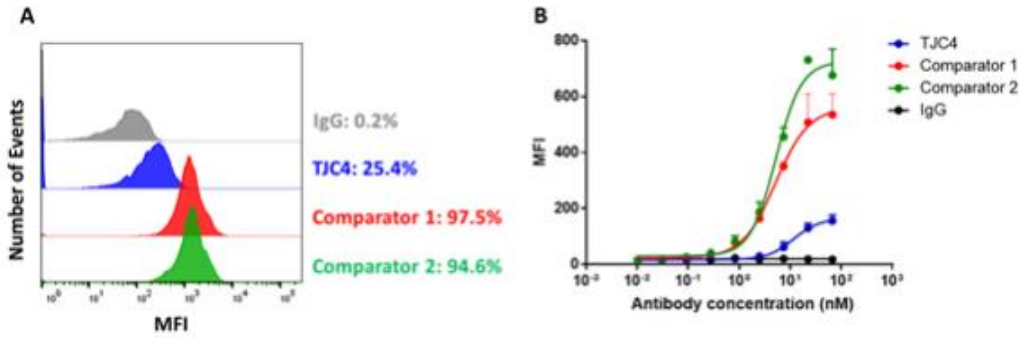


Figure: *Binding of CD47 monoclonal antibodies to RBCs. (A) Representative graph of the staining of human RBCs with CD47 monoclonal antibodies or control IgG (1 µg/ml); (B) Dose dependent binding of CD47 monoclonal antibodies with human RBCs from different healthy donors (n = 3). MFI: mean fluorescence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

Secondly, 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 lemzoparlimab 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 mg/ml. Results from a representative experiment are shown below.

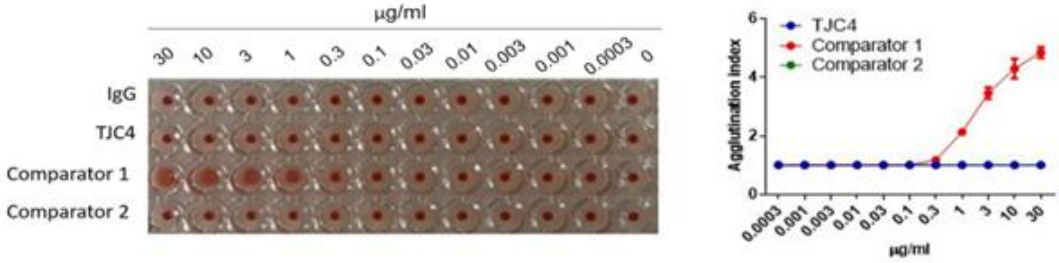


Figure: *Hemagglutination by CD47 monoclonal antibodies. Left: representative graph of hemagglutination (haze appearance) or lack thereof (precipitate) by different concentrations of control IgG, lemzoparlimab (TJC4), and comparator antibodies. Right: quantification through an index determined by the 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 lemzoparlimab 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 lemzoparlimab 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).

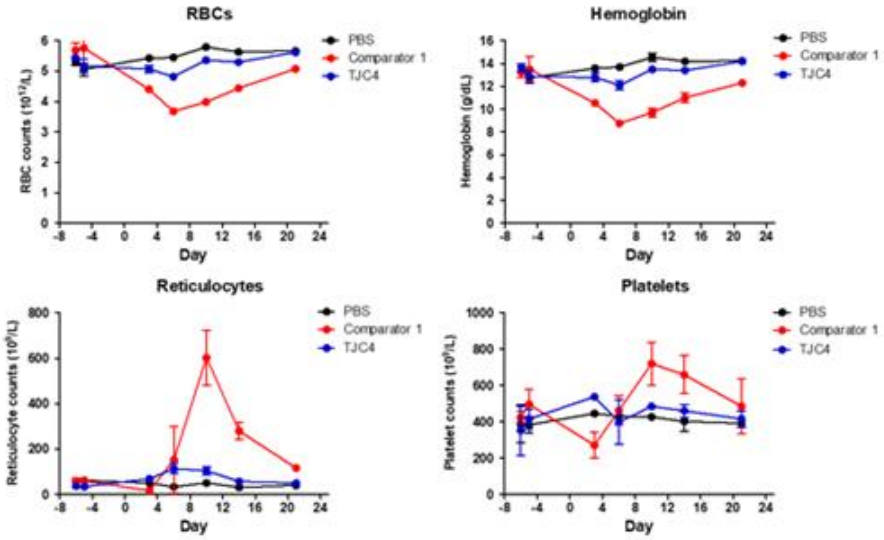


Figure: Hematological parameters in non-human primates treated with a single dose of CD47 antibodies. On Day 0, naive cynomolgus monkeys were IV injected with PBS control (n=2), lemzoparlimab (TJC4) (n=2, 10 mg/kg) or a comparator antibody (n=2, 10 mg/kg). Blood cells were counted, twice before drug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

Moreover, in a four-week GLP toxicology study, lemzoparlimab 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.

Four-week GLP Toxicology Study in Monkeys

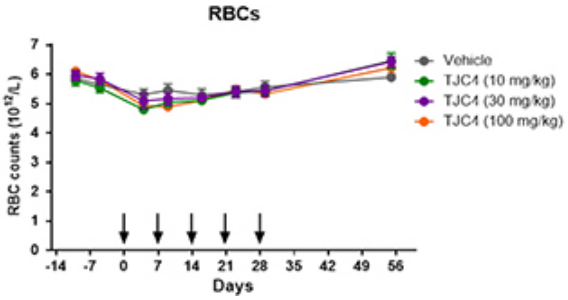


Figure: RBC counts in male cynomolgus monkeys treated with five consecutive weekly dose of lemzoparlimab (TJC4) at 0-100 mg/kg in a 4-week GLP toxicology study.

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

ELUCIDATION OF THE MOLECULAR MECHANISM UNDERLYING MINIMAL BINDING TO RBC

We set forth to investigate the molecular mechanism underlying the minimal binding of lemzoparlimab to RBC. The crystal structure of the CD47 antibody binding complex revealed that lemzoparlimab binds to a unique epitope of CD47 that is situated in a heavily glycosylated site on RBC. More specifically, the results of crystal structure analysis identified an N-glycosylation site located nearby the epitope residues. We hypothesized that the glycosylation site nearby the epitope may hinder lemzoparlimab from fully binding to its epitope on RBC. A series of experiments were carried out to address this hypothesis. RBCs were treated with PNGase to remove the N-linked oligosaccharides from glycoproteins, followed by testing of CD47 antibody binding to the de-glycosylated RBCs. The results showed that PNGase treatment of RBCs significantly increased the binding of lemzoparlimab as compared to a control antibody, providing the experimental evidence that removal of glycosylation site(s) on RBC effectively restores binding of lemzoparlimab to RBC.

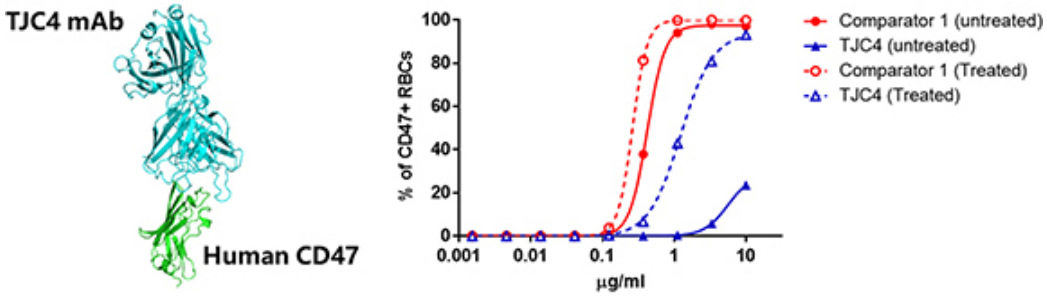


Figure: The left. Crystal structure of the complex of the Fab of lemzoparlimab (TJC4, Cyan) binding with the extracellular domain (ECD) of human CD47 (Green). The right. In a representative experiment, human RBCs were treated with PNGase for 1 hr followed by the addition of lemzoparlimab (TJC4) or a comparator CD47 antibody that binds strongly to RBC at the indicated concentrations. The binding of CD47 antibodies to the treated (de-glycosylated) or untreated RBCs was analyzed by flow cytometry.

Results of Phase 1 Clinical Trial

The ongoing Phase 1 study of lemzoparlimab in the U.S. is an open-label, multi-center, multiple dose study conducted in two parts to determine safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD) and efficacy of lemzoparlimab administered alone and in combination (NCT03934814). The first part is comprised of a single agent dose escalation (Part 1a) followed by two separate combination regimens in an escalating dose range with pembrolizumab (Part 1b) and with rituximab (Part 1c), respectively. The second part is a dose expansion study of the combination therapies.

The monotherapy dose escalation has been completed and the initial data from the monotherapy were presented at Society for Immunotherapy of Cancer (SITC) in November 2020 (poster #385). The data are described below.

Single Agent Dose Escalation

Study Design. NCT03934814 is an open label, Phase 1 study to evaluate the safety, tolerability, maximal tolerable dose (MTD) or maximum administered dose (MAD), PK, PD, and recommended phase 2 dose (RP2D) of lemzoparlimab in subjects with advanced, relapsed or refractory solid tumors and lymphoma. Part 1 of the study comprises a single agent dose escalation in a standard 3+3 design (1a) and 2 separate dose escalations in combination with pembrolizumab (1b) or rituximab (1c). Part 2 is a dose expansion study. Lemzoparlimab was administered as weekly IV infusions in successive dose cohorts (1, 3, 10, 20 and 30 mg/kg) without any priming dose. Twenty patients were enrolled. Clinical data from the Part 1a study were reported as of November 2020.

Safety. Lemzoparlimab was well tolerated up to 30 mg/kg on a weekly infusion schedule *without priming dosing*. No dose limited toxicities (DLTs) or drug-related severe adverse event (SAE) were reported throughout the study. Maximal tolerable dose (MTD) was not reached. All treatment-related adverse events (TRAEs) were either Grade 1 or Grade 2, except that one Grade 3 lipase increase was reported. No clinical or laboratory evidence of hemolytic anemia were observed throughout.

AE TERMS	1 mg/kg (N=4)		3 mg/kg (N=4)		10 mg/kg (N=4)		20 mg/kg (N=5)		30 mg/kg (N=3)		Total (N=20)
	Gr Any	Gr 3	Gr Any	Gr 3	Gr Any	Gr 3	Gr Any	Gr 3	Gr Any	Gr 3	Gr Any
Anemia	0	0	2	0	2	0	1	0	1	0	6 (30%)
Neutropenia	0	0	0	0	0	0	0	0	1	0	1 (5%)
Blood bilirubin increased	0	0	0	0	1	0	0	0	0	0	1 (5%)
Blood LDH decreased	0	0	0	0	0	0	0	0	1	0	1 (5%)
Lipase increased	0	0	0	0	0	0	0	0	1	1	1 (5%)
Lymphocyte count decreased	0	0	0	0	1	0	0	0	0	0	1 (5%)
Platelet count decreased	0	0	0	0	1	0	0	0	0	0	1 (5%)
Fatigue	0	0	2	0	2	0	1	0	2	0	7 (35%)
Chills	0	0	1	0	0	0	0	0	0	0	1 (5%)
Constipation	0	0	0	0	0	0	1	0	0	0	1 (5%)
Diarrhea	1	0	1	0	1	0	0	0	0	0	3 (15%)
Nausea	0	0	0	0	0	0	1	0	0	0	1 (5%)
Infusion related reaction	0	0	0	0	2	0	2	0	1	0	5 (25%)
Dyspnea	0	0	0	0	0	0	0	0	1	0	1 (5%)
Hypotension	0	0	0	0	0	0	0	0	1	0	1 (5%)

Table: Treatment-related adverse events (TRAE) by cohort.

A transient reduction in the hemoglobin levels during the first cycle was observed across all cohorts. The average drop was ~10% and was not dose-dependent. This finding is consistent with the results of pre-clinical GLP toxicity studies. None of the drug-related anemia reported was considered to be severe or hemolytic in nature.

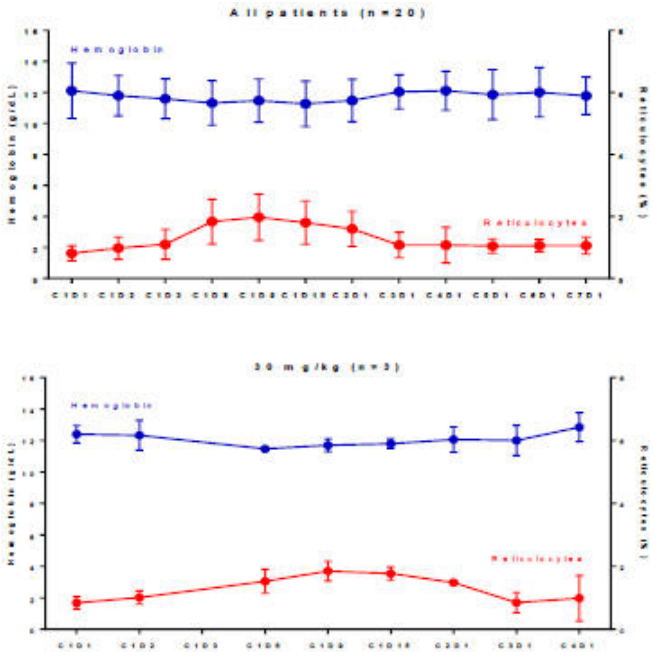


Figure: Time course of hemoglobulin and reticulocyte counts following lemzoparlimab treatment (all groups). Each cycle (C) is 21 days (D). Mean±SD is shown.

Pharmacokinetics. The PK profile of lemzoparlimab appeared linear at doses higher than 10 mg/kg following a single dose

administration, while its exposure was greater than dose proportional over the dose range of 1 to 10 mg/kg, suggesting that at higher doses, lemzoparlimab could overcome the CD47 “sink effect”. Five subjects were confirmed positive for anti-drug antibodies (ADA) following the first treatment: 3 were from 1 mg/kg, 1 from 3 mg/kg and 1 from 10 mg/kg. No impact of ADA was seen on safety or PK profiles.

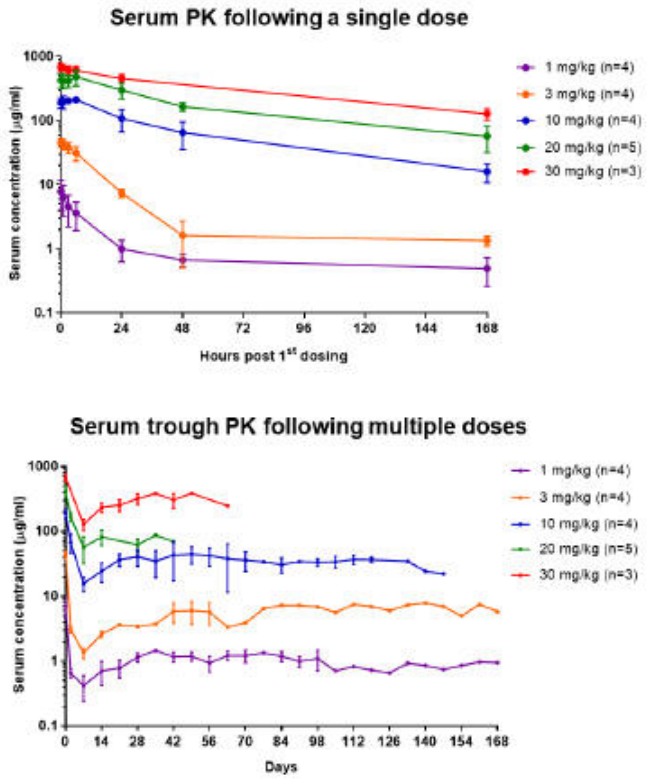


Figure: Serum PK of lemzoparlimab Q1W following a single dose (upper) and multiple doses (lower).

Pharmacodynamics. A dose dependent increase of the CD47 receptor occupancy (“RO”) on CD3+ T cells in the peripheral blood was observed after the escalation of the lemzoparlimab dosage. Maximal saturation of CD47 RO on peripheral T cells was achieved at 20 and 30 mg/kg following weekly administration of lemzoparlimab.

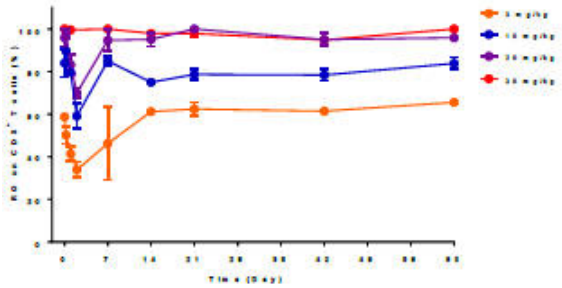


Figure: CD3+ T cell receptor occupancy.

Preliminary Efficacy. One confirmed Partial Response (PR) was observed in the 30 mg/kg monotherapy cohort (1/3) with 11 cycles completed so far. The patient who had metastatic melanoma had failed prior systemic treatment of nivolumab and ipilimumab. In addition, three patients achieved Stable Disease (SD) with SD duration longer than 16 weeks at dose cohorts cross 1 mg/kg, 10 mg/kg and 30 mg/kg. Two patients with head and neck squamous cell carcinoma (HNSCC) and renal cell carcinoma (RCC), respectively, failed nivolumab and the other with ovarian cancer received no prior PD-(L)1 inhibitor treatment.

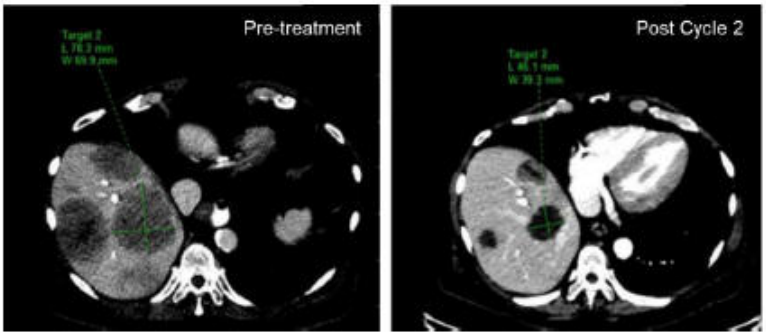


Figure: Responding hepatic metastases in a melanoma patient.

Summary of Clinical Data

Lemzoparlimab was well tolerated up to 30 mg/kg on a weekly infusion schedule without priming dosing strategy. No dose-limiting toxicity and no clinical or laboratory evidence of hemolytic anemia were observed throughout. Maximal tolerable dose (MTD) was not reached. Lemzoparlimab PK appeared to be linear at mid to high dose levels following a single dose with no significant “sink effect”. Lemzoparlimab monotherapy exhibited evidence of anti-tumor activity in both PD-(L)1 refractory and treatment nalve cancer patients. One confirmed Partial Response (PR) was observed in the 30 mg/kg cohort (n=3). This patient had failed prior treatments with checkpoint inhibitors. Three patients achieved Stable Disease (SD) with SD duration longer than 16 weeks starting at 1 mg/kg. Two patients failed nivolumab and the other received no prior PD-(L)1 inhibitor treatment.

Clinical Development Plan

The goal of our global and China clinical development plans is three-fold. We will evaluate the therapeutic role of lemzoparlimab in (1) hematologic malignancies; (2) solid tumors, in combination with other treatment agents; and (3) its application to advance the current treatment options of felzartamab as the second-line and the third-line potentially to a first-line treatment. However, our top priority is to launch lemzoparlimab as the first CD47 antibody product in China.

Hematologic malignancies. Our ambition is to achieve an accelerated marketing authorization of lemzoparlimab in China, potentially as the first CD47 antibody product in China. MDS and possibly NHL are being evaluated as the potential first indication(s), as they hold higher probability of success for accelerated approvals. With the approved IND from the China NMPA, we are initiating an abbreviated phase 2 clinical study of lemzoparlimab in combination with AZA in patients with AML and MDS, potentially bridging the clinical study, pending approval by the NMPA, to a registrational clinical trial in patients with MDS.

Moreover, we are continuing to enroll more patients with relapsed or refractory CD20+ diffuse large B cell lymphoma (DLBCL) and follicular lymphoma in a combination clinical trial with rituximab (Rituxan®) in the U.S. This clinical trial includes clinical sites in China through an IMCT (international multi-center clinical trial) mechanism in order to potentially bridge, pending approval by the NMPA, to a registrational clinical trial in NHL in China.

In addition, we will participate in a global Phase 3 clinical trial to be led by AbbVie in patients with newly diagnosed AML patients who are unfit for intensive chemotherapy for registrational purposes globally by AbbVie and in China by I-Mab. The objective of this pivotal trial is to confirm the efficacy and safety of lemzoparlimab in combination with AZA and venetoclax (Venclexta®) in the aforementioned patient population to support a NDA data package for submission.

Solid tumors. We are continuing to advance the current cohort expansion study in the U.S. combining lemzoparlimab with pembrolizumab (Keytruda®) to evaluate the safety and efficacy in patients with NSCLC and ovarian cancer. The results of this on-going clinical study are anticipated in Q4 2021.With more clinical data from our ongoing U.S. study, additional clinical data reports from the competing clinical trials and, more importantly, our translational medicine study findings where specimens of various tumor types are analyzed for CD47 expression, we are in preparation of an IND submission to China’s NMPA to initiate a phase 2 “basket” clinical trial in patients with advanced solid tumors that are selected for a higher probability of success in the second half of 2021.

Combination with felzartamab to enhance the treatment efficacy of the current second-line or third-line treatment of MM. We believe that lemzoparlimab may work synergistically with other pathways in immuno-oncology to offer significantly better treatment efficacy. Pre-clinical data generated in house and reported by others support the hypothesis that lemzoparlimab may work synergistically with CD38 antibody for multiple myeloma, to offer significantly better treatment efficacy and potentially move to a first-line treatment option. A clinical trial will be initiated in the second half of 2021 in China to evaluate safety and clinical efficacy of combination therapy of lemzoparlimab with felzartamab in patients with multiple myeloma.

Current Development Status and Expected Milestones

(1) The on-going clinical trial with lemzoparlimab in combination with pembrolizumab in patients with NSCLC and ovarian cancers in the U.S. is on track to deliver preliminary results by Q4 2021; (2) A new clinical trial of lemzoparlimab in combination with PD-1 therapy in patients with selected solid tumors will be initiated in the second half of 2021 in China; (3) The combination study of lemzoparlimab with AZA in untreated AML and MDS patients is set to commence in Q2 2021 in China. Patient enrollment is expected to complete by Q4 2021; (4) The on-going NHL clinical study with rituximab, involving clinical sites in both the U.S. and China, is expected to have topline results by Q4 2021; and (5) The combination study of lemzoparlimab with felzartamab in patients with MM is planned to start in the second half of 2021 in China.

Uliledlimab (TJD5): A Potential Highly Differentiated CD73 Antibody for Cancer Treatment

Summary

Uliledlimab 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. Uliledlimab displays sub-nanomolar binding affinity to CD73 and inhibits its nucleotidase activity. *In vitro*, uliledlimab completely reversed the AMP- or tumor cell-mediated suppression of T cells. *In vivo*, when combined with a PD-L1 antibody, uliledlimab exhibited a superior or synergistic inhibitory effect on tumor growth. The key differentiation of uliledlimab 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, uliledlimab, if approved, has the potential to become a highly differentiated CD73 antibody. Since the IPO in January 2020, we have made extensive efforts to understand the structural basis underpinning the mechanism of action that leads to the differentiated properties of uliledlimab from those of other CD73 antibodies. The key findings of our latest mechanistic study were presented at the AACR 2021 annual meeting.

We have made significant progress in global clinical development of uliledlimab. In the U.S., we have completed the initial assessment of a Phase 1 clinical study where uliledlimab was evaluated as a monotherapy lead-in and followed by combination with atezolizumab (Tecentriq®) in patients with solid tumors. Topline results from this clinical study show that uliledlimab is safe and well tolerated at the dose range evaluated and demonstrate clinical activity in patients with advanced solid tumors. The topline results are expected to be presented at ASCO 2021 annual meeting.

In parallel, we are conducting a Phase 1/2 clinical trial in China to evaluate uliledlimab in patients with advanced solid tumors. The first patient was dosed in May 2020 and this study was accelerated by leveraging data from the ongoing Phase 1 clinical study of uliledlimab in the U.S. as described above. Currently, we are advancing the Phase 1/2 dose escalation and cohort expansion study of uliledlimab as a single agent and in combination with toripalimab (TUOYI®), a PD-1 antibody, in patients with advanced or metastatic cancers who are refractory to or intolerant of available therapies. In February 2021, the first patient in the combination study was dosed which was significantly ahead of the previous planned clinical development timeline.

Therapeutic Indications

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 uliledlimab 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 uliledlimab 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 small group of global companies are among the front-runner having active clinical development programs with CD73 antibodies. Oleclumab (MEDI-9447) from Medimmune and BMS-986179 from Bristol-Myers Squibb are the two most advanced CD73 antibodies for cancer therapy, which are in Phase 2 clinical trials. BMS-986179 is being studied as a single agent and in combination with nivolumab 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 or chemotherapy. CPI-006 (from Corvus) is being evaluated in a Phase 3 clinical trial for the treatment of hospitalized patients with COVID-19 and in a multi-center Phase 1 oncology clinical trial. NZV-930 (from Novartis) and AK119 (from AkesoBio) have entered Phase 1 clinical trials for the treatment of solid tumors. Most recently, Arcus Biosciences reported promising results in their Phase 1b/2 trial of AB928, a small molecule CD73 inhibitor, in patients with pancreatic cancer.

Advantages of Uliledlimab

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. Immunologically, in addition to the reversal of adenosine mediated T cell suppression, uliledlimab directly increased B cell activation and antigen presentation as evidenced by upregulation of CD69, CD83, CD86 and HLA-DR, which was unaffected by the addition of adenosine. Combination of uliledlimab with a PD-(L)1 antibody showed synergistic anti-tumor activities both *in vitro* and *in vivo*. More importantly, uliledlimab, 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".

In summary, uliledlimab has the following key advantages: (1) uliledlimab exhibits a typical dose-response curve without the "hook effect" and with a complete inhibition of both soluble and surface-bound CD73; and (2) uliledlimab 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 micro-environment. CD73 is the rate-limiting enzyme that generates adenosine from extracellular AMP. Uliledlimab 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.

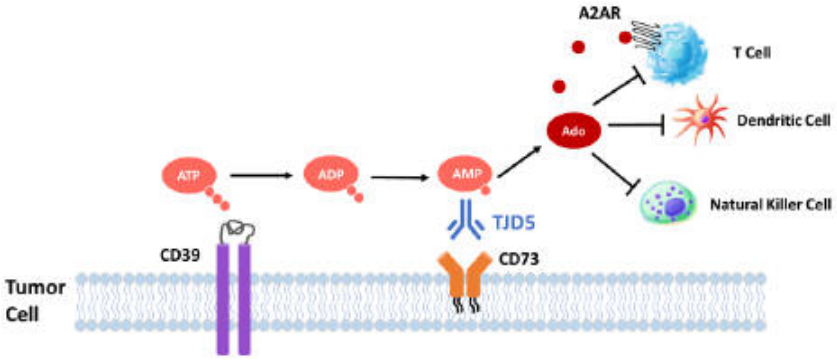


Figure: Schematic diagram of CD73-catalyzed adenosine (Ado) generation and immunosuppression by Ado in the tumor micro-environment.

Summary of Pre-clinical Results

Inhibition of CD73 by Uliledlimab. As shown in the figure below, uliledlimab 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.

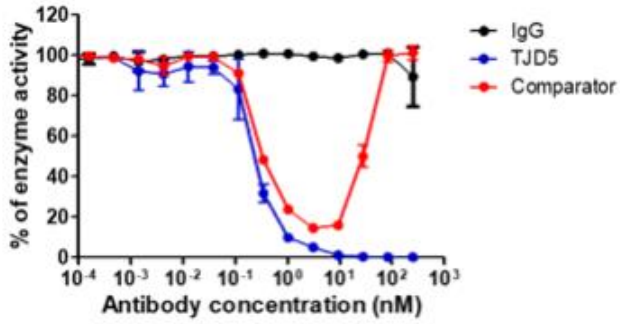


Figure: Inhibition of soluble CD73 enzymatic activity by CD73 antibodies.

Restoration of T Cell Activity by Uliledlimab 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 micro-environment where AMP is abundantly produced. However, this suppression could be reversed by uliledlimab 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 uliledlimab restored T cell activity as measured by IFN-g production in a concentration-dependent manner.

Stimulation of B Cell Activity Independent of Adenosine. In addition to the restoration of AMP mediated T cell suppression, we found that uliledlimab treatment could activate human B cells as evident by the up-regulation of activation markers CD69 and CD83 as well as antigen presentation markers CD86 and HLA-DR. As compared to T cells, the effects of uliledlimab on B cells were adenosine independent.

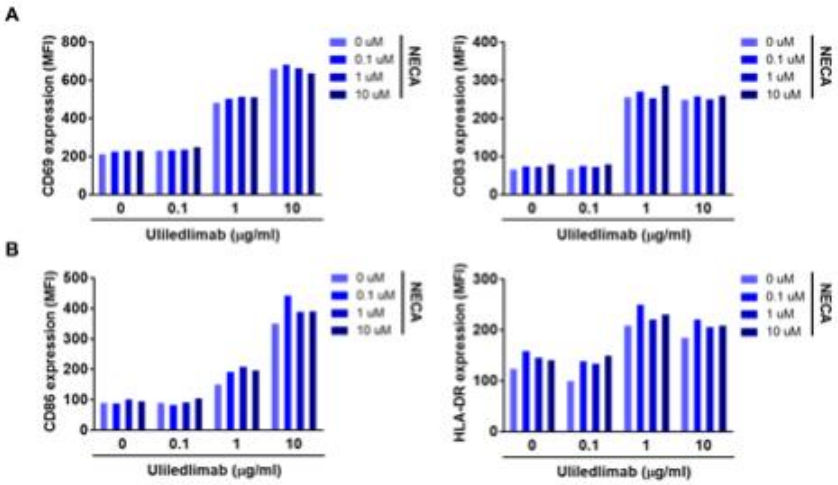


Figure: *Up-regulation of activation markers (A) and antigen presentation markers (B) on B cells by ulilediimab which was not affected by the addition of adenosine analog (NECA).*

In Vivo Anti-tumor Activity of Ulilediimab. Ulilediimab monotherapy inhibited in situ tumor derived CD73 activity, leading to the anti-tumor effect in a mouse xenograft model bearing A375 melanoma cells. To examine whether ulilediimab could enhance the anti-tumor activity of PD-1 or PD-L1 antibody, we evaluated the therapeutic effects of ulilediimab in combination with a PD-1 antibody in MC38 model using CD73 humanized mouse and PD-L1 antibody in the A375 xenograft model, respectively. The combination treatments resulted in stronger inhibition of tumor growth than monotherapy of PD-(L)1 antibody or ulilediimab.

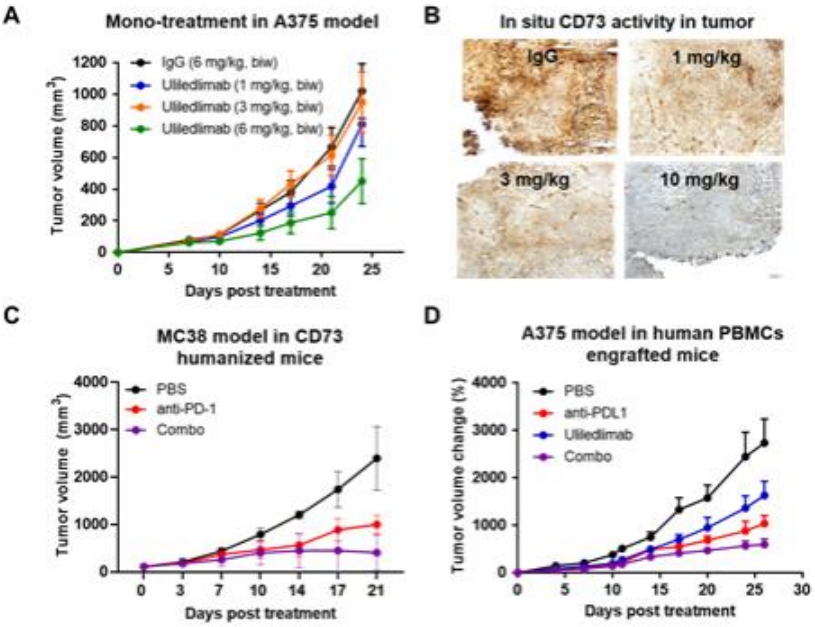


Figure: *Inhibition of tumor growth and in situ CD73 activity by ulilediimab alone or in combination with a PD-1 or PD-L1 antibody.*

Pharmacokinetics of Ulildlimab in Cynomolgus Monkeys. Following a single IV injection of ulildlimab at 5, 25 and 50 mg/kg, the mean C_{max} 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 ulildlimab with increasing dose. No apparent sex difference was observed in the main PK parameters. Positive ADAs against ulildlimab were detected in the majority of the animals, without an apparent impact on systemic exposure.

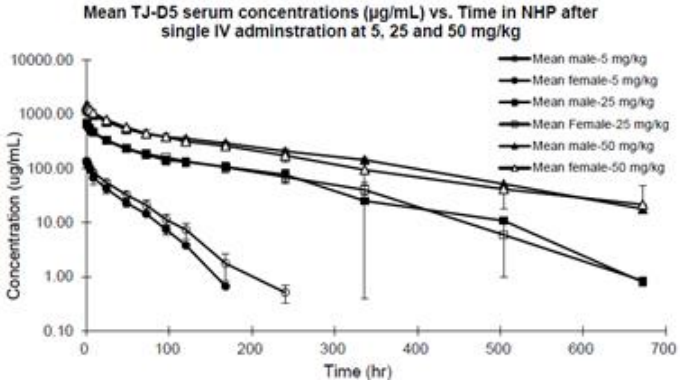


Figure: Concentration-time profile of ulildlimab in cynomolgus monkeys.

Repeat-dose Toxicology Study of Ulildlimab 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 ulildlimab. Forty cynomolgus monkeys were randomly assigned into four groups (5/sex/group) and given five weekly doses of ulildlimab at 20, 60 or 200 mg/kg via IV injection. Systemic exposures (C_{max} and AUC0-t) generally increased dose-proportionally, 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 ADAs against ulildlimab 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 ulildlimab-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 wellbeing 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 C_{max} and AUC values of 6,890 mg/ mL and 594,000 mg*hr/mL in males, respectively, and 6,450 mg/mL and 501,000 mg*hr/mL in females, respectively, on Day 22 of the dosing phase.

We presented the mechanistic analysis and pre-clinical data at 2021 American Association for Cancer Research (AACR) Annual Meeting. The key differentiation of ulildlimab when compared to other clinical stage antibodies of the same class, is related to its novel epitope. The differentiated mechanism of action works through a unique intra-dimer binding mode, resulting in a complete inhibition of the enzymatic activity while avoiding the aberrant pharmacological property known as the “hook effect”. With this differentiated mode of action, ulildlimab, has the potential to become a best-in-class CD73 antibody for its clinical advantages, if fully validated in the clinic.

Clinical Development Plan

We are rapidly advancing multiple clinical development programs of ulileclimab in the U.S. and China in parallel, leveraging the efficacy, biomarker analysis and safety data from both geographies to accelerate global development towards a pivotal clinical study in patients with selected solid tumor types. We plan to target different cancer indications in the U.S. and China based on unmet medical needs and registration pathways. In the U.S., we recently completed a Phase 1 clinical trial where the safety and efficacy signal of ulileclimab in combination with standard regimen of atezolizumab (TECENTRIQ®) were evaluated in patients with advanced or metastatic solid tumors. Topline results from the study showed that ulileclimab is safe and well tolerated at the dose range evaluated. The study also demonstrated clinical activity of ulileclimab in patients with advanced solid tumors. The clinical data set of this Phase 1 study has been selected for presentation at the 2021 ASCO annual meeting in June.

In China, a multi-center, open-label Phase 1/2 dose escalation and cohort expansion clinical trial of ulileclimab in combination with toripalimab (TUOYI®) is ongoing in patients with advanced or metastatic solid tumors. The study includes a dose escalation phase and a dose expansion phase. In the dose escalation phase, we will characterize safety, pharmacokinetic and pharmacodynamic profile of ulileclimab and explore preliminary clinical efficacy. In the dose expansion phase, we will continue to explore the clinical activities in different types of solid tumors and potential biomarkers in a "basket" trial design by leveraging the data from the ulileclimab trial in the U.S. One of the focused cancer indications is NSCLC, where we will look into the potential subpopulations, based on previous treatment lines, immuno-oncology treatment history and relevant biomarkers. Similarly, we will select a few other cancer types to be included in this basket clinical trial. We will test various relevant biomarkers, including adenosine-A2AR pathway markers, selected cytokines and gene signatures, to potentially correlate with clinical activity of ulileclimab. The overall results will guide us to rapidly advance clinical development towards a registrational study.

Current Development Status and Expected Milestones

In the U.S., we recently completed the Phase 1 clinical trial and plan to move forward with the cohort expansion study in 2021.

In China, we will complete the current dose escalation trial in Q2 2021 and present the preliminary efficacy and safety results at a scientific conference in the second half of 2021.

By leveraging the clinical data from the ulileclimab trial in the U.S., we have been facilitating the cohort expansion study of ulileclimab in combination with toripalimab (TUOYI®). The first patient dosing of this combination therapy was achieved in February 2021 and the study is on track with over 15 clinical sites involved in China.

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

Summary

Efineptakin alfa 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, efineptakin alfa is differentiated from an earlier generation of short-acting rhIL-7 and other T cell growth factor (e.g., interleukin-2). In December 2017, we acquired exclusive rights from Genexine to develop and commercialize efineptakin alfa in Greater China. Efineptakin alfa is positioned to meet unmedical need in two therapeutic areas of oncology. *Firstly*, it can potentially offer as a monotherapy or an oncology care product to cancer patients with 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 treatment-related lymphopenia, a clinical condition that weakens the anti-tumor activity of the immune system and the ability of the patients to continue required chemotherapy or radiation therapy, leading to worsened disease prognosis and poor clinical outcome. Currently, there is no treatment available for this condition. In May 2020, we obtained an IND approval from the NMPA and a Phase 2 clinical trial in GBM patients with lymphopenia is on-going.

Secondly, efineptakin alfa 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 efineptakin alfa 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 plan to initiate a Phase 2 combination clinical trial in the second half of 2021.

Therapeutic Indications

One of the target therapeutic indications of efineptakin alfa 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. Advanced solid tumor is another indication for efineptakin alfa as a combination therapy with PD-1 therapy. 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. Efineptakin alfa 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 therapies in the treatment of cancers and by the recent clinical data reported by Genexine (see elsewhere in this section).

Advantages of Efineptakin alfa

Efineptakin alfa has an advantage over other T lymphocyte cytokines with therapeutic potential in oncology. Pre-clinical and clinical results generated so far indicate that efineptakin alfa has a favorable immune function profile over recombinant human interleukin-2 (“rhIL-2”) in that efineptakin alfa 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 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 efineptakin alfa is a superior T cell cytokine investigational drug for cancer treatment-related lymphopenia and cancer immunotherapy.

Efineptakin alfa, 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 efineptakin alfa is also non-cytolytic, so it will not damage the T cells to which it binds. Unlike efineptakin alfa, 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. Efineptakin alfa as a monotherapy may enhance anti-tumor immunity by augmenting the number and functionality of T cells, whereas efineptakin alfa 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.

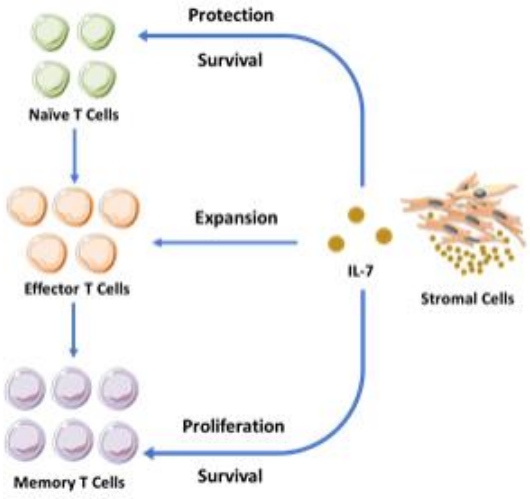


Figure: Role of IL-7 in T cell maintenance and proliferation.

Summary of Clinical Results

First-In-Human Phase 1a Trial in South Korea

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 efineptakin alfa via SC or intramuscular ("IM") administration in healthy volunteers. Each dose group consisted of 10 subjects, eight of whom were administered efineptakin alfa and two were given placebo via the same route of administration.

Safety. Efineptakin alfa 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 efineptakin alfa (see figure below). ALC initially decreased transiently in all efineptakin alfa 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 efineptakin alfa 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.

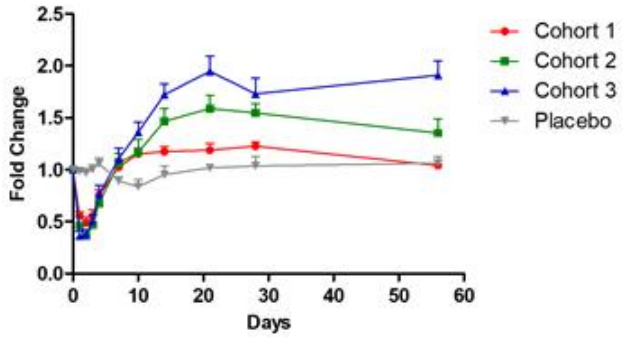


Figure: *Median fold changes of ALC following a single dose of efineptakin alfa in humans. Cohort 1: 20 ug/kg, SC; Cohort 2: 60 ug/kg, SC; and Cohort 3: 60 ug/kg, IM. (Source: Genexine)*

Efineptakin alfa 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.

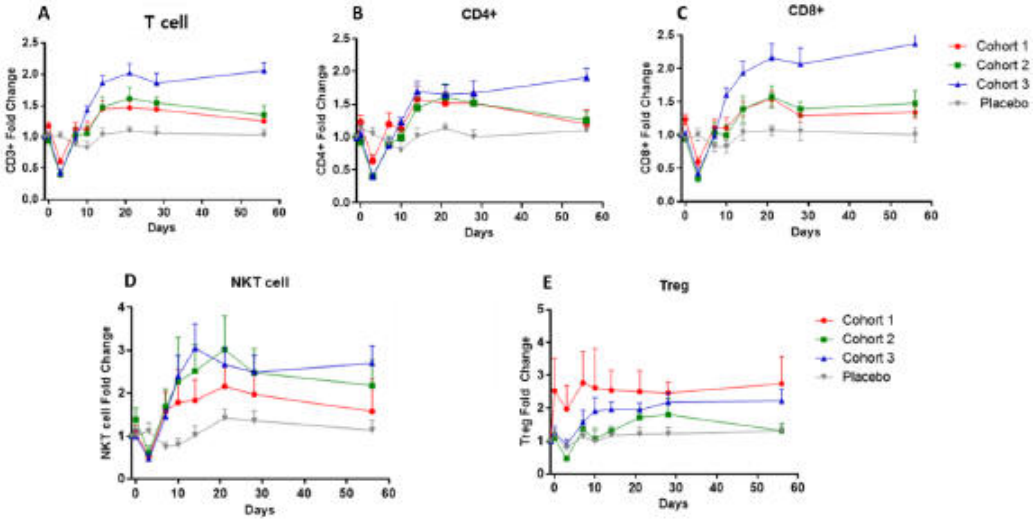


Figure: *Median fold changes of T cells and subsets following a single dose of efineptakin alfa in human subjects. Cohort 1: 20 ug/kg, SC; Cohort 2: 60 ug/kg, SC; Cohort 3: 60 ug/kg, IM. (A) CD3+T cells, (B) CD4+T cells, (C)CD8 + T cells, (D) Natural Killer T cells, and (E) regulatory T cells (Treg).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

Pharmacokinetics. Efineptakin alfa 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 efineptakin alfa showed approximately two-fold greater exposure than SC administration at the same dose level of 60 µg/kg. The higher plasma exposure of efineptakin alfa 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 efineptakin alfa. 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.

Phase 1b Trial in Cancer Patients in China

This two-part study is to evaluate the safety, tolerability, PK/PD profile, and anti-tumor activity of efineptakin alfa in Chinese patients with advanced solid tumors who progressed on or after standard therapy. Patients received efineptakin alfa every 4 weeks (in part A) or every 6 weeks (in part B) by intramuscular (IM) injection. Part A was a 3+3 design dose escalation from 240 µg/kg to up to 1200 µg/kg and was completed.

For part A, as of December 31, 2020, 16 patients (11 colorectal cancer, 3 gastric cancer, 1 nasopharyngeal carcinoma, and 1 laryngeal carcinoma) were enrolled and received efineptakin alfa treatment including 240 µg/kg (n = 3), 480 µg/kg (n = 3), 720 µg/kg (n = 4), 960 µg/kg (n = 3) and 1200 µg/kg (n = 3). No DLTs were reported and MTD was not reached. The most common TEAEs were transient lymphocyte count decrease (100%) which was likely due to IL-7-induced lymphocyte homing. Other common TEAEs were injection site reactions (93.8%) which recovered spontaneously or after topical treatment with antihistamines. Efineptakin alfa exposure (C_{max} and AUC_{last}) tended to increase dose proportionally in the range of 240-1200 µg/kg. Mean $T_{1/2}$ was consistent with results from Phase 1a. Dose-dependent increases in ALC and CD3+ T cells including naive and memory subsets were observed post first dose, while Treg cells were not significantly affected and CD4/Treg ratio was improved. More importantly, IFN-g secreting T cells were significantly amplified, suggesting enhanced anti-tumor potential after treatment. Based on these observations, 960 µg/kg and 1200 µg/kg were chosen for the ongoing part B expansion study, which is fully enrolled (n=12).

Phase 1b/2 Trial in TNBC Patients in the U.S. by Genexine

Our partner Genexine recently released new data from a Phase 1b/2 study of efineptakin alfa in combination with pembrolizumab (KEYTRUDA®) in patients with relapsed or refractory triple-negative breast cancer (TNBC) at 2020 SITC annual meeting. A total of 60 patients had been enrolled and treated with efineptakin alfa in combination with pembrolizumab with or without cyclophosphamide (“CPA”) chemotherapy. The median follow-up period of all treated patients (n=60) was 4.32 months (range 0.9–15.3 months) including 16 ongoing patients. The combination treatment of efineptakin alfa and pembrolizumab, with or without CPA, was safe and well tolerated. Combination (simultaneous treatment) of efineptakin alfa and pembrolizumab induced higher ORR (7/36, 19.4%) than sequential treatment of efineptakin alfa and pembrolizumab with CPA (2/24, 8.3%). In particular, the cohort (n=18) receiving 1,200µg/kg efineptakin alfa with pembrolizumab without CPA showed the highest ORR (27.8%, 5 PRs) with disease control rate (“DCR”) of 44.4% (5 PRs and 3 SDs). Of note, pembrolizumab monotherapy showed 5.3% ORR (KEYNOTE-086) in a Phase 2 study and failed to improve OS as ³ 2L treatment for mTNBC, compared to the standard chemotherapy.

Clinical Development Plan and Current Status

By leveraging the clinical results of Genexine’s ongoing clinical trials in South Korea and the United States, we aim to rapidly advance the clinical development of efineptakin alfa for approval in Greater China. Currently, a Phase 1b trial in China is about to complete. The study is designed to investigate the safety, tolerability and PK/PD response of efineptakin alfa in patients with advanced solid cancers. The clinical trial (NCT04001075) includes: (1) dose escalation of efineptakin alfa using a conventional “3 + 3” study design to identify a safe and active dose range which we have completed; and (2) dose expansion to confirm the safety and obtain preliminary evidence of efficacy for which we completed enrollment as of January 2021. The safety and tolerability profile as well as the PK/PD response are consistent with other ongoing studies of efineptakin alfa.

More importantly, our current clinical development plan is to focus on evaluating safety and efficacy of efineptakin alfa in cancer patients (1) as a broader oncology care treatment for those who suffer from lymphopenia commonly induced by chemotherapy and radiation therapy and (2) as a combination therapy with PD-1 therapy to achieve better clinical response and efficacy.

Cancers with lymphopenia. In December 2020, we initiated a phase 2 randomized, single-blind, placebo-controlled clinical trial (NCT04600817) to evaluate the safety and efficacy of efineptakin alfa in glioblastoma multiforme (GBM) patients with lymphopenia who have been treated with standard concurrent chemoradiotherapy. The study involves 160 patients who will receive either efineptakin alfa or a placebo once every eight weeks. The primary outcome of the study is the percentage of patients with an increase in the absolute lymphocyte counts and associated clinical response in relation to the treatment with efineptakin alfa. Our partner, Genexine, will share the clinical trial cost in return for an access to the clinical data.

Combination therapy with PD-1 therapy. By leveraging accumulative clinical data and experience with efineptakin alfa in the treatment of cancer patients in the U.S. and South Korea, including relapsed or refractory triple-negative breast cancer (TNBC), glioblastoma and high-risk skin cancer, we plan to submit a new IND in the second half of 2021 in China to initiate a Phase 2 combination therapy of efineptakin alfa with PD-1 therapy following a basket trial design to include selected tumor types, including TNBC.

Other Clinical Assets

Plonmarlimab (TJM2): A GM-CSF Monoclonal Antibody for Rheumatoid Arthritis and CRS-related Therapies

Summary

Plonmarlimab 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”). Plonmarlimab is a humanized IgG1 that displays high affinity binding to GM-CSF and blocks its signaling pathway and downstream effects. Plonmarlimab is being developed for the treatment of autoimmune and inflammatory diseases, including RA and cytokine release syndrome (“CRS”). We have completed a single-dose first-in-human study in healthy volunteers in the United States. In China, plonmarlimab is the first antibody of its class entering clinical development. We dosed the first patient in a Phase 1b study of plonmarlimab in August 2020 in China. We may expand plonmarlimab 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. If approved, plonmarlimab is expected to provide an effective treatment option as a disease-modifying anti-rheumatic drug (“DMARD”) therapy.

Since the COVID-19 outbreak, we have prioritized plonmarlimab in response to the urgent medical needs. In May 2020, we announced preliminary results from part 1 of a clinical study in the United States of plonmarlimab in patients with cytokine release syndrome (CRS) associated with severe COVID-19, in which plonmarlimab was found to be well tolerated. We are currently conducting part 2 of this clinical trial to evaluate the efficacy, safety and effects on cytokine levels following a single dose 6 mg/kg treatment of plonmarlimab or placebo (best supportive care) in patients with severe COVID-19.

Therapeutic Indications

Our initially focused therapeutic indication is RA, a chronic inflammatory disease that is characterized by 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. Plonmarlimab is one of the new biologics that potentially hold such a promise for the treatment of autoimmune diseases such as 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 plonmarlimab in treating these diseases, if initial studies in RA patients meet primary endpoints.

The therapeutic role of plonmarlimab 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 driver cytokines of CRS. Currently, there are no effective therapies to prevent CRS or associated 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 has 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 plonmarlimab as a treatment option for CRS associated with CAR-T therapy.

Furthermore, emerging data indicate that the common features among COVID-19 patients, particularly those who are severely or critically ill, include lymphopenia and significantly elevated serum levels of pro-inflammatory cytokines including GM-CSF, IL-6 and IFN-g. Moreover, recently published data indicate that COVID-19 can induce a cytokine storm instigated by extensive immune cell infiltration and the release of GM-CSF and IL-6. These inflammatory cytokines drive aberrant activation of monocytes and lymphocytes which in turn provoke increased production of more cytokines and chemokines in a feed forward cycle, resulting in the cytokine storm, or CRS, severe pulmonary complications and mortality. As IL-6 blocking antibody therapies failed in multiple trials in COVID-19, the current hope that targeting GM-CSF may impact the upstream of cytokine storm network to prevent or curb the hyperinflammation and immunopathology potentially associated with the complications of severe COVID-19.

Recently, Humanigen announced positive topline results from its Phase 3 clinical trial evaluating the efficacy and safety of lenzilumab in patients hospitalized with COVID-19. The study achieved its primary endpoint of ventilator-free survival measured through day 28 following treatment (HR: 1.54; 95%CI: 1.03-2.33, p=0.0365). The Kaplan-Meier estimate for invasive mechanical ventilation (“IMV”) and/or death was 15.6% (95%CI: 11.5-21.0) in the lenzilumab arm versus 22.1% (95%CI: 17.4-27.9) in the placebo arm, representing a 54% improvement in the relative likelihood of survival without the need for IMV. Although this study was not powered to demonstrate a statistically significant difference in mortality, a favorable trend in mortality was observed: 9.6% (95%CI: 6.4-14.2) in the lenzilumab arm compared with 13.9% (95%CI: 10.1-19.0) in the placebo arm (HR: 1.39; 95%CI: 0.82-2.39; p=0.2287). For our ongoing clinical trial with plonmarlimab in severe COVID-19, we have planned an interim analysis for safety and futility only in Q2 2021.

Advantages of Plonmarlimab

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 plonmarlimab thus far, the clinically active dose for plonmarlimab 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”).

Plonmarlimab 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.

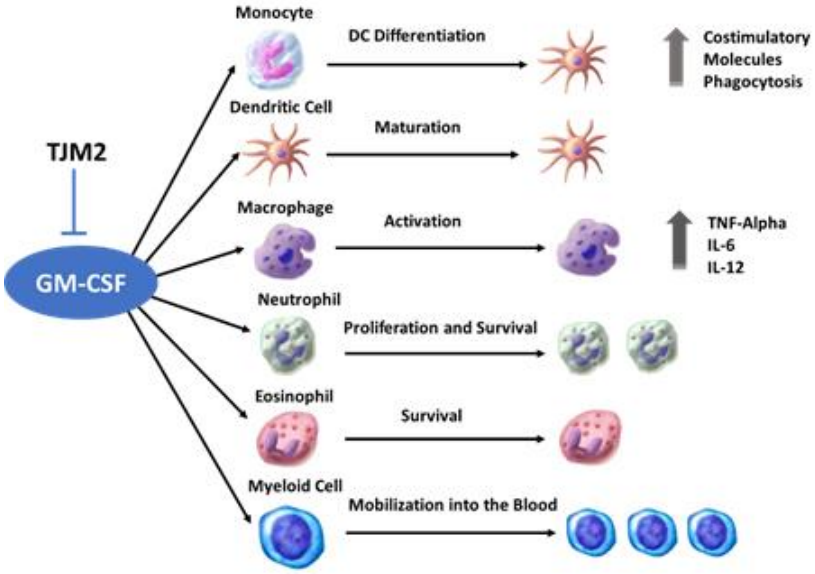


Figure: Role of GM-CSF in orchestrating coordinated immune response.

Summary of Pre-clinical Results

A series of nonclinical studies have been conducted to evaluate the pharmacology, PK, and toxicology profiles of plonmarlimab. Plonmarlimab could potently bind to human and monkey GM-CSF but not rodent GM-CSF. Plonmarlimab neutralized GM-CSF in a number of pharmacological studies in vitro and in vivo. Plonmarlimab 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 plonmarlimab treatment significantly reduced arthritis score and clinical symptoms in monkeys with established collagen-induced arthritis (a model of RA). Both 4-week and 13-week repeat-dose GLP general toxicology studies in non-human primates have been completed with sufficient safety margin. The nonclinical studies performed to date continue to support plonmarlimab in clinical studies.

Summary of Clinical Results

Completed single-dose first-in-human study in healthy volunteers in the U.S.

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 plonmarlimab (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 plonmarlimab and two receiving placebo IV infusions.

Safety. Plonmarlimab 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 plonmarlimab 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 plonmarlimab 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 plonmarlimab (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 C_{max} and exposure increased in an approximately dose-proportional manner, with C_{max} increased from 5.75 mg/mL to 260 mg/mL and AUC0-last increased from 90.5 day*mg/mL to 3780 day*mg/mL (see Figure below). In addition, $t_{1/2}$ was approximately 3 weeks across the tested dose range. Clearance of plonmarlimab decreased with increasing dose. Volume of distribution decreased slightly with increasing dose. In terms of immunogenicity, two subjects in the 3 mg/kg plonmarlimab cohort and 1 placebo subject were positive for ADA. No subject in the 10 mg/kg dose level was positive for ADA.

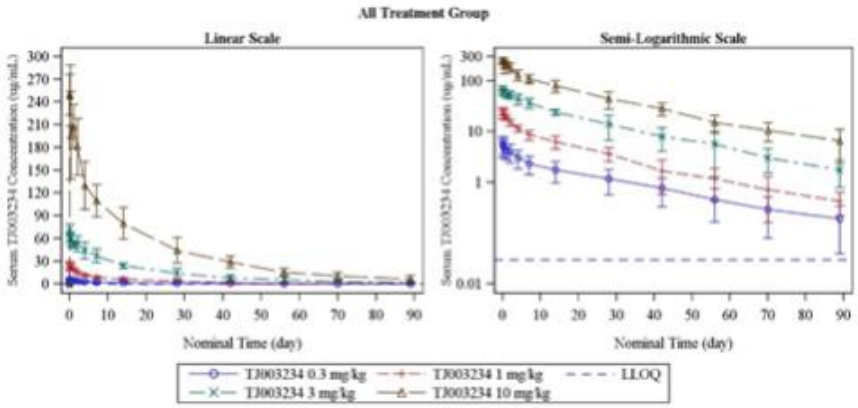


Figure: Mean±SD concentration-time plots of serum plonmarlimab (TJ003234) levels. Linear scale, left; semi-log scale, right. LLOQ, lower limit of quantitation.

Pharmacodynamics. Four hours after dosing, the induction of STAT5 phosphorylation by ex vivo GM-CSF in circulating monocytes was inhibited by at least 70% compared to the placebo following a single dose of plonmarlimab for all dose groups. Plonmarlimab inhibited GM-CSF-stimulated STAT5 phosphorylation 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 STAT5 inhibition by the treatment at doses of 3 mg/kg and above.

Ongoing study of plonmarlimab to treat COVID-19 patients with cytokine release syndrome

We are conducting a Phase 2/3 study of plonmarlimab in the U.S. in patients with CRS associated with severe COVID-19 (NCT04341116). This study adopts a robust clinical trial design and represents one of the first double-blind, placebo-controlled and randomized studies to evaluate the therapeutic role of anti-GM-CSF antibody in severe COVID-19 patients that could potentially lead to the registration of plonmarlimab in the U.S.

Part 1 of the study evaluated the safety and tolerability of plonmarlimab in a total of 24 patients who were randomized at a ratio of 1:1:1 to receive either a single dose of 3 mg/kg plonmarlimab, a single dose of 6 mg/kg plonmarlimab or placebo (standard care), administered by intravenous (IV) infusion. Data from part 1 of the study were reviewed by a data monitoring committee (DMC) to assess patient safety and tolerability. After comprehensive review and analysis, the DMC concluded that we could commence part 2 of the study as planned, indicating that plonmarlimab was safe and well-tolerated in severe COVID-19 patients in the study. The DMC also endorsed the recommended protocol changes, including broadening the inclusion criteria and dosing all patients at 6 mg/kg of plonmarlimab or placebo. Part 2 of the study with a design similar to part 1 targets the same patient population (N=360) and is enrolling patients. It will evaluate the efficacy, safety and cytokine levels following a single dose of 6 mg/kg plonmarlimab or placebo in patients with severe COVID-19. To preserve the original clinical trial design with blinding and data integrity, the clinical efficacy data will be revealed upon the planned interim analysis.

DMC's assessment and positive recommendation is a testament to our science-focused clinical development capabilities. The DMC's confirmation of plonmarlimab's safety profile bolstered the drug's potential to address the complications among the severe and critically ill COVID-19 patients and could ultimately save lives.

Clinical Development Plan

Data from the first-in-human study support continued development of plonmarlimab. In August 2020, we announced that the first patient had been dosed in a Phase 1b study to evaluate plonmarlimab in patients with RA in China. This trial is a multi-center, double-blind, placebo-controlled study of about 63 patients who will receive a single dose or multiple doses of the treatment for up to eight weeks. The single dose escalation part will be completed by the second half of 2021.

In addition, we are currently developing plonmarlimab for the treatment of cytokine storm in severe and critically ill COVID-19 patients. The part 2 of our clinical study is on track in the U.S. to evaluate the efficacy, safety and cytokine levels following a single dose of 6 mg/kg plonmarlimab or placebo (best supportive care) in patients with severe COVID-19. An interim analysis is planned when at least 100 subjects have finished Day 14 visits for safety and futility only, which is expected in Q2 2021. The results from this COVID-19 study will also be used to further evaluate the potential therapeutic role of plonmarlimab in reducing or preventing cytokine storm and neurotoxicity associated with CAR-T therapy through collaborations.

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

Summary

Olamkicept is the only clinical stage selective interleukin-6 ("IL-6") inhibitor that works through the trans-signaling mechanism. In November 2016, we acquired an exclusive license from Ferring International Center SA ("Ferring") to develop and commercialize olamkicept in Greater China and South Korea with an option of licensing worldwide rights. IL-6 is an important driver cytokine 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"), olamkicept 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. Olamkicept demonstrated therapeutic effects in pre-clinical animal models of autoimmune diseases, including inflammatory colitis. Moreover, the safety and tolerability profile of olamkicept was studied in three clinical trials in Germany involving 128 subjects. We believe that olamkicept has the potential to become a highly differentiated therapy to target autoimmune diseases.

As part of our fast-to-market strategy for olamkicept, we selected ulcerative colitis ("UC") as the first indication for the following reasons: (1) olamkicept was shown to be effective in animal models of colitis; (2) an exploratory Phase 2a biomarker trial showed promising interim treatment effects of olamkicept in UC patients; and (3) even though UC incidence is increasing rapidly, innovative biologic treatments for this disease are lacking in China. We have now completed a Phase 2 proof-of-concept study in 91 patients with active UC and announced positive topline results of the study in April 2021. The detailed data presentation has been submitted to professional meetings held at Digestive Disease Week (DDW) 2021 in the U.S. in May and at European Crohn's and Colitis Organization (ECCO) meeting in July 2021. In April 2021, we and Ferring signed a memorandum of understanding (MoU) to explore a possible collaboration to advance the development and commercialization of olamkicept in the U.S. and Canada, the European Union and Japan, if so agreed.

Therapeutic Indications

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 a4ß7 antibody that blocks lymphocytes from accumulating in the intestinal wall, was the first non-anti-TNF-α biologics approved for UC STELARA® (ustekinumab), an anti-IL-12/IL-23 antibody was approved for the treatment of adult patients with moderately to severely active ulcerative colitis in June 2020. In China, Remicade and Entyvio are currently the only two biologics 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. Thus, as the only clinical stage selective interleukin-6 ("IL-6") inhibitor that works through the trans-signaling mechanism, we believe olamkicept has the potential to become a differentiated IL-6 blocker for UC, if approved.

Advantages of Olamkicept

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. Olamkicept 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 olamkicept 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

Olamkicept 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, olamkicept works as a decoy by binding to a complex consisting of IL-6 and soluble IL-6 receptor ("sIL-6R"), thereby preventing olamkicept 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. Olamkicept is not expected to affect the beneficial effects of IL-6, such as the acute immune response against infection mediated by the classical pathway.

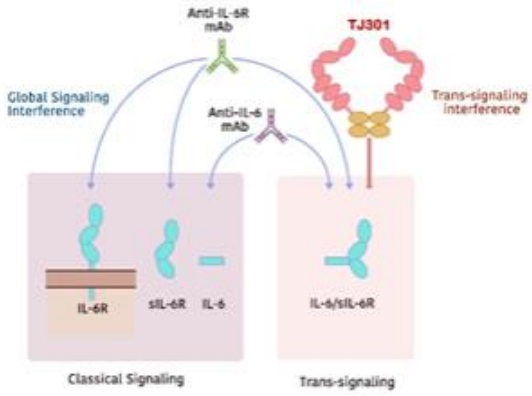


Figure: Classical signaling and trans-signaling pathways ofIL-6. Anti-IL-6R and anti-IL-6 block both pathways, whereas olamkicept blocks only trans-signaling. IL-6R: IL-6 receptor; sIL-6R: Soluble IL-6 receptor.

Summary of Clinical Results

Ferring has completed two Phase 1 trials to evaluate olamkicept's preliminary safety and clinical pharmacology. Olamkicept 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. We have now completed a Phase 2 proof-of-concept study in 91 patients with active UC in Greater China and South Korea.

Phase 1 Clinical Trial: Single Dose Ascending Trial

Study Design. The first-in-human trial of olamkicept 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 olamkicept. Several dose levels were tested, ranging from 0.75 mg to 750 mg, with each dose level including six subjects receiving olamkicept and two receiving placebo.

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

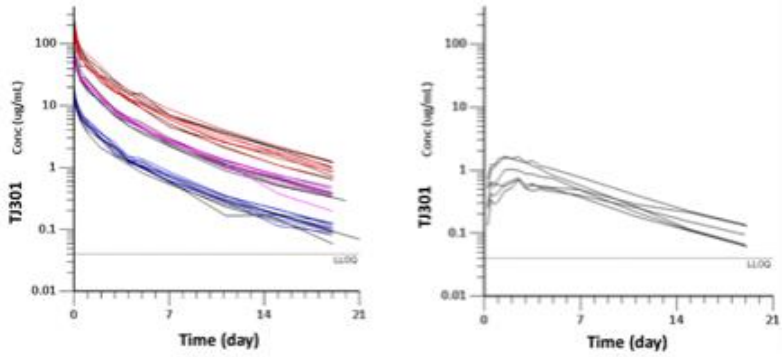


Figure: Single dose pharmacokinetic profile of olamkicept. Left, healthy subjects (colored lines) and IBD patients in remission (gray lines) received a single IV infusion at 75 mg (blue lines), 300 mg (magenta lines) or 600 mg (red lines) fixed doses. Right, healthy subjects received a single SC injection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

Safety. Olamkicept 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 olamkicept 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.

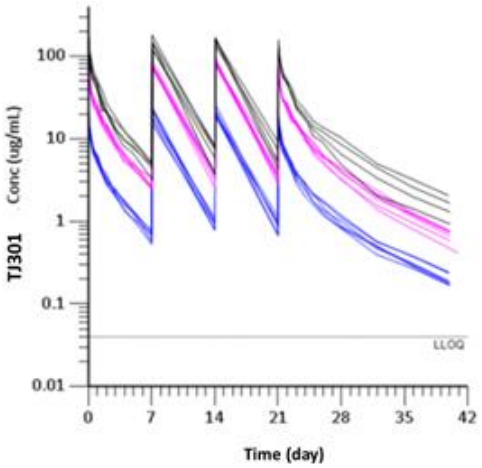


Figure: Multiple dose pharmacokinetic profile of olamkicept. Healthy subjects received weekly IV infusions at 75 mg (blue lines), 300 mg (magenta lines) or 600 mg (gray lines) fixed doses. LLOQ, lower limit of quantitation. (Source: Ferring Pharmaceuticals)

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, olamkicept 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 olamkicept in adult patients with active IBD. Nine UC patients and seven CD patients were dosed with olamkicept (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. Olamkicept 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 olamkicept.

Pharmacokinetics. After single and repeated IV administration of olamkicept (600 mg, Q2W) to patients with UC and CD, similar serum exposure was observed after the first and last dosing events, with respect to C_{max} 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 olamkicept after the last administration was approximately 5.1 days. Circulating biological activity of olamkicept 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.

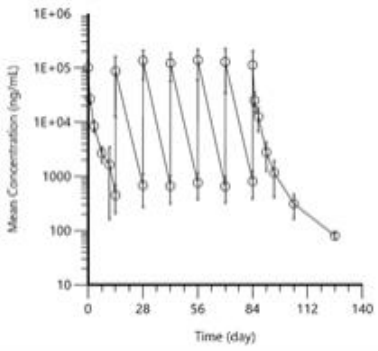


Figure: Time course of the mean serum concentration of olamkicept.

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 olamkicept, with 22% (2/9) reaching clinical remission, whereas 29% of CD patients (2/7) responded to olamkicept, 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.

Phase 2 Proof-of-Concept Study in Active UC (Multi-regional Clinical Trial)

Study Design. We are positioning olamkicept as a differentiated IL-6 blocker for the treatment of active UC that is not well-controlled by conventional therapies such as mesalazine. We have successfully completed a randomized, double-blind, placebo-controlled, dose-finding, proof-of-concept Phase 2 clinical trial for olamkicept in 91 patients with active UC in Greater China and South Korea (NCT03235752). This was a regional multi-center, randomized, double-blind and placebo-controlled study to evaluate the efficacy and safety of intravenous olamkicept (also known as TJ301) in adult patients with active UC. Overall, 91 patients were randomly assigned to receive biweekly treatment of placebo, 300 mg olamkicept or 600 mg olamkicept for 12 weeks in a 1:1:1 ratio. The primary endpoint was the proportion of patients achieving clinical response and the secondary endpoints included clinical remission and mucosal healing. Patients who were enrolled in the study had moderate to severe active UC (average full Mayo score 8.6) with a median disease duration of 4.6 years and with >95% having been on 5-ASA and >94% having had no prior biologics treatment.

Efficacy and Safety. This Phase 2 study is one of the first placebo-controlled, proof-of-concept studies of IL-6 inhibitors in UC and has met both its primary and key secondary endpoints, demonstrating significantly higher clinical response rates after 12 weeks of treatment in patients receiving 600 mg olamkicept compared to those on placebo ($p=0.032$). Significantly more patients in the 600 mg olamkicept group achieved clinical remission and mucosal healing than in placebo ($p<0.001$), which are two key secondary endpoints of the study. Olamkicept was well tolerated and showed an excellent safety profile that is considered to be the clinical differentiation of olamkicept because of its underlying mechanism of action. Detailed data analysis has been submitted to professional meetings held at Digestive Disease Week (DDW) 2021 in the U.S. in May and at European Crohn's and Colitis Organization (ECCO) meeting in July 2021.

Enoblituzumab: A Potential Highly Differentiated Humanized B7-H3 Antibody for Immuno-oncology Treatment

Summary

Enoblituzumab is an investigational, humanized, Fc-optimized monoclonal antibody directed at B7-H3, a member of the B7 family of immune regulators. B7-H3 is a promising immuno-oncology target as it is widely expressed across multiple tumor types, minimally expressed on normal tissues and is believed to play a key role in regulating immune response against cancers. Increasing pre-clinical and clinical evidence suggests that B7-H3 antibody and PD-1 antibody may work in concert to elicit an optimal T cell activation for the treatment of a variety of cancers. The expression of B7-H3 has been shown to be associated with adverse clinical features and negative outcomes in various solid tumors. Together, these observations suggest that enoblituzumab has a wide potential range of cancer applications as either a monotherapy or in combination with PD-1 therapies or small molecule drugs.

At the molecular level, enoblituzumab is engineered to possess an enhanced anti-tumor ADCC function. Originally developed by MacroGenics, enoblituzumab has been or is currently being evaluated in clinical trials as a monotherapy or in combination with CTLA-4 or PD-1 therapies in patients with B7-H3-expressing cancers. Enoblituzumab has also been 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, with enoblituzumab monotherapy treatment demonstrating increased CD8 T-cell infiltration in tumors with more focused T-cell repertoires. Clinical studies conducted by MacroGenics indicate that combination therapy with enoblituzumab and pembrolizumab resulted in anti-tumor activity on recurrent or metastatic squamous cell carcinoma of the head and neck ("SCCHN") and non-small cell lung cancer ("NSCLC").

We acquired Greater China rights of enoblituzumab from MacroGenics. In the first quarter of 2021, MacroGenics initiated a Phase 2 study of enoblituzumab in a chemotherapy-free regimen in combination with either retifanlimab (an investigational PD-1 antibody) in front-line patients with SCCHN who are PD-L1 positive or with tebotelimab (an investigational PD-1 x LAG-3 bispecific DART® molecule) in SCCHN patients who are PD-L1 negative. We expect to participate in a subsequent Phase 3 global study if and when initiated. In addition, we will initiate a combination clinical trial of enoblituzumab with a PD-1 therapy in selected cancer patients in the second half of 2021 and continue to generate additional pre-clinical data to position enoblituzumab in other combination therapies.

Therapeutic Indications

Squamous cell carcinoma of the head and neck ("SCCHN") is among the initial cancer indications which we will be focusing on. 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 antibodies were approved globally as second-line therapies. In 2019, Keytruda® (pembrolizumab from Merck & Co), used as a single agent or in combination with chemotherapy, was approved by the FDA as a first-line therapy for patients with metastatic or unresectable recurrent SCCHN. The average ORR for second-line therapies has been less than 15%.

In the first quarter of 2021, MacroGenics initiated an open-label, non-randomized Phase 2 study of enoblituzumab (NCT04634825) in a chemotherapy-free regimen in combination with either retifanlimab (an investigational PD-1 antibody) in front-line patients with squamous cell carcinoma of the head and neck (SCCHN) who are PD-L1 positive or with tebotelimab (an investigational PD-1 x LAG-3 bispecific DART® molecule) in SCCHN patients who are PD-L1 negative. The patients will receive enoblituzumab and retifanlimab or tebotelimab every 3 weeks for up to 35 cycles, and 80 patients in total will be enrolled. Based on the safety and efficacy data from the trial, we and MacroGenics will determine subsequent development options including a potential Phase 3 trial. We expect to participate in this subsequent Phase 3 global study if and when initiated. In addition, we plan to initiate an independent Phase 2 clinical trial of enoblituzumab in selected cancer types by a basket trial design, which is described later in this section.

Advantages of Enoblituzumab

Enoblituzumab is a potential highly differentiated humanized B7-H3 antibody for 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 therapy, 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 FcgRIIIA (CD16A) and decreased affinity for the human inhibitory FcgRIIB (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.

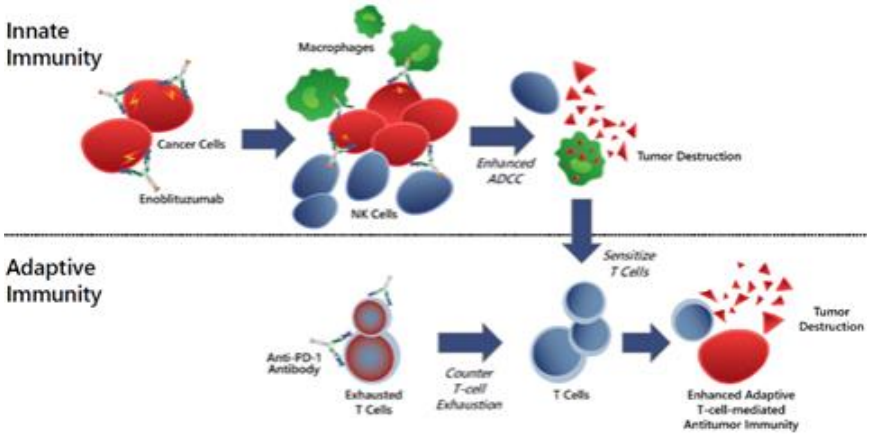


Figure: Enoblituzumab contributes to the coordination and engagement of innate and adaptive immunity to mediate tumor regression. Enoblituzumab binds to tumor cells, activates innate immune cells such as natural killer cells (NK cells) to kill cancer cells through ADCC. The released tumor antigens may 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 PD-1 monotherapy in 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

DRUG-RELATED AES (≥5% OF PATIENTS)	NO. (%) 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)	≥ 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

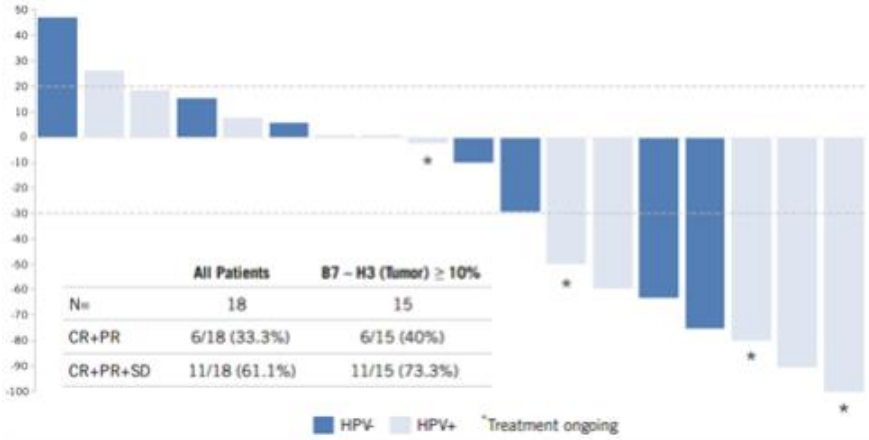
- *Drug-related AEs:*
  - Leading to treatment discontinuation: 6.8% (9 patients)
  - Leading to death: 0.8% (1 patient with pneumonitis)
- *Nature of events consistent with enoblituzumab or pembrolizumab alone*

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

Tumor Volume Change from Baseline (%)

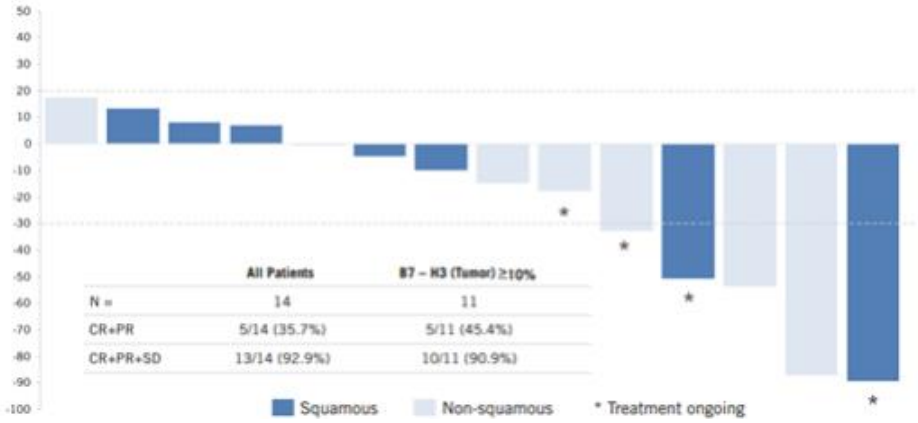


Source: MacroGenics

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 < 1%)

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 <10 mm; PR (partial response) means at least a 30% decrease in the sum of the target lesions, in comparison to the baseline sum diameter; PD (progressive disease) means a 20% increase in the sum of the diameters in comparison to the smallest sum of diameters with an absolute increase of at least 5 mm, provided that any new lesion is considered progressive disease; and SD (stable disease) means meeting neither the criteria for partial response nor for progressive disease, in comparison to the smallest sum of diameters.

Clinical Development Plan and Expected Timeline

By leveraging the clinical data from MacroGenics, we will advance the clinical development of enoblituzumab for approval in Greater China. In addition to planning on an advanced clinical trial in patients with SCCHN, following a potential global registrational study by MacroGenics, we will submit a new IND in Q2 2021 to initiate a Phase 2 clinical trial of enoblituzumab in combination with PD-1 therapy in patients with selected cancer types in China. The study is designed as a basket clinical trial involving NSCLC, SCCHN and two other selected cancer types based on the previous studies conducted by MacroGenics and our own pre-clinical work. Furthermore, we plan to evaluate the therapeutic role of enoblituzumab in combination with small molecule therapies as a potential front-line treatment for selected cancers. Additional pre-clinical work is in progress.

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

Summary

TJ210 is a fully human, high affinity antibody against human C5aR1 for the treatment of cancers and potentially autoimmune diseases. In November 2018, we obtained an exclusive license from MorphoSys to develop and commercialize TJ210 in Greater China and South Korea. Certain 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. TJ210 is designed to block the interaction between C5a and its receptor, thereby potentially neutralizing the immune suppressive function of C5a and enabling immune cells to attack the tumor.

Pre-clinical studies have shown that targeting the C5aR-C5a axis exerts anti-tumor activity with immune checkpoint inhibitors. Furthermore, in vitro activity was observed for blocking the C5a/C5aR pathway also at very high C5a concentrations, leading to a long duration of action. TJ210 demonstrated a good safety profile with no observed adverse effects up to the highest dose tested in non-clinical safety studies. In September 2020, we received an IND approval from the FDA to initiate a Phase 1 clinical trial to evaluate the safety, tolerability, PK and PD of TJ210 in patients with solid tumors. In January 2021, we dosed the first patient in this trial. A separate IND application with the China NMPA was also approved in February 2021. 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 plan to work jointly with MorphoSys to further explore TJ210’s potentials in these indications.

Therapeutic Indications

Traditionally regarded as the critical innate immune response, complement components, especially C5a/C5aR axis, has been demonstrated to be major contributors to immune suppression in the tumor micro-environment (“TME”) thereby disabling T cell function and promoting tumor progression. Correspondingly, blockade of C5a/C5aR signaling bears great potentials for cancer immunotherapy in combination with immune check pointers or T cell engagers. High expression of C5aR in TME is correlated with poor diagnostic outcomes in various tumors, including colorectal carcinoma, renal cancer, gastric cancer, and a number of squamous carcinomas. In addition, activation of complement cascade in those tumors either plays a critical role in cancer development or correlates with tumor grade and metastatic status. We will start with all tumor types in the Phase 1 trial, then select those bearing the above properties for further testing.

IPH5401, an anti-C5aR antibody, initially developed by Novo Nordisk then acquired by Innate Pharma, has been tested in a Phase 1/2 trial in combination with Durvalumab for patients with selected solid tumors. No further development was planned for IPH5401 which is tested to prevent excessive lung inflammation associated with ARDS in COVID-19 patients. Another antibody targeting C5a, IFX-1, developed by InflaRx, will initiate a Phase 2 trial on PD-1/PD-L1 resistant cSCC patients by the mid of 2021, alone and in combination with pembrolizumab.

Advantages of TJ210

TJ210 is a human IgG1 subclass monoclonal antibody that specifically binds to the C5aR and thereby blocks interaction with its ligand, the complement component 5a ("C5a"). Mutation to the IgG1 silent the Fc effector function. C5aR1 blocking plays an important role in the development and/or progression of various cancers and potentially autoimmune diseases. 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 competitor antibody IPH5401 from Innate Pharma, TJ210 shows a more potent functional response, especially when C5a concentrations are high, indicating a stronger potential for TJ210 at pathologic concentrations. Key results from pre-clinical studies show that TJ210 selectively binds to the N-terminus of C5aR1 with high affinity and is not cross-reactive to other related G-protein-coupled receptors ("GPCRs"). TJ210 also demonstrated a good safety profile of a 4-week repeat dose GLP toxicity study in cynomolgus monkeys, with no observed adverse effects up to the highest dose tested at 200mg/kg and no impact on neutrophils.

Mechanism of Action

TJ210 is a C5aR-directed antagonist monoclonal antibody. C5aR (also known as C5aR1 or CD88) is a GPCR and is one of the two high-affinity receptors for its ligand, C5a. An extensive investigation of the TME has uncovered molecular mechanism linking imbalanced complement activation and cancer progression. Upon activation, complement components including C5a is released into the TME, inducing recruitment of immunosuppressive cells including TAMs, TANs, MDSCs, Tregs and DCs thus inhibiting cytotoxic T-cell attack to the tumor. Immunosuppressive cytokines, such as Arg-1, IL-10 and TGF-ß, are also released. In addition, C5a can interact with its receptors to promote angiogenesis through an upregulation of growth factor and enhancement of endothelial cell proliferation. C5a generation through an autocrine manner or intracellular protease from cleavage of C5 produced by tumor cells can act on the surface receptors and induce signaling pathways such as PI3K-AKT, leading to promotion of tumor cell adhesion, proliferation, migration and stemness.

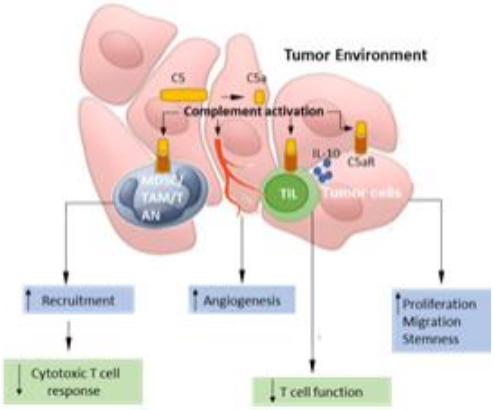


Figure: Role of C5a/C5aR axis in the tumor micro-environment.

Summary of Pre-clinical Results

TJ210 displays specific and high affinity binding to human C5aR1 (Figure A), and in vitro analysis reveals dose-dependent inhibition on neutrophil migration induced by C5a, with a mean IC_{50} and IC_{90} of 13.4 and 35.8 nM, respectively (Figure B).

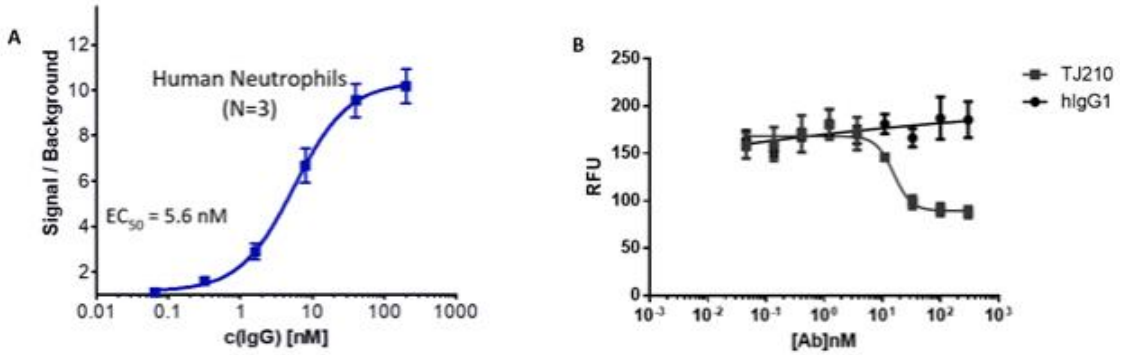
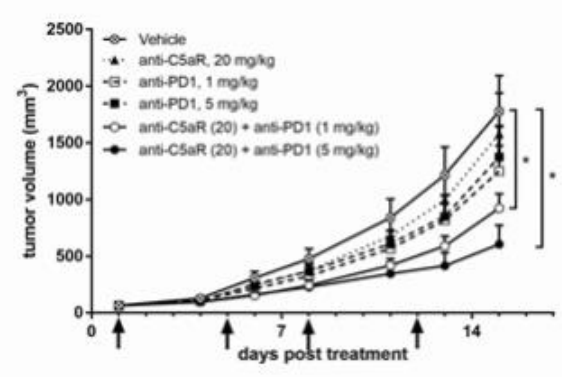


Figure: *A) Concentration-dependent binding of TJ210 to human neutrophils from three donors. FACS binding data were plotted as signal over background ratio versus TJ210 concentrations. B) Migration of freshly isolated human neutrophils towards C5a (1 nM) in a transwell assay system in the presence or absence of TJ210. Calcein-stained cells were measured at 485/538 nm to detect the fluorescent signal (RFU).*

Inhibition of C5a or its receptor C5aR in mice 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 multiple tumor models. The figure below shows that anti-PD1 and anti-C5aR combination treatment synergistically reduced tumor volume as calculated by the Q value in a syngeneic MC38 tumor model.



Group	Test articles	N	Dose level (mg/kg)	TGI (%)	Q value
1	Vehicle	6	-	--	--
2 (A)	anti-C5aR	6	20	11.56	--
3 (B)	anti-PD1	6	1	30.77	--
4 (A+B)	anti-C5aR + anti-PD1	6	20+1	**49.86***	**1.29**
5 (B)	anti-PD1	6	5	23.50	--
6 (A+B)	anti-C5aR + anti-PD1	6	20+5	**68.29***	**2.11**

Figure: *Synergistic anti-tumor activity of anti-C5aR mouse surrogate antibody and anti-mouse PD1 in syngeneic MC38 mouse tumor model. Top panel, MC38 tumor growth curve in mice treated with the indicated test articles (arrows indicate the time of i.p. injections twice a week. Asterisks indicate P<0.05 on day 15. Bottom table, group assignment and synergy determination. TGI, tumor growth inhibition. Synergy is determined by Q value, which is calculated by the formula TGI(A+B)/[TGI(A)+TGI(B)-TGI(A)*TGI(B)]. A synergy is found when Q is ³1.15, an antagonism is found if Q<0.85 and an addition is called if Q value is between 0.85 and 1.*

TJ210 exerts strong anti-tumor activity by blocking the activation and migration of C5aR1-expressing myeloid cells and has a highly differentiated potential, as it binds to a novel epitope and possesses superior functional properties. Compared to the only competitor antibody IPH5401 from Innate Pharma, TJ210 shows a more potent functional response, especially when C5a concentrations are high, indicating a stronger potential for TJ210 at pathologic concentrations.

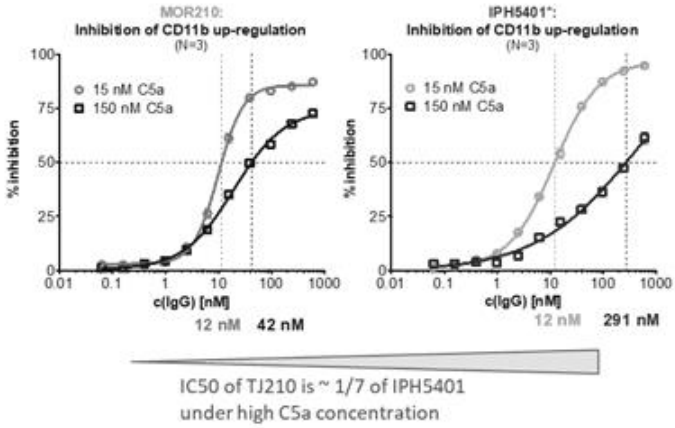


Figure: *Inhibition of C5a-induced CD11b upregulation by C5aR mAb in human whole blood assay. Briefly, heparinized blood was incubated with serial dilutions of TJ210 or IPH5401, and then human C5a was added (15 or 150 nM) and further incubated. Fluorescence was measured by FACS Array. Median fluorescence intensity (MFI) of the gated granulocytes or monocytes in the CD11b-PE channel was calculated. The inhibition curves were generated using GraphPad Prism via the nonlinear regression function.*

TJ210 is specifically designed to bind to C5a receptors in both humans and monkeys, making pre-clinical safety assessment possible. In the 4-week GLP toxicity study, cynomolgus monkeys tolerated TJ210 up to 200 mg/kg which is the no-observed-adverse-effect-level (NOAEL) in that study, without impact on neutrophils. TJ210 showed a linear PK profile in monkeys, with a half-life over 100 hours, consistent with a typical IgG1 monoclonal antibody.

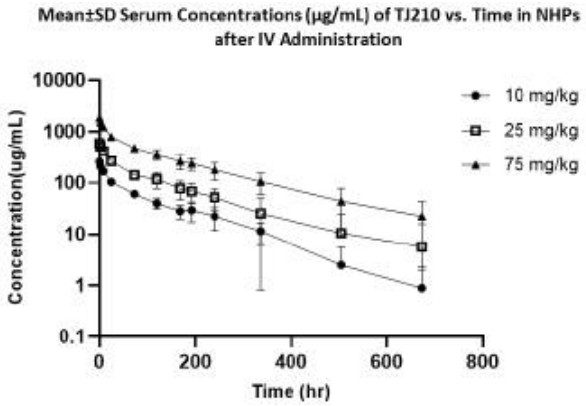


Figure: *Cynomolgus monkeys were administered a single IV injection of TJ210 at 10, 25 and 75 mg/kg. Blood samples were collected at multiple time slots for concentration-time analysis using a validated MSD method.*

Clinical Development Plan

In September 2020, the U.S. FDA approved our IND for TJ210 to initiate a Phase 1 clinical trial to evaluate the safety, tolerability, PK and PD of TJ210. In January 2021, we announced the dosing of the first patient in this trial to target completion of the patient recruitment by the end of 2021. The development program will evolve into further clinical combination studies of TJ210 with checkpoint inhibitors. A separate IND application with the NMPA in China was also approved in February 2021 and the trial will commence in 2021 as scheduled. 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 plan to work jointly with MorphoSys to develop this asset in the area of autoimmune disease.

TJ-CD4B: A Novel, Tumor-Dependent T Cell Engager for Gastric and Other Cancers

Summary

TJ-CD4B 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 whose expression is normally restricted to epithelial cells of the gastric mucosa, but becomes widely expressed in select tumors (such as gastric and pancreatic cancers), making it a highly attractive tumor target. Although a CLDN18.2 monoclonal antibody (zolbetuximab) 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-CD4B, which provides two key advantages over current CLDN18.2 antibodies and 4-1BB agonistic antibodies. First, TJ-CD4B (also known as TJ033721) 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-CD4B are T cells stimulated by the 4-1BB antibody moiety, making the 4-1BB antibody only active at the tumor site. This localized T cell activation conditional upon tumor engagement is expected to exert strong anti-tumor activity while dramatically reducing systemic side effects such as liver toxicity seen in clinical studies. In a humanized mouse model, a short course of TJ-CD4B treatment not only suppressed tumor growth to a greater extent than anti-CLDN18.2 or anti-4-1BB alone or in combination, but also displayed a memory response that resisted tumor re-challenge. We have completed pre-clinical work and have successfully obtained an IND approval from the U.S. FDA in the first quarter of 2021 to initiate a Phase 1 clinical trial in patients with cancers. A separate IND was submitted to China NMPA in April 2021 to commence a Phase 1 clinical trial in China.

Therapeutic Indications

Gastric cancer (GC) is one of the leading causes of cancer-related deaths worldwide. Treatment for advanced gastric or gastro-esophageal junction (GEJ) adenocarcinoma involves combination of chemotherapy, targeted therapies and now immune therapies. However, the clinical benefit has been modest, with an ORR ranging from 3% to 11%. Therefore, there is a huge unmet medical need for GC treatment. CLDN18.2 has been identified as a new GC tumor marker. Clinical data showed that over 70% GC patients in Asia and Europe are CLDN18.2 positive. The monoclonal antibody zolbetuximab can bind to CLDN18.2 on the tumor surface and stimulate tumor killing through ADCC and CDC. It has demonstrated clinical efficacy (and thus target validation) and was well tolerated when combined with standard chemotherapy in early clinical trials. However, the efficacy was still limited to CLDN18.2 high-expressing tumors. Apart from monoclonal antibodies such as the most advanced asset zolbetuximab which is in Phase 3, there are several CLDN18.2 antibody-based treatment modalities being developed with the hope of increased efficacy. These modalities include antibody-drug conjugates, CAR-Ts and CD3-based bispecific T cell engagers, most of which are still at the preclinical stage. However, despite their anticipated high efficacy, these treatment approaches are associated with significant safety concerns stemming from drug toxicity or immunotoxicity. CAR-Ts also face other challenges, such as limited tissue penetration and lack of persistence.

Advantages of TJ-CD4B

We believe that a carefully designed 4-1BB-based bispecific T cell engager such as TJ-CD4B can strike a proper balance between high efficacy and overall safety. First, TJ-CD4B is a more potent CLDN18.2 binder than zolbetuximab and binds to tumor cells with a wider spectrum of CLDN18.2 expression allowing it to target even the low expressors. Second, TJ-CD4B is equipped with a 4-1BB agonistic antibody moiety that strongly stimulates activated T cells and NK cells. Studies have shown that 4-1BB and CD28 are the strongest co-stimulatory molecules for anti-tumor activity but CD28 stimulation can lead to T cell exhaustion while 4-1BB prevents it, making 4-1BB the most desirable T cell co-stimulator. Moreover, unlike previous generations of 4-1BB agonist antibodies with hepatotoxicity issues, TJ-CD4B binds to a distinct 4-1BB epitope that only triggers 4-1BB signaling upon CLDN18.2 but not Fc receptor interaction. This unique tumor associated antigen (TAA)-dependent property is expected to drastically reduce peripheral T cell activation and hepatic and systemic immunotoxicity without compromising anti-tumor activity. These properties, if proven in the clinic, enable TJ-CD4B to be highly differentiated from other CLDN18.2-based compounds.

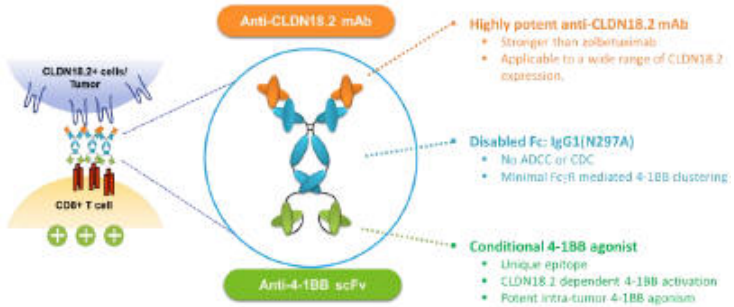


Figure: Schematic diagram of the overall structure of TJ-CD4B and its components. The 4-1BB agonistic antibody is a single chain Fv (scFv) connected to the C-terminus of a disabled Fc in a full anti-CLDN18.2 antibody via a flexible linker. The design allows the molecule to fit in the immune synapse (left) and trans-activate T cells only upon tumor cell binding.

Key Pre-clinical Results

Broad and potent binding to CLDN18.2-positive cells by TJ-CD4B. As shown in the figure below, TJ-CD4B consistently exhibited stronger binding than the reference antibody zolbetuximab in cells with high, moderate and even low levels of CLDN18.2.

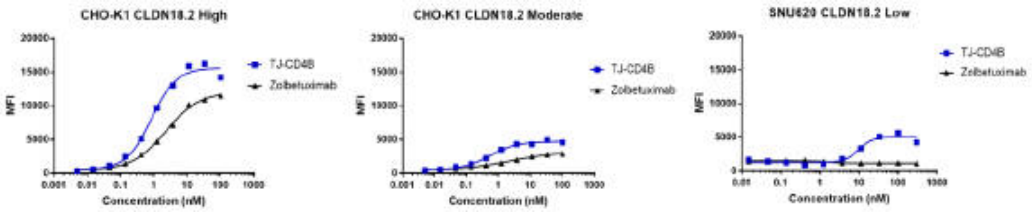


Figure: More potent binding by TJ-CD4B than zolbetuximab to cells expressing various levels of CLDN18.2.

CLDN18.2-dependent 4-1BB Activation and T Cell Activity by TJ-CD4B. The ability of TJ-CD4B to ligate 4-1BB and activate downstream signaling was tested in a co-culture of CLDN18.2-positive or negative target cells with T cells as effectors. The results in the figure show that TJ-CD4B elicited by far the strongest 4-1BB-mediated NF-kB reporter activity, only in the presence of CLDN18.2+ cells but not CLDN18.2- cells. In contrast, urelumab (first generation 4-1BB antibody) induced NF-kB reporter activity regardless of target cell CLDN18.2 expression. Importantly, 1A10, the parental 4-1BB antibody from which TJ-CD4B is derived, did not engender NF-kB reporter activity even in the presence of CLDN18.2+ cells, confirming a strict TAA-dependence on T cell activation. Dose-dependent CLDN18.2-restricted T cell activation by TJ-CD4B was further demonstrated in a PBMC-target cell coculture system by measurement of IL-2 production.

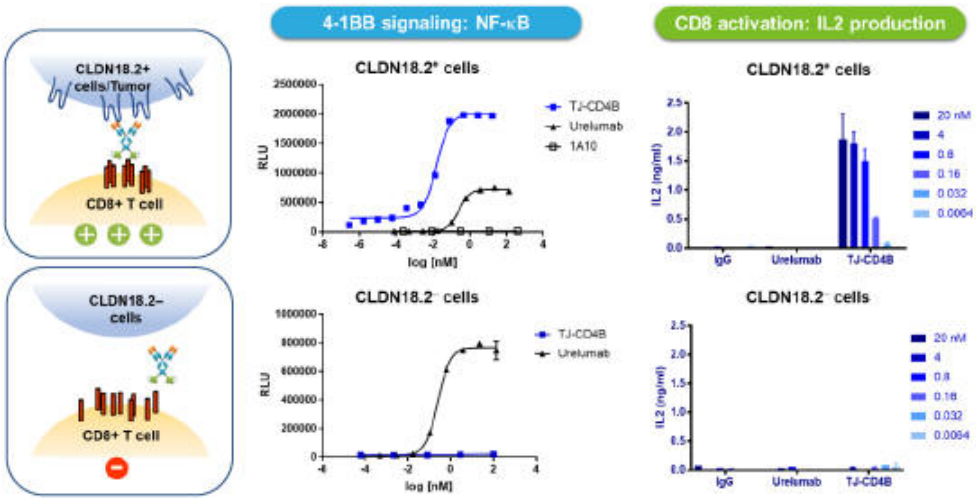


Figure: *Dose-dependent CLDN18.2-restricted T cell activity by TJ-CD4B but not urelumab in T cell and target cell co-culture system. Left, co-culture scheme; Middle, NF-kB reporter activity; Right, IL-2 production.*

In a further experiment where human PBMCs were co-cultured with gastric cancer cells derived from patient biopsies, TJ-CD4B was found to increase IL-2 production in a dose-dependent and CLDN18.2 expression-dependent manner.

Superior in vivo Anti-tumor Efficacy of TJ-CD4B. In mice grafted with tumor cells expressing human CLDN18.2, TJ-CD4B treatment twice a week for 3 weeks completely suppressed tumor cell growth in 6 out of 7 mice, delivering far better efficacy than equimolar doses of single agents alone or in combination. Remarkably, when these tumor-free mice were re-challenged with a second tumor implant a month after drug cessation, they remained totally protected, indicating that TJ-CD4B produced a durable anti-tumor response. Immune cell analysis revealed a significant increase in CD45+ and CD8+ T cells that infiltrated the tumor tissue after TJ-CD4B treatment but there were no changes in the periphery, suggesting that TJ-CD4B could turn cold tumor into hot tumor and the effect was localized. The anti-tumor efficacy of TJ-CD4B was dose-dependent with a minimal efficacious dose of 0.4 mg/kg.

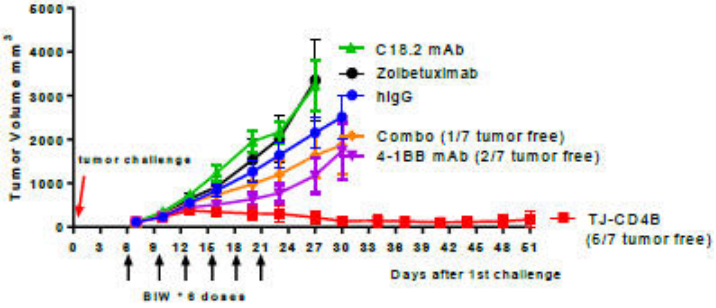


Figure: *Potent in vivo anti-tumor activity of TJ-CD4B in a mouse tumor model. Mice transgenic for humanized 4-1BB were grafted with MC38 cells expressing human CLDN18.2. Mice were treated with IgG or zolbetuximab as control, or with parental CLDN18.2 mAb, parental 4-1BB mAb or both, and with TJ-CD4B (4 mg/kg) twice a week for 3 weeks. All mAbs were dosed at the molar equivalent of 3 mg/kg.*

Preclinical summary. Animal PK and toxicity studies have been completed. Importantly, in the 4-week GLP monkey toxicity study, TJ-CD4B was well tolerated with no major findings. There was no liver toxicity noted, nor was there evidence of systemic immune activation. There were mild stomach changes that were considered on-target but non-adverse and were reversible. NOAEL was determined to be 100 mg/kg with a sufficient therapeutic window.

Clinical Development Plan

We have a comprehensive clinical development plan in execution to develop TJ-CD4B in the United States and China in parallel. In March 2021, we obtained an IND approval with the U.S. FDA for a monotherapy Phase 1 clinical trial in patients with advanced solid tumors including gastric cancer to investigate to assess safety, tolerability, PK, PD and preliminary efficacy. Our goal is to set forth to conduct dose escalation with a Bayesian optimal interval design before going into dose expansion by targeting specific cancers (gastric, gastroesophageal junction or GEJ, esophageal and pancreatic). In conjunction with the clinical study, we will evaluate the expression of CLDN18.2 in tumor biopsies with the aim to develop it as a potential companion diagnostic and clinical monitoring marker. Later in 2021, we will submit a separate IND to China NMPA to initiate a new clinical study focusing on patients with gastric, GEJ, esophageal and pancreatic cancers.

TJ-L14B: A PD-L1-Based Tumor-Dependent T-Cell Engager for Solid Cancers

Summary

TJ-L14B is a bi-specific antibody targeting both PD-L1 and 4-1BB and was developed in collaboration with ABL Bio. Also known as ABL503, it was designed to overcome limited efficacy by anti-PD-(L)1 and anti-4-1BB-related toxicity. Similar to TJ-CD4B, 4-1BB-stimulated T cell activity only occurs upon tumor cell binding by the anti-PD-L1 part of TJ-L14B. This localized T cell activation is expected to exert strong anti-tumor activity while reducing systemic side effects such as liver toxicity. In a humanized mouse tumor model, a short course of TJ-L14B treatment not only displayed greater anti-tumor efficacy than anti-PD-L1 or anti-4-1BB alone or in combination, but also showed evidence of immunological memory response that resisted tumor re-challenge. GMP material at 1000-L scale was successfully produced. We received IND approval from the U.S. FDA for a Phase 1 study for TJ-L14B in January 2021 and dosed the first patient in April 2021. We share the global rights with ABL-Bio except for Greater China and South Korea for which ABL-Bio has sole rights.

Therapeutic Indications

As stated before, new therapeutic options are urgently needed for PD-(L)1 relapsed or refractory cancer patients. One strategy is to maximize T cell activity by simultaneously turning off co-inhibitory pathways such as PD-1/PD-L1 and turning on co-stimulatory pathways such as 4-1BB, which is one of the most potent potentiators as discussed earlier. Indeed, several companies have been developing PD-L1 x 4-1BB bi-specific antibodies, and the most advanced are from Genmab, Inhibrx and Merus, all in Phase 1.

Advantages of TJ-L14B

We believe that based on publicly available information and preclinical studies TJ-L14B has the potential to be a highly differentiated PD-L1 and 4-1BB bispecific antibody. In terms of format, some of the leading compounds are monovalent heterodimers which may affect the potency of each arm and may encounter cumbersome CMC issues. In addition, as detailed earlier, the anti-4-1BB moiety of TJ-L14B binds to a novel epitope that only triggers 4-1BB signaling upon tumor binding leading to reduced cytokine release and hepatic and systemic immunotoxicity without compromising anti-tumor activity. TJ-L14B is also more specific than certain competitor molecules in terms of 4-1BB binding relative to other TNFR family of co-stimulatory molecules. These potential advantages, if proven in the clinical trials, could enable TJ-L14B to be highly differentiated from other competitor compounds.

Key Pre-clinical Results

PD-L1 level-dependent 4-1BB Agonism and T Cell Activity. The ability of TJ-L14B to ligate 4-1BB and activate downstream signaling was tested in a co-culture of PD-L1+ target cells with T cells as effectors. The results in the figure show that the level of NF-kB reporter activity elicited by TJ-L14B correlated with the level of PD-L1 expression on the target cells. In contrast, urelumab induced NF-kB reporter activity regardless of target cell PD-L1 expression. Importantly, TJ-L14B promoted the proliferation of CD8+ tumor-infiltrating lymphocytes obtained from human tumor samples in a similar extent to urelumab while the parental anti-PD-L1 and anti-4-1BB antibodies either alone or in combination had no effect, confirming a strict PD-L1-dependence on T cell stimulation by TJ-L14B.

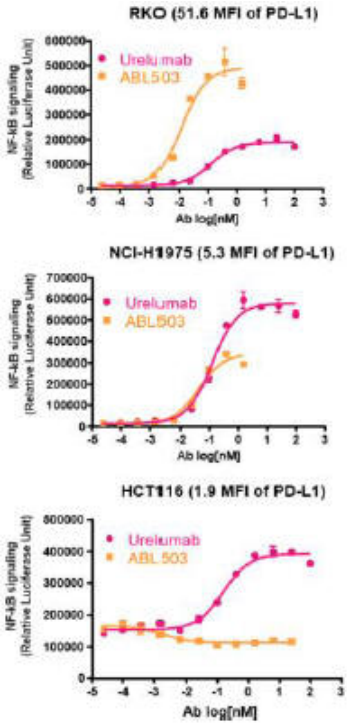
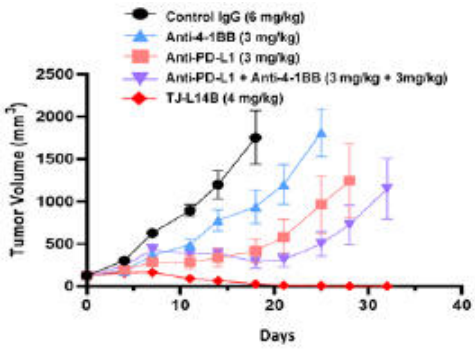


Figure: *Dose-dependent PD-L1-restricted T cell activity by TJ-L14B/ABL503 but not urelumab in a co-culture system of T cells and target cells expressing different levels of PD-L1 (as represented by mean fluorescent intensity (MFI) values).*

Superior in vivo Anti-tumor Efficacy of TJ-L14B. In mice grafted with tumor cells expressing human PD-L1, TJ-L14B treatment every 3 days for 4 times suppressed tumor cell growth in a dose-dependent manner, delivering far better efficacy than equimolar doses of single agents alone or in combination. Remarkably, when the treated tumor-free mice were re-challenged with a second tumor graft after drug cessation, they remained totally protected, indicating that TJ-L14B produced a durable anti-tumor response.



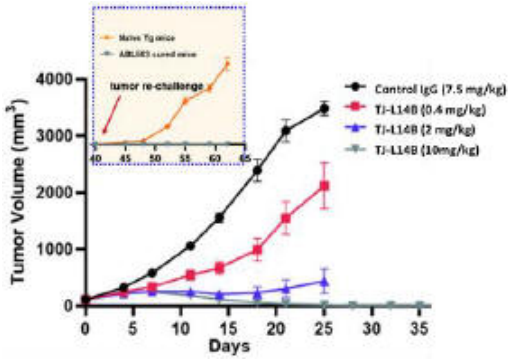


Figure: *Potent in vivo anti-tumor activity of TJ-L14B in a mouse tumor model. Mice transgenic for humanized 4-1BB were grafted with MC38 cells expressing human PD-L1. Mice were treated with the indicated antibodies every 3 days for 4 times. Tumor-free animals were re-challenged with a second dose of tumor on day 40 with treatment-naïve animals as control. TJ-L14B is also known as ABL503.*

Preclinical summary. In contrast to certain competitor PD-L1 x 4-1BB bispecific antibodies, TJ-L14B did not induce cytokine release (including IL-6 and TNF-α) up to 0.83 mg/ml, which corresponded to a human equivalent dose of 15 mg/kg. Animal PK and toxicity studies have also been completed. Results of these studies indicate that the NOAEL was 15 mg/kg/dose. This dose was also considered the highest non-severely toxic dose. A starting dose of 0.7 mg is proposed for the first-in-human (FIH) study. There is a >3000-fold safety margin between the proposed FIH dose and the nonclinical safety assessment studies including *in vitro* cytokine release assays and GLP toxicology studies.

Clinical Development Plan

TJ-L14B is being developed first for oncology indications in the U.S. An IND approval has been obtained from the U.S. FDA for a FIH, open-label, multicenter, multidose, dose escalation and expansion monotherapy study, which will assess safety, tolerability, PK, PD and preliminary efficacy in adult patients with any progressive locally advanced (unresectable) or metastatic solid tumors. Specific oncology indication(s) will be confirmed further. TJ-L14B will be administered IV on day 1 and day 15 of a 4-week treatment cycle. The first patient was dosed in April 2021.

Pre-Clinical Assets

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. We have completed IND-enabling studies and are in pre-IND consultations with the U.S. FDA on the path forward.

Other Bi-Specific Antibodies Under Pre-Clinical Development

We have, over the years, discovered and generated a panel of proprietary monoclonal antibody sequences that can be used to engineer bi-functional or bi-specific antibody molecules that are enabled with unique immunologic properties by dual targeting. The overarching goal behind these bi-specific molecules is to converge enhanced immune responses onto targeted tumor environment to convert immunologically non-responsive 'cold' tumors into responsive 'hot' tumors. TJ-L1C4 (PD-L1 and CD47), TJ-L1T6 (PD-L1 and TIGIT) and TJ-L1I7 (PD-L1 and IL-7) are dual-targeting bi-specific or bi-functional antibodies. There are designed to engage tumor cells to concentrate in tumor tissue through a common PD-L1 antibody arm and provide additional stimulation or activation of either T cells or macrophages through a second arm, i.e. CD47, TIGIT or IL-7. In a series of in vivo and in vitro studies, these bi-specific antibodies exert the unique properties to show an enhanced anti-tumor effect or to overcome the resistance of tumors to PD1/PD-L1 treatment, which are otherwise not achievable through either monoclonal antibodies or combination. We are in the process of validating these bi-specific antibodies in pre-clinical development.

TJ-C4GM is a "fortified" version or a next generation of CD47 antibody, which is specifically designed for the treatment of solid tumors through CD47-mediated macrophage killing mechanism. There is evidence that majority of tumor-associated macrophages residing in tumor belong to a tumor-promoting M2 phenotype rather than a tumor-killing M1 phenotype and are prone to resistance to CD47 antibody therapy. Thus, treatment of solid tumors with CD47 antibody alone may have limited efficacy because of the presence of M2 but not M1 macrophages that are required for anti-tumor activity. TJ-C4GM is a novel molecule composed of lemzoparlimab with an engineered GM-CSF moiety fused at the C-terminus of the antibody heavy chain. As GM-CSF is a potent cytokine known to convert M2 macrophages to M1 macrophages, TJ-C4GM is shown to exert a markedly increased phagocytic effect on solid tumors through a concert action by lemzoparlimab and GM-CSF. This unique functional property of TJ-C4GM is confirmed in a series of *in vitro* and *in vivo* studies where TJ-C4GM demonstrated a superior anti-tumor activity against solid tumors, which is not achieved by lemzoparlimab or GM-CSF used either alone or in combination. TJ-C4GM is under pre-clinical development.

Licensing and Collaboration Arrangements

A. In-Licensing Arrangements

Licensing Agreement with MorphoSys (Felzartamab)

In November 2017, we entered into a license and collaboration agreement with MorphoSys AG ("MorphoSys") with respect to the development and commercialization of felzartamab (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

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.

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.

In November 2018, we entered into an intellectual property license agreement with Genexine with respect to GX-G3 (TJ102). Under this agreement, Genexine granted to us 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 GX-G3 for the treatment of any disease in Taiwan and Hong Kong. We will also receive an exclusive license to use any improvements related to GX-G3 that Genexine develops or acquires free of charge in Taiwan and Hong Kong. Under this agreement, the scope of improvements is limited to GX-G3 and does not include the hyFc platform. We paid an upfront license fee of US$0.1 million and milestone payments of US$0.9 million to Genexine. No other milestone payments are due under this agreement.

Licensing Agreement with Genexine (Efineptakin alfa)

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.

In May 2020, we and Genexine entered into an amendment to this agreement, whereby both parties desire to establish a collaboration on TJ107 GBM Study in Greater China. Under the terms of the expanded collaboration, we will be mainly responsible for using commercially reasonable efforts to conduct the Phase 2 GBM clinical trial in Greater China, and Genexine will share the development strategies, data and costs for success of this clinical trial. As of December 31, 2020, the costs incurred for the development of this new indication was RMB4.2 million (US$0.6 million) and thus RMB2.8 million (US$0.4 million) was recorded in our audited consolidated financial statements for the year ended December 31, 2020.

Licensing Agreement with Ferring (Olamkicept)

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 U.S. 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 and milestone payment of US$1 million to MorphoSys. No other milestone payments or royalties are due under this agreement in the reporting period. 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

License and Collaboration Agreement with AbbVie

In September 2020, we, through our subsidiaries I-Mab Biopharma Co., Ltd. and I-Mab Biopharma US Limited, entered into a license and collaboration agreement with AbbVie Ireland Unlimited Company ("AbbVie") for the development and commercialization of certain compounds and products that target CD47, including lemzoparlimab (which targets a unique epitope of CD47).

Under this agreement, we grant AbbVie an exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize the licensed compounds and products (but excluding products that are directed to both a CD47 epitope that is not the same or substantially similar to the epitope targeted by lemzoparlimab and a non-CD47 target) anywhere in the world outside of Mainland China, Hong Kong and Macau, and to conduct development and manufacturing activities in Mainland China, Hong Kong and Macau to further AbbVie's commercialization of the licensed products outside of Mainland China, Hong Kong and Macau, except that, with respect to products containing either our preclinical CD47-PDL1 compound or our preclinical CD47-GMCSF compound, AbbVie will not develop, manufacture or commercialize such products until the parties come to financial terms on such products following AbbVie's exercise of its rights of first negotiation. We have granted AbbVie a license and cannot commercialize products containing our preclinical CD47-PDL1 compound or our preclinical CD47-GMCSF compound outside of Mainland China, Hong Kong and Macau even if AbbVie does not exercise its right of first negotiation or we are unable to come to financial terms on such products. We also grant AbbVie a co-exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize licensed compounds and products that are directed to both a CD47 epitope that is not the same or substantially similar to the epitope targeted by lemzoparlimab and a non-CD47 target (excluding such compounds and products that have been developed by us) anywhere in the world.

Under this agreement, AbbVie grants us an exclusive, royalty-free, sublicensable license under its technology and any joint technology developed under this agreement to clinically develop and commercialize in Mainland China, Hong Kong and Macau certain of the licensed compounds and products that (1) only target CD47, including lemzoparlimab, and (2) to the extent AbbVie exercises its rights of first negotiation for such licensed compounds and products, consist of our preclinical CD47-PDL1 compound or our preclinical CD47-GMCSF compound.

We are responsible for conducting certain initial development activities, at our cost and expense, following which AbbVie assumes the responsibility and costs for all development, manufacture and commercialization activities of the licensed compounds and products outside of Mainland China, Hong Kong and Macau. Under this agreement, AbbVie is required to use commercially reasonable efforts to develop, seek and obtain approval of, and commercialize at least one licensed product in at least two indications in the United States and at least three of the United Kingdom, France, Germany, Italy and Spain.

We are responsible for the development and commercialization of the licensed compounds and products in Mainland China, Hong Kong and Macau. We are required to use commercially reasonable efforts to develop, seek and obtain approval of, and commercialize at least one licensed product in at least two indications in mainland China.

During the term of the Agreement, we are not permitted to develop, manufacture or commercialize a compound or product that is directed (1) solely to CD47 or (2) to an epitope that is the same or substantially similar to the epitope targeted by lemzoparlimab, and AbbVie is not permitted to market a monoclonal antibody that is solely directed to a CD47 epitope that is the same or substantially similar to the epitope targeted by lemzoparlimab for an indication in any country where the licensed product has received regulatory approval for such indication. Additionally, during the first five (5) years after the first commercial sale of a licensed product outside of Mainland China, Hong Kong and Macau, AbbVie will not market any monoclonal antibody solely directed to CD47 for an indication in any country where the licensed product has received regulatory approval for such indication in such country. AbbVie's exclusivity restrictions will not prevent it from marketing an antibody that demonstrates additive or synergistic effects in combination with a licensed product, or an improvement on a licensed product based on improved efficacy or safety data.

Under this agreement, we and AbbVie formed a joint governance committee that consists of three representatives from each of us. The joint governance committee will oversee and coordinate the development of the licensed compounds and products in both of our territories, including the review and approval of each of our respective development plans, the review and approval of clinical trials and commercialization in Mainland China, Hong Kong and Macau, and discussing commercialization strategies in each of our territories. The joint governance committee may create working groups as it deems appropriate.

Under this agreement, AbbVie has paid us an upfront payment of US$180 million and milestone payment of US$20 million. Based on the achievement of certain clinical development and regulatory milestones, including first commercial sales in various markets, we may earn additional milestone payments of up to US$840 million. Further, based on the achievement of certain sales-related milestones, we may earn additional milestone payments. In addition to the upfront and milestone payments that we may earn, we may also earn tiered royalties consisting of low-to-mid teen percentages of global net sales.

We will not owe any milestone payments for our development or commercialization in Mainland China, Hong Kong and Macau, but we are required to pay AbbVie tiered royalties in the mid-to-high single-digit percentages of net sales of licensed products in those countries.

Under this agreement, we grant AbbVie several rights of first negotiation with respect to our products, including a right of first negotiation to exercise its right to products containing either our preclinical CD47-PDL1 compound or our preclinical CD47-GMCSF compound outside of Mainland China, Hong Kong and Macau. This right of first negotiation is exercisable following completion of preclinical activities sufficient to initiate IND-enabling, GLP-conforming animal toxicology studies, and if AbbVie exercises this right, the parties shall negotiate an amendment to allow AbbVie to develop, manufacture and commercialize that product in exchange for additional regulatory and sales milestones that could equal or exceed US$500 million plus royalty payments.

We also grant AbbVie other rights of first negotiation for rights to commercialize: (1) our preclinical CD47-PDL1 compound or our preclinical CD47-GMCSF compound in Mainland China, Hong Kong and Macau; (2) our multi-specific or bi-specific licensed compounds that contain a targeting moiety that is directed to both an epitope on CD47 that is not the same or substantially similar to the epitope targeted by lemzoparlimab and a non-CD47 target, as well as any products containing such compounds anywhere in the world; and (3) each licensed product that contains a licensed compound as its sole active ingredient that is directed solely to CD47 in Mainland China, Hong Kong and Macau.

AbbVie grants us a right of first negotiation for rights to: (1) commercialize its multi-specific or bi-specific compounds that contain a targeting moiety that is directed to both an epitope on CD47 that is not the same or substantially similar to the epitope targeted by lemzoparlimab and a non-CD47 target, as well as any products containing such compounds in Mainland China, Hong Kong and Macau; and (2) develop and commercialize licensed compounds as part of combination products (other than products that contain a licensed compound directed against both an epitope on CD47 that is not the same or substantially similar to the epitope targeted by lemzoparlimab and a non-CD47 target) in Mainland China, Hong Kong and Macau.

This agreement may be terminated by either party in the event of an uncured material breach. If the material breach and failure to cure is by AbbVie with respect to some countries, but not others, we have the right to terminate this agreement solely with respect to the countries to which the breach relates. If the material breach and failure to cure is by us with respect to our obligations in Mainland China, Hong Kong and Macau, AbbVie will have the right to reduce payments to us by a certain percentage.

AbbVie has certain termination rights if it determines not to continue development and commercialization based on documented safety concerns. AbbVie may also terminate this agreement in part or in whole for convenience following prior written notice of a certain period. AbbVie may also terminate this agreement immediately following certain breaches by us of anti-bribery and anti-corruption laws. AbbVie also has termination rights related to the approval process under the Hart-Scott-Rodino Antitrust Improvements Act. If we stop material clinical development and commercialization activities in Mainland China, Hong Kong and Macau without justification, AbbVie may reduce any royalties that would have been due to us by a certain percentage.

If AbbVie stops material clinical development and commercialization activities without justification, we may terminate this agreement. We also have certain termination rights if AbbVie or its affiliates challenge our valid patents related to the licensed products.

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 (乐普生物). 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: uliledlimab, 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, Israel, Jordan, Kuwait, Lebanon, Malta, Morocco, Oman, Qatar, Saudi Arabia, Tunisia, United Arab Emirates, and Palestine) regions, as well as Sri Lanka. If and when we and KG enter into the definitive licensing agreement for uliledlimab, we will be eligible to receive from KG an aggregate amount of up to approximately US$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

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$1.0 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 (i) co-develop our proprietary CD73 antibody, TJD5 (the "TJD5 Agreement") and (ii) collaborate to co-develop up to five bispecific antibodies (the "BsAbs Agreement"). Both agreements may be terminated by either party for the other party's uncured material breach, bankruptcy or insolvency or for other reasons. In April 2020, Tracon issued a notice of disputes with respect to the TJD5 Agreement and the BsAbs Agreement. As of the date of this annual report, these disputes have not been resolved. In February 2021, we sent Tracon a notice to terminate the TJD5 Agreement, which would result in a prespecified termination fee of US$9.0 million owing to Tracon.

In March 2021, we entered into two collaboration agreements with Complix, an EU-based biotech company (the "Complix Agreement"), and Affinity, a Shanghai-based biotech company (the "Affinity Agreement"), respectively, allowing us to access cutting-edge technology platforms to create next generation of novel and highly differentiated drug candidates, including Cell Penetrating Alphabodies ("CPAB") for otherwise intractable intracellular drug targets and masked antibodies for targeted tumor-site activation. Under the Complix Agreement, both parties will collaborate to discover, develop and commercialize novel therapeutics for mutually agreed targets based on the Complix's proprietary technology. Under the Affinity Agreement, both parties will collaborate to develop lead compounds for mutually agreed targets based on Affinity's Tumor MicroEnvironment Activated body ("TMEAbody") platform technology.

In March 2021, we entered into a license and collaboration agreement with Genbase, a Shanghai-based biotech company to develop bi-specific antibodies or/and multi-specific antibodies using antibody sequences from both companies. Under this agreement, Genbase granted to us a non-transferable, sublicensable, and royalty-bearing license under Genbase parental antibody technology and Genbase parental antibody improvements owned and controlled by Genbase to make, develop and commercialize the licensed compounds and licensed products in all uses and indications worldwide.

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, 2020, our owned patent portfolio consists of (i) 22 issued patents, including six issued in the U.S., six issued in the PRC, five issued in Korea and five issued in other jurisdictions; and (ii) 241 pending patent applications, including 18 PCT patent applications, 18 U.S. patent applications, 16 PRC patent applications and 211 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, 2020, we in-licensed the Greater China and Korea rights relating to (i) 24 issued patents, including fourteen issued in the PRC, one issued in Korea, seven issued in Hong Kong and two issued in Taiwan; and (ii) 31 pending patent applications, including four PCT patent applications, nine PRC patent applications, nine Hong Kong patent applications, six Taiwan patent applications, two Korean patent applications and one Macau patent application. The in-licensed patents and patent applications primarily relate to felzartamab, eftansomatropin alfa, olamkicept, enoblituzumab and efineptakin alfa.

Felzartamab	As of December 31, 2020, we exclusively licensed from MorphoSys ten issued patents (including six issued in the PRC, three issued in Hong Kong and one issued in Taiwan) and ten pending patent applications (including two PCT applications, two in the PRC and three in Hong Kong, two in Taiwan and one in Macau) relating to felzartamab. 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 2040, 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.
Eftansomatropin alfa	As of December 31, 2020, we (i) exclusively licensed from Genexine two pending PRC patent applications directly relating to eftansomatropin alfa and (ii) exclusively licensed from Genexine three issued patents in the PRC relating to a hyFc platform that develops eftansomatropin alfa. 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.
Olamkicept	As of December 31, 2020, we exclusively licensed from Ferring two issued patents in the PRC and Korea relating to olamkicept and six patient applications in the PRC, Hong Kong and Korea relating to olamkicept. 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, 2020, 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.
Efineptakin alfa	As of December 31, 2020, we (i) exclusively licensed from Genexine one pending PRC patent application directly relating to efineptakin alfa and (ii) exclusively license from Genexine three issued patents in the PRC relating to a hyFc platform that develops efineptakin alfa. 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.
Plonmarlimab	As of December 31, 2020, we owned one PCT patent application that relates to plonmarlimab and it has entered national phases in China, the United States and 24 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.
Lemzoparlimab	As of December 31, 2020, we owned two PCT patent application, one of which has entered national phases in the PRC, the United States and 26 other jurisdictions, and the other has entered national phase in the United States and the PRC. 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.
Ulileddlimab	As of December 31, 2020, we owned one PCT patent application and it has entered national phases in the PRC, the United States, and 24 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, 2020, we had (i) three registered trademarks in Hong Kong, 16 registered trademarks in the PRC, two registered trademarks in the United States, 43 trademark applications in the PRC, 14 trademark applications in Hong Kong, 17 trademark applications in Macau, 16 trademark applications in Taiwan and four trademark applications in the United States; (ii) 12 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 “Risk Factors—Risks Related to Our Intellectual Property.”

Enterprise Social Responsibility

As an integral part of our business and as a core value, we strive to make a positive impact around the world through the transformational medicines that we research, develop, manufacture and deliver. We are committed to reflecting ethical, social and environmental responsibilities in our business decisions, ensuring that our products improve people’s lives and maintaining the sustainability of our business.

Our contribution to improving healthcare and alleviating suffering was evidenced by our work responding to the COVID-19 outbreak. We joined the global effort by initiating the development of plonmarlimab to treat cytokine storm in severely ill patients with COVID-19. Cytokine storm is characterized by a surge of 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 complications in COVID-19 patients. Research indicates plonmarlimab may be a potential treatment for cytokine storm associated with COVID-19 because the antibody effectively neutralizes circulating GM-CSF to control acute inflammatory responses, with potential advantages over conventional IL-6 antibodies. We received IND clearance from the FDA in April 2020 and our study commenced initially in the United States. Following a safety assessment of the first part of the study, a Phase 2/3 trial is ongoing in patients with cytokine release syndrome associated with severe COVID-19. Initial data indicated that plonmarlimab is safe and well-tolerated in the severe COVID-19 patients in the study.

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 implemented employee caring programs to provide health supplies and demonstrated support for the global I-Mab family.

To help medical communities and health care providers in different parts of the world understand the experiences treating and managing severe COVID-19 patients, we, in collaboration with American Academy of Medical Education and Ding Xiang Yuan, a leading medical media in China, brought together nine distinguished clinical experts from China and the U.S. in April 2020 for a virtual webinar to share insights and important lessons from the frontlines.

We have also been on the forefront to promote diversity and inclusiveness in the workplace. In 2020, we launched the Women's Leadership Council ("WLC") globally to support the organization's future female leaders to accelerate their career and personal development. We organized our global WLC ambassador program and selected eight outstanding female employees to champion our mission of elevating women in scientific leadership.

International Recognition and Awards

The remarkable achievements made by us are well recognized by the international community of pharma industry. We received numerous international awards and citations in 2020 in recognition of our achievements in drug innovation, industry leadership, cross-border collaboration and successful business achievements. We, along with our partner AbbVie, received the Deal of the Year award from BioCentury-Bay Helix for our global strategic partnership to develop and commercialize lemzoparlimab. We were listed among the 50 Smartest Companies in China by MIT Technology Review, a leading global technology business magazine. We also received the China Healthcare New Power Award from People.cn, a top-tier Chinese national media and was among the 10 Biotechs to Know in China by FiercePharma, an influential U.S.-based trade journal. Our Founder and Chairman, Dr. Jingwu Zhang Zang, was named Medical Innovation Pioneer among the 50 leaders in listed companies by 2020 Global Founders Summit. These awards reflect the impact we have made on the innovation development of the healthcare industry as well as the leadership we have demonstrated throughout the year.

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.

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 have historically been regulated by the Catalogue for the Guidance of Foreign Investment Industries (2017 Revision) issued on June 28, 2017 and effective from July 28, 2017, the Special Management Measures (Negative List) for the Access of Foreign Investment (2018) issued on June 28, 2018 and effective from July 28, 2018, and the Special Management Measures (Negative List) for the Access of Foreign Investment (2019) issued on June 30, 2019 and effective from July 30, 2019. 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. Currently, the Catalogue for the Guidance of Foreign Investment Industries (2017 Revision), the Special Management Measures (Negative List) for the Access of Foreign Investment (2018) and the Special Management Measures (Negative List) for the Access of Foreign Investment (2018) have all been replaced. The currently effective industry entry clearance requirements governing investment activities in the PRC by foreign investors are set out in two categories, namely the Special Management Measures (Negative List) for the Access of Foreign Investment (2020), and the Catalogue of Industries for Encouraging Foreign Investment (2020 Version), which were promulgated by the National Development and Reform Commission (the "NDRC"), and the MOFCOM, and took effect on July 23, 2020 and on January 27, 2021, respectively. The Catalogue of Industries for Encouraging Foreign Investment (2020 Version) and the Special Management Measures (Negative List) for the Access of Foreign Investment (2020) further reduce restrictions on the foreign investment and expand the scope of industries in which foreign investments are encouraged. Industries not listed in these two catalogues are generally deemed "permitted" for foreign investment unless specifically restricted by other PRC laws.

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 National Healthcare Security Administration, 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 became 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 divided 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 application 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, 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 the PRC issued the PRC Administrational Rules on the Management of Human Genetic Resources (effective from July 1, 2019) ("Genetic Rules"), 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.

On October 17, 2020, the Standing Committee of the NPC promulgated the Biosecurity Law of the PRC, which became effective from April 15, 2021. The new law restates the approval and notification requirements of human genetic resources sampling, collecting, utilizing and exporting, as provided in the Genetic Rules. Moreover, the promulgation of the new law, which takes the form of national law, further demonstrates the commitments of protecting China's human genetic resources and safeguarding state biosecurity by the PRC government.

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. On April 23, 2020, the NMPA and NHC jointly issued the amended Administration of Quality of Drug Clinical Practice (the "new GCP"), effective from July 1, 2020. The new GCP was highly consistent with ICH E6 (R2) in its structure and content, and highly emphasized the protection of subjects, in particular, the protection of vulnerable subjects was provided through reinforcing the ethics committee's responsibilities. Furthermore, the new GCP clarified the investigator's responsibilities for medical decisions relevant to the clinical trials and overseeing the clinical trials to ensure the accuracy and completeness of the source data, it also included the sponsor's responsibilities for implementing and maintaining the quality management system, requiring that the electronic data management system used by the sponsor should be verifiable, equipped with grant of modification authority and data security measures, to ensure the data modification process is completely recorded and tracked. The new GCP also prohibited the conduct of biological sample testing irrelevant to the study protocol approved by the ethics committee.

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 May 17, 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.

On July 7, 2020, the NMPA promulgated the Evaluation and Approval Working Process for Revolutionary Therapeutic Drugs (Trial), the Evaluation and Approval Working Process for the Conditional Approval Application of Drugs (Trial) and the Priority Evaluation and Approval Working Process for Drugs (Trial), repealing the Opinions on Encouraging the Prioritized Evaluation and Approval for Drug Innovations, which provide for fast track clinical trial approval, drug registration pathway or conditional approval to innovative drugs or drugs with revolutionary therapeutic effects.

On November 19, 2020, CDE promulgated the Clinical Technical Guidelines for Conditional Approval of Drugs (Tentative), which became effective on the same day, to accelerate the marketing of clinically urgent drugs with outstanding clinical value in China. According to such guidelines, during the period of drug clinical trials, a drug may be applied for conditional approval if it meets the following conditions: (i) for the treatment of seriously life-threatening diseases with no existing effective treatment available, as well as medicines urgently needed for public health, whose clinical trials have shown efficacy and whose clinical value can be predicted; (ii) vaccines that are urgently needed in response to major public health emergencies or other vaccines that are identified as being urgently needed by the NHC, and whose benefits are assessed to outweigh the risks.

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, at the stage of clinical trial application, depending on the characteristics of the drug and the corresponding 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, at the stage of new drug application, depending on the characteristics of the drug and the corresponding 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 applicants 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 or a research and development institution, which has obtained a drug registration certificate is 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.

On October 17, 2020, the Standing Committee of the NPC promulgated the Amendment to the Patent Law. The Amendment to the Patent Law, which will become effective from June 1, 2021, extends the validity period for design and the time limitation of actions for infringement of patent rights, and increases the maximum amount of infringement compensation. Meanwhile, the Amendment to the Patent Law implements a "compensation for patent term" (the "Term Compensation") measure. In the event that an invention patent is granted after the forth (4th) anniversary of the date of application and the third (3rd) anniversary of the date of the request for substantive examination, the Patent Administration Department of the State Council shall, at the request of the patentee, provide the Term Compensation for the unreasonable delay in the process of granting the patent, except for the unreasonable delay caused by the applicant. In particular, in order to compensate the time taken for the review and approval of new drugs, if the new drug-related invention patents are approved for marketing in China, the Patent Administration Department of the State Council shall provide the Term Compensation to the patentee, for the duration of patent rights at the request of the patentee. The Term Compensation shall not exceed five (5) years, and the total effective patent right period after the new drug is approved for marketing shall not exceed fourteen (14) years.

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. On May 28, 2020, the NPC approved the Civil Code of the People’s Republic of China (the “Civil Code”), which took effect on January 1, 2021 and replaced the General Principles of the Civil Law of the PRC and Tort Liability Law of the PRC. According to the Civil Code, patients have the right to claim compensation from the drug marketing authorization holder, medical institution or manufacturer for damage caused by drug defects.

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.

On April 10, 2020, SAFE promulgated the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business, which allows eligible enterprises to make domestic payments using their capital funds, foreign credits and the income under capital accounts of overseas listing, without providing evidentiary materials concerning authenticity of such capital for banks in advance, provided that their capital use shall be authentic and in line with provisions, and conform to the prevailing administrative regulations on the use of income under capital accounts. The administering bank shall perform ex-post sampling in accordance with the relevant requirements.

Dividend Distribution

Pursuant to the PRC Company Law and Foreign Investment Law of the PRC, 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.

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 strategically important and advantageous that we own and control our GMP manufacturing process in order to ensure quality, secure production slots and maximize cost-effectiveness for clinical trial materials and commercial supplies. We intend to build a comprehensive biologics manufacturing facility in Hangzhou, China (the "Hangzhou Facility") as part of our strategic plan to become a fully integrated biopharma company. We have taken concrete steps to execute this plan. These steps include detailed operational planning for the facility, actions taken to secure an appropriate site, and negotiations with external financing providers. The Hangzhou Facility targets to have a pilot capacity of 2 production lines (1 line configured with 2 x 2,000L and another line with 1 x 2,000L) by 2022 and commercially progressive capacity up to 8 x 4,000L to begin operation by the end of 2023. Construction is expected to commence in April 2021 and ready for use by the end of 2023. The project will be financed by a combination of internal and external sources. In September 2020, a group of domestic investors in China invested a total of US$120 million (in RMB equivalent) in cash. Upon closing, I-Mab Hangzhou became an affiliate of us. We, through our wholly owned subsidiary, and parties acting in concert, remain the majority shareholder of I-Mab Biopharma (Hangzhou) Limited ("I-Mab Hangzhou"), the entity holding the Hangzhou Facility, and retain a managing role and take full control to build and operate the manufacturing facility. We plan to prioritize our therapeutic focus and resources on immuno-oncology in our global ambition to become a leading immuno-oncology company. This goal has been accelerated by our recent global strategic partnership with AbbVie and its commercialization plan for the initial oncology products. I-Mab Hangzhou is positioned to provide manufacturing capabilities for us, as well as the continued development of selected biologics assets that are unessential to our immuno-oncology focus, i.e. olamkicept, plonmarlimab (excluding cytokine release syndrome indications) and a few pre-clinical CMC-stage programs. We believe that this strategic alignment is necessary to maximize the pipeline value and balance the development risk for us.

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 and Dr. Jane Meng. 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, Dr. Taylor B. Guo, Dr. Jane Meng, Dr. Claire Xu and Richard Cheng Li, 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 and Thomas Song, 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, Yuan Meng, Sophie Song, Michelle Yang, Dr. Claire Xu, Dr. Jane Meng 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;

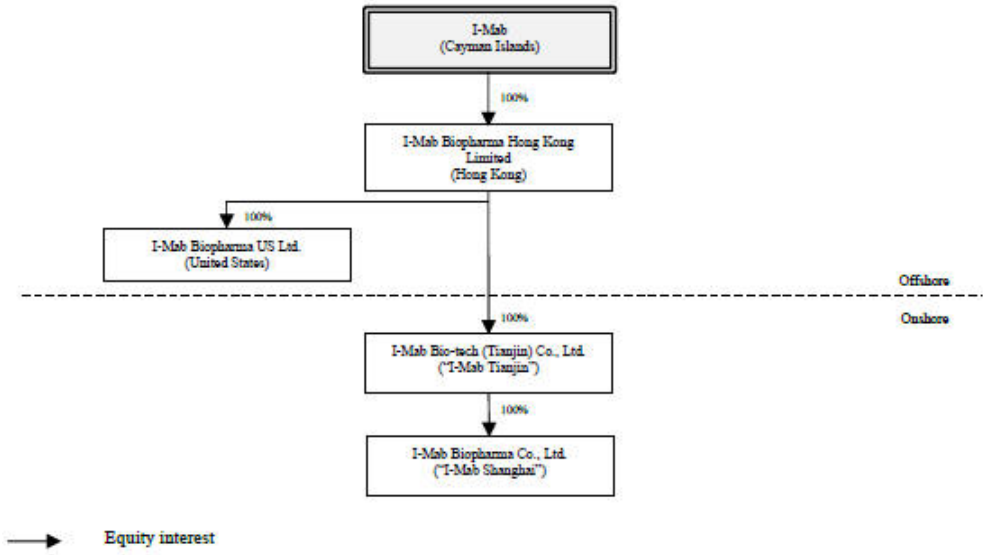
- continuous quality management system improvement;
- non-conformance management via quality issue management process;
- development and execution of quality audit program; and
- regulatory inspection readiness.

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 the date of this annual report:



D. Property, Plant and Equipment

Our headquarter is located in Shanghai, China, where we lease and occupy approximately 2,851 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 14,495 square meters of office space and manufacturing space in Hangzhou, approximately 187 square meters of office space 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 15 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 to the end of 2019 of our operations. In 2018 and 2019, our net losses were RMB402.8 million and RMB1,452.0 million, respectively. In 2020, we achieved corporate profitability with net income of RMB470.9 million (US$72.2 million) which was primarily attributable to the revenues recognized in connection with the strategic collaboration with AbbVie of RMB1,542.7 million (US$236.4 million). 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 drug assets through our strengthened and expanded network of global partnerships and alliances. In 2018, 2019 and 2020, our revenue consisted primarily of payments from granting licenses to use and otherwise exploit certain of our intellectual properties linked to our drug 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 fifteen 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 felzartamab, eftansomatropin alfa, olamkicept and plonmarlimab. 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, 2020. 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, 2018, 2019 and 2020. 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 Pandemic

As of the date of this annual report, the impact of the ongoing global coronavirus- 19 (COVID-19) pandemic to our business has been limited. To date, although COVID-19 has caused some delays in the initiation of the ongoing trials of certain clinical-stage drug candidates in early 2020, the COVID-19 pandemic has not had a material impact on our ongoing clinical activities, in particular, clinical activities related to our late-stage drug candidates, such as felzartamab, eftansomatropin alfa and olamkicept. See "Item 4. Information on the Company—B. Business Overview—Our Drug Candidates" for our clinical development plans for our drug candidates. As of the date of this annual report, the outbreak of COVID-19 has not caused any early termination of our clinical trials or necessitated removal of any enrolled patients. We have employed various measures to mitigate impacts of the COVID-19 pandemic on our currently ongoing trials in Greater China and the United States. We worked closely with our CROs to monitor the situation and manage the process of our clinical trials. We maintained contact with our patients to ensure that they remain on the trials and that any information they need will be readily available. In addition, we believe the COVID-19 pandemic has not significantly impacted our ability to carry out our obligations under existing contracts or disrupted any supply chains that we rely upon.

As of the date of this annual report, we have not had any suspected or confirmed COVID-19 cases on our premises or among our employees. To prevent any spread of COVID-19 in our offices and research facilities, we have adopted a thorough disease prevention scheme to protect our employees from contracting COVID-19. The measures we have implemented include, among others, regularly sterilizing and ventilating our offices, checking the body temperature of our employees, keeping track of the travel history and health conditions of employees and their immediate family members, providing face masks to employees attending the office, minimizing in-person meetings to the extent possible and encouraging employees to wear masks when needed. As of the date of this annual report, our ongoing clinical trials and CROs had resumed full and normal operations and the COVID-19 pandemic had not resulted in a major disruption to our operations.

Taking into account our past and prospective cash burn rate, including but not limited to future clinical development and administrative expenses, lease payment, capital expenditure and current financial position, our ability to control the speed and breadth of our clinical development and business development activities and our expansion in headcount, our current internal resources, we estimate that our financial resources can support our research and development activities and business operations for at least the next 12 months.

Although we believe we have implemented strategies to potentially minimize the impact of the COVID-19 pandemic to our business, we expect that we may experience delays with respect to the initiation and patient enrollment of certain additional trials. The extent to which the COVID- 19 pandemic impacts the timing of these additional trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, any restrictions on the ability of hospitals and trial sites to conduct trials that are not designed to address the COVID-19 pandemic and the perceived effectiveness of actions taken in China and the United States to contain and treat the disease. We will continue to evaluate the impact of the COVID-19 pandemic to our business.

In addition, there are still uncertainties with regard to the continued development of COVID-19 and its implications, and we will continue to assess the situation and seek to put in place relevant mitigating measures where necessary. The above analyses are made by our management based on currently available information concerning COVID-19. We cannot guarantee that the outbreak of COVID- 19 will not further escalate or have a material adverse effect on our business operations. Please also see "Item 3. Key Information—D. Risk Factors—Risks Related to Our Industry, Business and Operations—Our business, financial condition and results of operations could be adversely affected by the COVID-19 pandemic." and "Item 3. Key Information—D. Risk Factors—Risks Related to Our Industry, Business and Operations— Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses."

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, 2018, 2019 and 2020 from granting licenses to use and otherwise exploit certain of our intellectual properties in connection with our drug 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:

- Felzartamab, a potential highly differentiated CD38 antibody for multiple myeloma and autoimmune diseases, if approved;
- Eftansomatropin alfa, a potential highly differentiated long-acting growth hormone for growth hormone deficiency, if approved;
- Efineptakin alfa, the first long-acting recombinant human IL-7 with the potential for cancer treatment-related lymphopenia and cancer immunotherapy, if approved;
- Lemzoparlimab, a potential highly differentiated CD47 antibody for immuno-oncology, if approved;
- Uliledlimab, a potential highly differentiated CD73 antibody for cancer treatment, if approved;
- Plonmarlimab, a GM-CSF monoclonal antibody for rheumatoid arthritis and CRS-related therapies, if approved;
- Olamkicept, a potential highly differentiated IL-6 blocker for ulcerative colitis and other autoimmune diseases, if approved;
- Enoblituzumab, a potential highly differentiated humanized B7-H3 antibody for immuno-oncology treatment, if approved;
- TJ210, a potential highly differentiated antibody targeting myeloid derived suppressor cells in cancers and autoimmune diseases, if approved;
- TJ-CD4B, a novel, tumor-dependent T-cell engager for gastric and other cancers, if approved; and
- TJ-L14B, a PD-L1 based tumor-dependent T-cell engager for solid cancers, if approved.

We incurred research and development expenses of RMB426.0 million, RMB840.4 million and RMB984.7 million (US$150.9 million) for the years ended December 31, 2018, 2019 and 2020, respectively, representing 86.5%, 56.2% and 71.0% 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, 2018, 2019 and 2020, our administrative expenses amounted to RMB66.4 million, RMB654.6 million and RMB402.4 million (US$61.7 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 the equity transfer of I-Mab Hangzhou and other financial assets, fair value change of short-term investments and subsidy income.

Other expenses consist primarily of the net loss resulting from the conversion of a portion of our convertible promissory notes, loss on the termination agreement with Everest and net foreign exchange losses.

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, our holding entity, did its business registration in Hong Kong and had a Hong Kong tax file number. 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. Under the current Hong Kong Inland Revenue Ordinance, from the year of assessment 2018/2019 onwards, our subsidiary in Hong Kong is subject to profits tax at the rate of 8.25% on assessable profits up to HK$2,000,000; and 16.5% on any part of assessable profits over HK$2,000,000. For the years ended December 31, 2018, 2019 and 2020, 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.

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") (as amended in 2017 and 2018), 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 based on the assessment as of December 31, 2020. Therefore, we have provided full valuation allowances for the deferred tax assets as of December 31, 2018, 2019 and 2020.

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, 2018, 2019 and 2020, 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,			
	2018	2019	2020	
	RMB	RMB	RMB	US$
	(in thousands, except for per share data)			
Summary Consolidated Statements of Comprehensive Income (Loss) Data:				
Revenues				
Licensing and collaboration revenue	53,781	30,000	1,542,668	236,424
Expenses				
Research and development expenses [(1)]	(426,028)	(840,415)	(984,689)	(150,910)
Administrative expenses [(1)]	(66,391)	(654,553)	(402,409)	(61,672)
Income (loss) from operations	(438,638)	(1,464,968)	155,570	23,842
Interest income	4,597	30,570	24,228	3,713
Interest expense	(11,695)	(2,991)	(957)	(147)

	For the Year Ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$
	(in thousands, except for per share data)			
Summary Consolidated Statements of Comprehensive Income (Loss) Data:				
Other income (expenses), net	(16,780)	(20,205)	412,892	63,278
Equity in loss of an affiliate [(1)]	—	—	(108,587)	(16,642)
Fair value change of warrants	61,405	5,644	—	—
Income (loss) before income tax expense	(401,111)	(1,451,950)	483,146	74,044
Income tax expense	(1,722)	—	(12,231)	(1,874)
Net income (loss) attributable to I-Mab	(402,833)	(1,451,950)	470,915	72,170
Deemed dividend to Series C-1 preferred shareholders extinguishment of Series C-1 Preferred Shares	—	(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)	—	—
Net income (loss) attributable to ordinary shareholders	(402,833)	(1,485,001)	470,915	72,170
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of nil tax	53,689	10,747	(120,920)	(18,531)
Total comprehensive income (loss) attributable to I-Mab	**(349,144)**	**(1,441,203)**	**349,995**	**53,639**
Net income (loss) attributable to ordinary shareholders	**(402,833)**	**(1,485,001)**	**470,915**	**72,170**
Weighted-average number of ordinary shares used in calculating net income (loss) per share				
Basic	6,529,092	7,381,230	134,158,824	134,158,824
Diluted	6,529,092	7,381,230	157,231,652	157,231,652
Net loss per share attributable to ordinary shareholders				
Basic	(61.70)	(201.19)	3.51	0.54
Diluted	(61.70)	(201.19)	3.00	0.46
Net income (loss) per ADS attributable to ordinary shareholders				
—Basic	(141.91)	(462.74)	8.07	1.24
—Diluted	(141.91)	(462.74)	6.90	1.06

Notes:

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

	For the Year Ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$
	(in thousands)			
Research and development expenses	1,056	470	284,431	43,591
Administrative expenses	2,464	514,733	209,033	32,036
Equity in loss of an affiliate	—	—	32,707	5,013
Total	3,520	515,203	526,171	80,640

Year Ended December 31, 2020 Compared to Year Ended December 31, 2019

Revenues

Our revenues generated from licensing and collaboration increased from RMB30.0 million for the year ended December 31, 2019 to RMB1,542.7 million (US$236.4 million) for the year ended December 31, 2020. Our revenues generated for the year ended December 31, 2020 solely consisted of the revenue recognized in connection with the strategic collaboration with AbbVie.

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,				
	2019		2020		
	RMB	%	RMB	US$	%
	(in thousands, except percentages)				
CRO service fees	521,920	62.1	439,537	67,362	44.6
In-licensed patent right fees	166,844	19.9	28,266	4,332	2.9
Employee benefit expenses	106,313	12.7	460,149	70,521	46.7
Material costs for drug candidates	6,117	0.7	15,610	2,392	1.6
Other expenses	39,221	4.6	41,127	6,303	4.2
Total	**840,415**	**100.0**	**984,689**	**150,910**	**100.0**

Our research and development expenses increased by 17.2% from RMB840.4 million for the year ended December 31, 2019 to RMB984.7 million (US$150.9 million) for the year ended December 31, 2020, primarily attributable to (i) an increase in employee benefit expenses of employees involved in research and development from RMB106.3 million for the year ended December 31, 2019 to RMB460.1 million (US$70.5 million) for the year ended December 31, 2020, mainly due to an increase in share-based compensation by RMB284.0 million (US$43.6 million); (ii) partially offset by the decreases in CRO service fees and in-licensed patent right fees from RMB521.9 million and RMB166.8 million for the year ended December 31, 2019 to RMB439.5 million (US$67.4 million) and RMB28.3 million (US$4.3 million) for the year ended December 31, 2020, respectively. The decrease of CRO service fees was mainly due to the evolution of our outsourcing model in 2020 through hiring more dedicated headcounts on our clinical programs to replace CRO services. The decrease of in-licensed patent right fees was mainly due to that we paid the upfront fee of US$15.0 million to MacroGenics in 2019.

In 2020, 77.6% and 22.4% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. In 2019, 87.3% and 12.7% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. In 2020, felzartamab and lemzoparlimab represented approximately 36.9% and 13.4% of our external research and development expenses, which primarily included payments to CROs and CMOs. In 2019, felzartamab represented approximately 41.4% 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 2020 and 2019. 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 decreased from RMB654.6 million for the year ended December 31, 2019 to RMB402.4 million (US$61.7 million) for the year ended December 31,2020, primarily attributable to the decrease in employee benefit expenses by RMB305.7 million (US$46.9 million) due to decrease of share-based compensation expenses.

Interest Income

We recorded RMB30.6 million of interest income for the year ended December 31, 2019 and RMB24.2 million (US$3.7 million) of interest income for the year ended December 31, 2020. The change was primarily attributable to the interest income derived from bank deposits and an increase in bank balance.

Interest Expense

We recorded RMB3.0 million of interest expense for the year ended December 31, 2019 and RMB1.0 million (US$0.1 million) of interest expense for the year ended December 31, 2020. The change was primarily attributable to the interest expense related to our short-term borrowings, of which RMB80.0 million was borrowed in July 2018 and repaid in June 2019, RMB50.0 million was borrowed in June 2019 and repaid in June 2020, respectively.

Other Income (Expenses), Net

We recorded RMB20.2 million of other income for the year ended December 31, 2019 and RMB412.9 million (US$63.3 million) of other income for the year ended December 31, 2020. The change was primarily attributable to RMB407.6 million gain recognized as a result of transfer of equity of I-Mab Hangzhou from I-Mab Hong Kong to a group of domestic investors. The equity transfer realized the fair value appreciation in the pipeline assets as well as the employment of a team of designated management and workforce.

Equity in Loss of An Affiliate

We recorded equity in loss of an affiliate of nil for the year ended December 31, 2019 and RMB108.6 million (US$16.6 million) for the year ended December 31, 2020. The change was primarily due to that I-Mab Hangzhou became an affiliate of our company since September 15, 2020.

Fair Value Change of Warrants

We recorded a gain from change in the fair value of warrant liability of RMB5.6 million for the year ended December 31, 2019 and nil for the year ended December 31, 2020. The change was primarily attributable to the fact that the holders of Series B Warrants have unconditionally and irrevocably waived and cancelled the Tranche II of Series B Warrants in July 2019.

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 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	%
	(in thousands, except percentages)			
CRO service fees	212,278	49.8	521,920	62.1
In-licensed patent right fees	108,794	25.5	166,844	19.9
Employee benefit expenses	56,630	13.3	106,313	12.7
Material costs for drug candidates	19,652	4.6	6,117	0.7
Other expenses	28,674	6.8	39,221	4.6
Total	**426,028**	**100.0**	**840,415**	**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 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 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 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 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, felzartamab represented approximately 41.4% of our external research and development expenses, which primarily included licensing fees and payments to CROs and CMOs. In 2018, efineptakin alfa and felzartamab 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 for the year ended December 31, 2019, primarily attributable to (i) RMB365.3 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 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 due to headcount increase, and (iv) the increase in third-party professional expenses by RMB41.4 million.

Interest Income

We recorded RMB4.6 million of interest income for the year ended December 31, 2018 and RMB30.6 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 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 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 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.

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 fair value measurements of wealth management products, warrants and put right liabilities, impairment of accounts receivables, contract assets, other receivables, long-lived assets, intangible assets and goodwill, useful lives of property, equipment and software, recognition of right-of-use assets and lease liabilities, variable consideration in collaboration revenue arrangements, determination of the standalone selling price of each performance obligation in our revenue arrangements, valuation of share-based compensation arrangements and deferred tax assets valuation allowances. 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. The entity performs the following five steps to account for the arrangements that an entity determines are within the scope of ASC 606: (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.

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. For any units of account that are reflective of a vendor-customer relationship those units of account are accounted for within the scope of ASC 606. For any units of account that are not accounted for under ASC 606 and therefore 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.

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 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 or milestone payments based on the level of sales 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).

Contract Assets and Liabilities

Contract assets primarily represent revenue earnings over time that are not yet billable based on the terms of the contracts. We do not have impairment losses associated with contracts with customers for the years ended December 31, 2019 and 2020.

Contract liabilities consist of fees invoiced or paid by our customers for which the associated performance obligations have not been satisfied and revenue has not been recognized based on our revenue recognition criteria described above.

Contract assets and contract liabilities are reported in a net position on an individual contract basis at the end of each reporting period. Contract assets are classified as current in the consolidated balance sheet when we expect to complete the related performance obligations and invoice the customers within one year of the balance sheet date, and as long-term when we expect to complete the related performance obligations and invoice the customers more than one year out from the balance sheet date. Contract liabilities are classified as current in the consolidated balance sheet when the revenue recognition associated with the related customer payments and invoicing is expected to occur within one year of the balance sheet date and as long-term when the revenue recognition associated with the related customer payments and invoicing is expected to occur in more than one year from the balance sheet date.

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 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.

Long-term Investments

Our long-term investments include equity investments in an affiliate in which we do not have a controlling financial interest, but has the ability to exercise significant influence over the operating and financial policies of the investee. The investment is accounted for using the equity method of accounting in accordance with ASC topic 323, Investments—Equity Method and Joint Ventures ("ASC 323"). Under the equity method, we initially record our investments at fair value. We subsequently adjust the carrying amount of the investment to recognize our proportionate share of the equity investee's net income or loss after the date of investment. When the liquidation rights and priorities as defined by an equity investment agreement differ from what is reflected by the underlying percentage ownership interests, applying the percentage ownership interest to U.S. GAAP net income in order to determine earnings or losses does not accurately represent the income allocation and cash flow distributions that will ultimately be received by the investors. As such, for this type of investments, we use the Hypothetical Liquidation at Book Value ("HLBV") method for allocating earnings or losses of the equity method investee. The HLBV method is considered as a balance sheet approach. Specifically, a calculation is prepared at each balance sheet date to determine the amount that we would receive if an equity investment entity were to liquidate all of its assets (as valued in accordance with U.S. GAAP) and distribute that cash to the investors based on the contractually defined liquidation priorities. The difference between the calculated liquidation distribution amounts at the beginning and the end of the reporting period, after adjusting for capital contributions and distributions, is our share of the earnings or losses from the equity investment for the period.

As it relates to the share-based compensation awarded by an equity method investee to its own employees, we recognize our proportionate share of the compensation expense over the vesting period, included in the equity in loss of affiliate in the consolidated statements of comprehensive income (loss). As it relates to the share-based compensation awarded by us to the equity method investee employees that are based on our stock, when the other investors do not provide proportionate value to the investee or we do not receive any consideration, we expense the entire cost associated with the award in the same period the costs are recognized by the investee, to the extent that our claim on the investee's book value has not been increased. The expenses recognized by us is included in the equity in loss of affiliate in the consolidated statements of comprehensive income (loss).

We evaluate the equity method investment for impairment under ASC 323. An impairment loss on the equity method investments is recognized in losses when the decline in value is determined to be other-than-temporary. No impairment charge was recognized for the year ended December 31, 2020.

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, 2018, 2019 and 2020:

	Numbers of Shares	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2018	1,179,633	0.77
Vested	(1,179,633)	
Outstanding at December 31, 2019	—	—
Vested	—	
Outstanding at December 31, 2020	—	—

No share-based compensation expense was recognized in the year ended December 31, 2020.

Shared-based compensation expenses relating to restricted shares were included in:

	For the Year Ended December 31,			
	2018	2019	2020	
	RMB'000	RMB'000	RMB'000	US$'000
Research and development expenses	1,056	470	—	—
Administrative expenses	2,464	1,096	—	—
	3,520	1,566	—	—

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 offering, 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 1,470,000, 640,000 and nil stock options to employees, all with an exercise price of US$1, for the years ended December 31, 2018, 2019 and 2020, respectively. No options were exercisable as of December 31, 2018 and 2019 and 6,790,924 stock options were exercisable as of December 31, 2020.

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, 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
Forfeited	(338,876)	1.00	—	—
Exercised	(1,439,373)	0.72	—	—
Surrendered	(332,566)	1.00	—	—
Outstanding as of December 31, 2020	7,702,066	0.97	6.75	150,415
Exercisable as of December 31, 2020	6,790,924	0.97	6.75	132,650

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,	
	2018	2019
Expected volatility	61.32%-62.13%	54.64%
Risk-free interest rate (per annum)	2.81%-3.06%	2.15%
Exercise multiple	2.80	2.80
Expected dividend yield	—	—
Contractual term (in years)	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 no stock options granted to employees under the 2017 Plan for the year ended December 31, 2020. On January 17, 2020, we completed our initial public offering. After achieving this performance condition, the options continue to vest based only on service period completed according to the graded vesting schedule. We have begun recognizing share-based compensation expense for the options granted using the graded vesting method with a cumulative catch-up for the service period completed to date during the year ended December 31, 2020 and recognized RMB52,802 thousand, RMB69,213 thousand and RMB4,277 thousand share-based compensation expenses in administrative expenses, research and development expenses and equity in loss of an affiliate, respectively, relating to options vested cumulatively. According to the amendments to the 2017 Plan, the maximum aggregate number of shares which may be granted pursuant to all awards under the 2017 Plan was changed to 9,609,084. Each of our founders, namely Zheru Zhang, Lili Qian, Zhengyi Wang and Lei Fang surrendered 83,142 unvested stock options that were granted to him or her under the 2017 Plan before, totaling 332,566 unvested options, for no consideration, and these stock options were cancelled immediately.

Second Amended and Restated 2018 Employee Stock Option Plan (the "2018 Plan")

On February 22, 2019, our company adopted the 2018 Plan, which was subsequently amended and restated on July 22, 2019. Under the amended and restated 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—B. 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. The vesting schedule shall generally be 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 16(d) to our consolidated financial statements for further details).

The amount of share-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 16(d) to our consolidated financial statements) recognized in the year ended December 31, 2019 was RMB365,329 thousand, which were allocated to our administrative expenses.

The following table sets forth the stock options activities under the 2018 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, 2019	13,536,588	1.00	8.86	64,840
Surrendered	(2,544,917)	1.00	—	—
Exercised	(402,000)	1.00	—	—
Outstanding as of December 31, 2020	10,589,671	1.00	8.15	206,499
Exercisable as of December 31, 2020	9,764,670	1.00	8.15	190,411

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:

	For the 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.

On January 17, 2020, our Company completed its IPO. After achieving this performance condition, the options continue to vest based only on service period completed according to the graded vesting schedule. We have begun recognizing share-based compensation expenses for the options granted using the graded vesting method with a cumulative catch-up for the service period completed to date during the year ended December 31, 2020 and recognized RMB48,055 thousand, RMB65,656 thousand and RMB226 thousand share-based compensation expense in administrative expenses, research and development expenses and equity in loss of an affiliate, respectively, relating to options vested cumulatively. According to the amendments to the 2018 Plan, the maximum aggregate number of shares which may be granted pursuant to all awards under the 2018 Plan was changed to 11,005,888. Dr. Jingwu Zhang Zang, chairman of our Company, surrendered 2,544,917 unvested options that were granted to him under the 2018 Plan, for no consideration, and these stock options were cancelled immediately.

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 thousand (equivalent to approximately RMB148,308 thousand) 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 thousand (equivalent to approximately RMB148,308 thousand) as share-based compensation costs (included in administrative expenses) in the condensed 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. Under the 2019 Plan, the maximum aggregate number of ordinary shares available for issuance shall initially be 100,000. The options shall vest 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. Stock options granted to 3 independent directors under the 2019 Plan will be generally exercisable under the following terms: (a) a cliff vesting of 1/3 of the option on the first anniversary of the vesting commencement date (January 17, 2020); (b) a cliff vesting of 1/3 of the option on the second anniversary of the vesting commencement date (January 17, 2020); (c) a vesting of the remaining 1/3 of the option on the third anniversary of the vesting commencement date (January 7, 2020). In the last year of the grantee's service, the options shall vest on a prorated basis to reflect the portion of the year during which the grantee provided services to our Company.

For the year ended December 31, 2020, our Company granted 72,000 stock options to 3 independent directors (all with an exercise price of US$6.09) and recognized RMB1,171 thousand share-based compensation expenses relating to the options vested. No options were exercisable as of December 31, 2020.

The following table sets forth the stock option activities of the 2019 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, 2019	—	—	—	—
Granted	72,000	6.09	—	—
Outstanding as of December 31, 2020	72,000	6.09	9.33	1,038
Exercisable as of December 31, 2020	—	—	—	—

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:

	For the Year Ended December 31, 2020
Expected volatility	54.88%
Risk-free interest rate (per annum)	0.79%
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 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.

2020 Share Incentive Plan (the "2020 Plan")

In July 2020, we adopted the 2020 Plan. Under the 2020 Plan, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards shall be 10,760,513, provided that the maximum number of shares may be issued pursuant to awards in the form of restricted share units under this plan shall not exceed 7,686,081 ordinary shares.

Stock options granted to employees under the 2020 Plan are graded vesting in four years with 25% vesting each year. For the year ended December 31, 2020, we granted 1,068,733 stock options to its employees and recognized RMB4,357 RMB10,435 and RMB1,619 share-based compensation expenses in administrative expenses, research and development expenses and equity in loss of an affiliate, respectively, in the consolidated statement of comprehensive income. No option became exercisable as of December 31, 2020.

The following table sets forth the stock options activities of 2020 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, 2019	—	—	—	—
Granted	1,068,733	5.91	—	—
Forfeited	(24,365)	5.91	—	—
Outstanding as of December 31, 2020	1,044,368	5.91	9.62	15,237
Exercisable as of December 31, 2020	—	—	—	—

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:

	For the Year Ended December 31, 2020
Expected volatility	56.51%
Risk-free interest rate (per annum)	0.86%
Exercise multiple	2.20-2.80
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 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.

Restricted share units granted to employees under the 2020 Plan will be exercisable under the following items:

(a) 1/3 of the awarded restricted share units shall vest based on the following time attribution:(i) a vesting of 25% of the time attribution based restricted share units on the first anniversary of the applicable adoption date;(ii) a vesting of 25% of the time attribution based restricted share units on the second anniversary of the applicable adoption date;(iii) a vesting of 25% of the time attribution based restricted share units on the third anniversary of the applicable adoption date;(iv) a vesting of 25% of the time attribution based restricted share units on the fourth anniversary of the applicable adoption date.

(b) 1/3 of the awarded restricted share units shall vest based on our weighted average market value during the last 30 days prior to the initial vesting date, the terms and conditions of which are set forth in the executed award agreements. In the event that dilution of additional share issuance occurs, the market value targets herein shall be adjusted accordingly with the proportion of additional share issuance. In the event that the average market value of Standard & Poor's 500 index falls by more than 20% from the date of grant, it shall be deemed as a decline of the market, and the board of us or a committee that board delegated its powers or authority to shall adjust the vesting schedule as appropriate.

(c) 1/3 of the awarded restricted share units shall vest based on certain performance conditions:(i) a vesting of 20% of the performance conditions based restricted share units if one of the performance conditions has been met at the initial vesting date;(ii) a vesting of 40% of the performance conditions based restricted share units if two of the performance conditions have been met at the initial vesting date;(iii) a vesting of 60% of the performance conditions based restricted share units if three of the performance conditions have been met at the initial vesting date;(iv) a vesting of 80% of the performance conditions based restricted share units if four of the performance conditions have been met at the initial vesting date; (v) a vesting of all of the performance conditions based restricted share units if five of the performance conditions or more have been met at the initial vesting date. As of December 31, 2020, it is probable that the 1/3 of the awarded restricted share units are fully vested because it is probable that at least five of the performance conditions will be met at the initial vesting date.

Notwithstanding the foregoing, if our company's weighted average market value during the last 30 days prior to the initial vesting date reaches US$2 billion or above, and to the extent such restricted share units have been granted and outstanding, any such restricted share unit (except for those are based on time attribution) shall vest in full with immediate effect, inure to the benefit of the related grantees.

For the year ended December 31, 2020, we granted 4,093,079 restricted share units to employees and recognized RMB76,663 RMB71,945 and RMB7,500 share-based compensation expenses in administrative expenses, research and development expenses and equity in loss of an affiliate, respectively, in the consolidated statement of comprehensive income. No restricted share units became exercisable as of December 31, 2020.

The following table sets forth the restricted share units activities of 2020 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, 2019	—	—	—	—
Granted	4,093,079	—	—	—
Forfeited	(13,461)	—	—	—
Outstanding as of December 31, 2020	4,079,618	—	9.70	83,632
Exercisable as of December 31, 2020	—	—	—	—

Apart from the aforementioned restricted share units, up to 1,446,875 shares can be issued in the form of restricted share unit to eligible grantees that the board of our company or a committee that board delegated its powers or authority determined appropriate with immediate effect of being fully vested, which are defined as special awards and are subject to terms and conditions under 2018 Plan.

For the year ended December 31, 2020, we granted 1,328,120 such restricted share units to employees and recognized RMB25,985 RMB67,182 and RMB19,085 share-based compensation expenses in administrative expenses, research and development expenses and equity in loss of an affiliate, respectively, in the consolidated statement of comprehensive income (loss). As of December 31, 2020, 565,200 restricted share units were vested, among which 558,200 restricted share units were vested but not issued as ordinary shares as the employees will not be entitled to the rights of ordinary shares from our company until they have the consideration for the transaction settled.

The following table sets forth the restricted share units subject to terms and conditions under 2018 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, 2019	—	—	—	—
Granted	1,328,120	1.00	—	—
vested	(565,200)	1.00	—	—
Outstanding as of December 31, 2020	762,920	1.00	9.65	14,877
Exercisable as of December 31, 2020	—	—	—	—

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 balance sheets.

Surrender of stock options

On January 17, 2020, our Company completed its IPO. 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 our founders, namely Zheru Zhang, Lili Qian, Zhengyi Wang and Lei Fang surrendered 83,142 unvested stock options that were granted to him or her under 2017 Plan before, totally 332,566 unvested options, for no consideration, and these stock options were cancelled immediately. 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. Dr. Jingwu Zhang Zang, chairman of our Company, surrendered 2,544,917 unvested options that were granted to him under 2018 Plan, for no consideration, and these stock options were cancelled immediately. Upon the completion of our initial public offering in January 2020, we recorded RMB91,051 thousand share-based compensation expense related to these surrendered options.

The stock options surrendered by the founders should be accounted for as capital contribution. As the founders did not get the title of the options to be surrendered and the number of share options would not be determined until listing, the capital contribution was not accounted for during the year ended December 31, 2019. For the year ended December 31, 2020, our Company has reclassified RMB91,051 thousand from additional paid-in capital—share-based compensation to additional paid-in capital—capital contribution relating to the options surrendered in the condensed consolidated statement of comprehensive income.

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, the restricted shares and the restricted share units 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, accounts receivables, contract assets, other receivables, short-term borrowings, accruals and other payables, warrant liabilities and put right liabilities. As of December 31, 2018, 2019 and 2020, except for short-term investments, other financial assets, warrants liabilities and put right 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, warrant liabilities and put right liabilities at fair value at each balance sheet date and changes in fair value are reflected in the consolidated statements of comprehensive income (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, warrant liabilities and put right liabilities at fair value on a recurring basis. As our short-term investments, other financial assets, warrant liabilities and put right 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, warrant liabilities and put right 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—2.27 Recent Accounting Pronouncements" of our consolidated financial statements included elsewhere in this annual report.

B. Liquidity and Capital Resources

Cash Flows and Working Capital

We have incurred net losses and negative cash flows from our operations for the years ended December 31, 2018 and 2019. We generated net income and positive cash flow from our operations for the year ended December 31, 2020, which was primarily attributable to the collection of the upfront payment from AbbVie. 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 RMB402.8 million and RMB1,452.0 million for the years ended December 31, 2018 and 2019, respectively, and net income of RMB470.9 million (US$72.2 million) for the year ended December 31, 2020. Our primary use of cash is to fund our research and development activities. We used RMB280.7 million and RMB868.0 million in cash for our operating activities for the years ended December 31, 2018 and 2019, respectively, and generated RMB433.6 million (US$66.4 million) in cash from our operating activities for the year ended December 31, 2020. 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, and we also received total net proceeds of approximately US$105.3 million from our initial public offering. As of December 31, 2020, we had cash, cash equivalents and restricted cash of RMB4,790.3 million (US$734.1 million). Our cash, cash equivalents and restricted cash consist primarily of cash in bank and on hand. In September 2020, we entered into definitive subscription agreements with a consortium of institutional investors to raise approximately US$418 million through a private placement. The private placement consists of (i) the sale to the institutional investors of approximately US$418 million of our 29,133,502 ordinary shares (equivalent to 12,666,740 ADSs) at a purchase price equivalent to US$33 per ADS, representing a 2.9% premium to the 30-day volume weighted average price; and (ii) warrants to subscribe for an aggregate of 5,341,267 ordinary shares (equivalent to 2,322,290 ADSs) at an exercise price equivalent to US$45 per ADS, representing a 40.3% premium to the 30-day volume weighted average price, which may further increase the proceeds of approximately US$104.5 million if the warrants are fully exercised. The warrants will remain exercisable at the election of the institutional investors within 12 months after the closing of the private placement.

The following table sets forth a summary of our cash flows for the periods presented:

	For the Year Ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$
	(in thousands)			
Summary Consolidated Statements of Cash Flow Data:				
Net cash (used in) generated from operating activities	(280,705)	(867,982)	433,558	66,446
Net cash generated from (used in) investing activities	9,500	212,462	(201,901)	(30,943)
Net cash generated from financing activities	1,479,669	152,709	3,440,481	527,277
Effect of exchange rate changes on cash and cash equivalents and restricted cash	59,754	15,163	(106,643)	(16,344)
Net increase (decrease) in cash, cash equivalents and restricted cash	1,268,218	(487,648)	3,565,495	546,436
Cash, cash equivalents and restricted cash, beginning of the year	412,713	1,680,931	1,193,283	182,879
Cash, cash equivalents and restricted cash, end of the year	1,680,931	1,193,283	4,758,778	729,315

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, 2020, 9.5% 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 foreign-owned subsidiaries in China, which could materially and adversely affect our liquidity and our ability to fund and expand our business”. In addition, the COVID-19 pandemic may materially and adversely affect our ability to raise additional capital in future and our liquidity. See “Item 3. Key Information—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 generated from operating activities for the year ended December 31, 2020 was RMB433.6 million (US$66.4 million). Our net income was RMB470.9 million (US$72.2 million) for the same period. The difference between our net income and our net cash generated from operating activities was primarily attributable to certain non-cash expenses, including share-based compensation of RMB493.5 million (US$75.6 million), equity in loss of an affiliate of RMB108.6 million (US$16.6 million), non-cash gains on deconsolidation of a subsidiary of RMB407.6 million (US$62.5 million) and changes in certain working capital items, including an increase in the accounts receivable of RMB130.5 million (US$20.0 million), an increase in the contract assets of RMB227.4 million (US$34.8 million), an increase in the prepayments and other receivables of RMB58.7 million (US$9.0 million), partially offset by an increase in the accruals and other payables of RMB173.7 million (US$26.6 million). The change in share-based compensation was attributable to the grant of stock options to certain directors and employees of our company under the 2017 Plan, 2018 Plan, 2019 Plan and 2020 Plan.

Net cash used in operating activities for the year ended December 31, 2019 was RMB868.0 million. Our net loss was RMB1,452.0 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 and loss on the termination agreement with Everest of RMB23.0 million, and changes in certain working capital items, including an increase in the research and development funding of RMB53.1 million, an increase in the accruals and other payables of RMB188.4 million, partially offset by an decrease in advance from customers of RMB14.2 million and an decrease in repayments and other receivables of RMB48.8 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.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 was RMB201.9 million (US$30.9 million). The net cash increase was primarily attributable to RMB2,503.7 million (US$381.9 million) of the cash received from proceeds from disposal of short-term investments, partially offset by RMB2,492.0 million (US$383.7 million) of purchase of short-term investments, and cash disposed of resulting from deconsolidation of a subsidiary, I-Mab Hangzhou of RMB257.7 million (US$39.5 million).

Net cash generated from investing activities for the year ended December 31, 2019 was RMB212.5 million. The net cash increase was primarily attributable to RMB256.0 million of the cash received from disposal of other financial assets and RMB134.0 million of purchase of short-term investments, partially offset by RMB102.0 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.

Financing Activities

Net cash generated from financing activities for the year ended December 31, 2020 was RMB3,440.5 million (US$527.3 million), primarily attributable to the proceeds from the initial public offering of our company, net of payment of offering issuance cost of RMB698.7 million (US$107.1 million), the proceeds from private placement, net of payment of issuance cost of RMB2,782.5 million (US$426.4 million), partially offset by the repayment of bank borrowings of RMB50.0 million (US$7.7 million).

Net cash generated from financing activities for the year ended December 31, 2019 was RMB152.7 million, primarily attributable to the proceeds from issuance of convertible preferred shares, net of issuance cost of RMB183.5 million and the repayment of bank borrowings of RMB80.0 million, partially offset by the proceeds of bank borrowings of RMB50.0 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.

Capital Expenditures

Our capital expenditures were incurred for purposes of purchasing property, equipment and software. Our capital expenditures were RMB14.4 million, RMB12.2 million and RMB8.0 million (US$1.2 million) in the years ended December 31, 2018, 2019 and 2020, respectively.

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, 2020 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, 2020:

	Total		Less Than 1 Year		1-3 Years		3-5 Years		More Than 5 Years	
	RMB	US$	RMB	US$	RMB	US$	RMB	US$	RMB	US$
	(in thousands)									
Operating lease commitments	14,901	2,283	8,901	1,364	6,000	919	—	—	—	—

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, 2020.

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.	65	Founder and Chairman
Joan Huaqiong Shen, M.D., Ph.D.	59	Director and Chief Executive Officer
Zheru Zhang, Ph.D.	58	Director and President
Jielun Zhu	45	Director and Chief Financial Officer
Wei Fu	39	Director
Mengjiao Jiang	40	Director
Jie Yu	46	Director
Bing Yuan	52	Director
Chun Kwok Alan Au	48	Independent Director
Conor Chia-hung Yang	58	Independent Director
Pamela M. Klein	59	Independent Director
Weimin Tang, Ph.D.	55	Executive Vice President of Global Business Development
Yunhan Lin, Ph.D.	43	Vice President of Corporate Development
Neil Warma	58	General Manager of I-Mab US
Ivan Yifei Zhu	52	Chief Commercial Officer
Gigi Qi Feng	39	Chief Communications Officer
Richard Cheng Li	37	Chief Legal Officer

Jingwu Zhang Zang, M.D., Ph.D., is our founder and chairman. Our board of directors appointed Dr. Zang as the chairman of the board in March 2021. Prior to this appointment, Dr. Zang served as our director and honorary chairman from October 2019 to March 2021, and 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. Dr. Klein has also served as the consulting chief medical officer at Olema Oncology since 2018. 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.

Weimin 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.

Ivan Yifei Zhu has served as our chief commercial officer since August 2020. Mr. Zhu has more than 20 years of successful commercialization experience at global and domestic pharma and biotech companies. Prior to joining us, Mr. Zhu served as vice president and general manager of the sales division of Qilu Pharmaceutical Group where he managed the company's sales and marketing team. From April 2018 to March 2019, Mr. Zhu served as the chief commercial officer of BeiGene (HKEX: 6160) where he played an instrumental role in the expansion of BeiGene's commercialization team and the implementation of its commercialization strategies. Mr. Zhu also worked for Xi'an Janssen for more than 20 years where he held various senior management positions. During this period, he built and managed numerous business units, covering a wide range of therapeutic areas including oncology, immunotherapy, skin diseases, infectious diseases and the central nervous system. Mr. Zhu received his bachelor's degree in medicine from Zhejiang University in 1992.

Gigi Qi Feng has served as our chief communications officer since October 2020 and served as our vice president and global head of corporate communications from April 2020 to October 2020. Prior to joining us, Ms. Feng served as Amgen's Japan Asia Pacific regional head of corporate affairs from March 2018 to March 2020, where she led communications efforts including executive communications, media relations, employee engagement and philanthropy to build the Amgen brand across 14 markets in the Asia Pacific region. Prior to joining Amgen, Ms. Feng held progressive China, Asia Pacific and global communications leadership roles at Sanofi from November 2013 to March 2018, positioning the company as a scientific partner of choice. Prior to that, Ms. Feng led the strategic communications group at an international public affairs consultancy from December 2009 to November 2013 with a focus on the healthcare industry. She also worked at the U.S. Consulate General in Shanghai from 2005 to 2009, where she managed consulate-wide communications and large-scale events. Ms. Feng received her bachelor's degree in Government and Asian studies from Cornell University in 2003 and completed an EMBA program in business strategy from Harvard Business School in 2015.

Richard Cheng Li has served as our chief legal officer since March 2021. From December 2013 to May 2018 and from April 2020 to March 2021, Mr. Li worked at the Shanghai office of Covington & Burling LLP, a U.S. law firm, with his last position being an of counsel, leading the firm's China life sciences transaction practice. From May 2018 to March 2020, Mr. Li served as the legal director of 6 Dimensions Capital, a life sciences venture capital firm, in charge of all the legal matters relating to 6 Dimensions' global investments. From August 2008 to June 2012 and from September 2013 to December 2013, Mr. Li worked in the corporate practice group in the Shanghai office of Hogan Lovells International LLP, an international law firm. Mr. Li received his bachelor's degree in law in 2006 and master's degree in international law in 2008 from Sun Yat-sen University, and his LL.M. degree from Columbia Law School in 2013. Mr. Li has been admitted to the New York State bar and passed the PRC bar exam.

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).

Chen Dong, Ph.D., has served on our scientific advisory board since September 2020. Dr. Dong is a professor and the director of the Institute for Immunology at Tsinghua University. Prior to joining Tsinghua University in 2013, Dr. Dong served as a professor of immunology and the director of the Center for inflammation and Cancer at the University of Texas MD Anderson Cancer Center from 2004 to 2013. Dr. Dong's research focuses on understanding the molecular mechanisms whereby immune and inflammatory responses are normally regulated, and applying this knowledge to the understanding and treatment of autoimmunity and allergy disorders as well as cancer. The work from Dr. Dong's group has led to the discoveries of Th17 and T follicular helper (Tfh) cell subsets in the immune system and elucidation of their biological and pathological functions. Dr. Dong has over 200 publications and was rated highly cited researcher for six years from 2014 to 2019. The honors he has received include the 2009 American Association of Immunologists-BD Bioscience Investigator Award and 2019 International Cytokine and Interferon Society Biolegend-William E. Paul Award. He is a fellow of the American Association for the advancement of Science and a member of the Chinese Academy of Sciences. Dr. Dong is currently an Editor for Immunity, Editor-in-chief for Frontiers in Immunology- T Cell Biology and Associate Editor for China Sciences- Life Sciences.

Jun Ma, has served on our scientific advisory board since December 2020. Dr. Ma is Chief Physician, Professor, Doctoral Supervisor, Director of Harbin Institute of Hematology & Oncology, Chief Supervisor of Supervisory Committee, Chinese Society of Clinical Oncology (CSCO), Vice Chairman of ACOS, Chairman of Union for China Leukemia Investigators of CSCO, Past-Vice Chairman of Chinese Society of Hematology, Vice Chairman of CMDA for Hematologist Committee, Vice Chairman of CMDA for Oncology Committee and Past-Chairman of Union for China Lymphoma Investigators of CSCO. Dr. Ma studied in the University of Tokyo Hospital since 1979. He was devoted to giving the treatment for benign and malignant diseases of hematological system. He earns the fame for treating Leukemia and lymphoma. In 1982, he built the very first multiple hematopoietic progenitor cells culture system in vitro in China. Since 1983, he used the sequential therapy of ATRA and ATO to treat APL for 1200 cases or so. And disease free survival (DFS) were 85% in 10 years, which achieved international advanced level. He has published about 200 articles in Journals from home and abroad, with over 40 monographs and has earned 20 national, provincial and municipal Science & Technology awards. He has taken 8 programs from National R&D Program (863 Program) and 25 projects from provincial, municipal scientific research project.

B. Compensation of Directors and Executive Officers

For the fiscal year ended December 31, 2020, we paid an aggregate of approximately US$7.8 million for salaries and benefits in cash to our executive officers. 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 28, 2021, options to purchase an aggregate of 7,115,955 ordinary shares under the 2017 Plan had been granted and remained outstanding, excluding options that were forfeited, cancelled or exercised after the relevant grant date.

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 28, 2021, the number of ordinary shares underlying outstanding options that we granted under the 2017 Plan, excluding options that were forfeited, cancelled or exercised after the relevant grant date.

Name	Ordinary Shares Underlying Outstanding Options	Exercise Price (US$/Share)	Date of Grant	Date of Expiration
Zheru Zhang	*	1.00	October 1, 2017	October 1, 2027
Joan Huaqiong Shen	*	1.00	October 1, 2017	October 1, 2027
Jielun Zhu	*	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
Other grantees	3,162,321	1.00	October 1, 2017 to July 25, 2019	October 1, 2027
Total	**7,115,955**			

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 28, 2021, awards to purchase an aggregate of 9,948,512 ordinary shares under the 2018 Plan had been granted and remained outstanding, excluding options that were forfeited, cancelled or exercised after the relevant grant date.

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 any time 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 February 28, 2021, the number of ordinary shares underlying our outstanding options that we granted under the 2018 Plan, excluding options that were forfeited, cancelled or exercised after the relevant grant date.

Name	Ordinary Shares Underlying Outstanding Options	Exercise Price (US$/Share)	Date of Grant	Date of Expiration
Jingwu Zhang Zang	7,252,023	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
Other grantees	*	1.00	July 25, 2019	February 22, 2029
Total	**9,948,512**			

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 28, 2021, options to purchase an aggregate of 72,000 ordinary shares under the 2019 Plan had been granted and remained outstanding, excluding options that were forfeited, cancelled or exercised after the relevant grant date.

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.

The following table summarizes, as of February 28, 2021, the number of ordinary shares underlying outstanding options that we granted under the 2019 Plan, excluding options that were forfeited, cancelled or exercised after the relevant grant date.

Name	Ordinary Shares Underlying Outstanding Options	Exercise Price (US$/Share)	Date of Grant	Date of Expiration
Chun Kwok Alan Au	*	6.09	April 30, 2020	April 30, 2030
Conor Chia-hung Yang	*	6.09	April 30, 2020	April 30, 2030
Pamela M. Klein	*	6.09	April 30, 2020	April 30, 2030
Total	**72,000**			

Note:

* Less than 1% of our total outstanding shares.

2020 Share Incentive Plan

In July 2020, we adopted 2020 Share Incentive Plan, which we refer to as the 2020 Plan, to promote the success and enhance the value of our company. Under the 2020 Plan, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards shall be 10,760,513 ordinary shares; provided that the maximum number of ordinary shares may be issued pursuant to awards in the form of restricted share units under the 2020 Plan shall not exceed 7,686,081 ordinary shares. As of February 28, 2021, options to purchase an aggregate of 1,052,025 ordinary shares and restricted share units to receive an aggregate of 5,106,141 ordinary shares under the 2020 Plan had been granted and remained outstanding, excluding awards that were forfeited, cancelled, exercised or vested after the relevant grant date.

The following paragraphs describe the principal terms of the 2020 Plan:

Type of Awards. The plan permits the awards of options, restricted shares, restricted share units or other share-based awards.

Plan Administration. Our board of directors or one or more committees or subcommittees of the board of directors, or the Committee, 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 restrictions 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 employees, directors and consultants of our company. However, we may grant options that are intended to qualify as incentive share options only to our employees and employees of our subsidiaries.

Vesting Schedule. The options and restricted share units shall vest according to the schedules specified in the plan, unless otherwise determined by the plan administrator. The vesting schedule of other share-based awards shall be determined by the plan administrator, 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 or modify the plan in accordance with our articles of association.

The following table summarizes, as of February 28, 2021, the number of ordinary shares underlying outstanding options and restricted share units that we granted under the 2020 Plan, excluding awards that were forfeited, cancelled, exercised or vested after the relevant grant date.

Name	Ordinary Shares Underlying Options and Restricted Share Units	Exercise Price (US$/Share)	Date of Grant	Date of Expiration
Jingwu Zhang Zang	*(1)	N/A	September 4, 2020 to February 8, 2021	—
Zheru Zhang	*(1)	N/A	September 4, 2020 to February 8, 2021	—
Joan Huaqiong Shen	*(1)	N/A	September 4, 2020 to February 8, 2021	—
Jielun Zhu	*	5.91	August 14, 2020	August 14, 2030
	*(1)	N/A	August 14, 2020 to February 8, 2021	—
	*(1)	1.00	August 14, 2020	—
Weimin Tang	*(1)	N/A	September 4, 2020 to February 8, 2021	—
	*(1)	1.00	September 4, 2020	—
Yunhan Lin	*	5.91	August 14, 2020	August 14, 2030
	*(1)	N/A	August 14, 2020	—
Gigi Qi Feng	*(1)	N/A	September 4, 2020	—
Neil Kumar Warma	*(1)	N/A	December 12, 2020	—
Other grantees	*	5.91	August 14, 2020	August 14, 2030
	*(1)	N/A	August 14, 2020 to February 8, 2021	—
	*(1)	1.00	August 14, 2020 to September 4, 2020	—
Total	**6,158,166**			

Note:

* Less than 1% of our total outstanding shares.
(1) Represents restricted share units.

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. As of February 28, 2021, all participants in Biomaster Trust are our employees or former employees.

Participants in Biomaster Trust transfer their equity awards granted under the 2017 Plan and the 2018 Plan to TMF Trust for their benefit. 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. 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.

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 134, 185 and 228 employees as of December 31, 2018, 2019 and 2020, respectively. As of December 31, 2020, 198 employees were located in China and 30 were located outside China. The table below sets forth our employees by function as of December 31, 2020:

	Number
Management	9
Research and development	128
Chemistry, manufacturing and controls	36
General and administrative	42
Business and corporate development	9
Commercial	4
Total	**228**

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 March 31, 2021 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 166,532,087 total outstanding ordinary shares as of March 31, 2021 (excluding 2,982,401 ordinary shares issued to our depositary bank for bulk issuance of ADSs reserved for future issuances upon the exercising or vesting of awards granted under our share incentive plans).

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	
	Number	%
Directors and Executive Officers:**		
Jingwu Zhang Zang[(1)]	11,819,553	6.8%
Joan Huaqiong Shen	2,224,235	1.3%
Zheru Zhang	2,188,694	1.3%
Jielun Zhu	*	*
Wei Fu[(2)]	31,043,576	18.6%
Mengjiao Jiang	—	—
Jie Yu	—	—
Bing Yuan	—	—
Chun Kwok Alan Au	*	*
Conor Chia-hung Yang	*	*
Pamela M. Klein	*	*
Weimin Tang	*	*
Yunhan Lin	*	*
Neil Warma	*	*
Ivan Yifei Zhu	—	—
Gigi Qi Feng	—	—
Richard Cheng Li	—	—
All Directors and Executive Officers as a Group	49,231,263	27.2%

	Ordinary Shares Beneficially Owned	
	Number	%
Principal Shareholders:		
C-Bridge entities[2]	31,043,576	18.6%
Hillhouse entities[3]	19,050,560	11.2%
Tasly entities[4]	13,442,283	8.1%
GIC Private Limited[5]	12,176,616	7.3%
Genexine [6]	9,799,885	5.9%
Hony entity [7]	8,561,616	5.1%

Notes:

* Less than 1% of our total ordinary shares on an as-converted basis outstanding as of March 31, 2021.

** 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 Kong. 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) 3,817,113 ordinary shares directly held by Mabcore Limited, a British Virgin Islands company and (ii) 8,002,440 ordinary shares issuable upon exercise of options exercisable and vest of restricted share units within 60 days after March 31, 2021 held by Dr. Zang through Doctor Zang 2020 Dynasty Trust. Dr. Zang, through himself and The Jingwu Zhang Zang 2018 Irrevocable Family 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 Irrevocable Family Trust was established under the laws of New York and is managed by Ms. Ying Qin Zang, as the trustee and Dr. Zang as the settlor. The Doctor Zang 2020 Dynasty Trust was established under the laws of the State of California and is managed by Dr. Zang as the settlor and investment trustee and Ms. Ying Qin Zang as the trustee. 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 3,817,113 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. The registered address of Mabcore Limited is Trinity Chambers, P.O. Box 4301, Road Town, Tortola, British Virgin Islands.

(2) Represents (i) 3,931,802 ordinary shares directly held by IBC Investment Seven Limited, a Hong Kong limited liability company, (ii) 5,574,560 ordinary shares directly held by CBC SPVII LIMITED, a Hong Kong limited liability company, (iii) 12,229,916 ordinary shares directly held by CBC Investment I-Mab Limited, a British Virgin Islands limited liability company, (iv) 2,369,546 ordinary shares directly held by C-Bridge II Investment Ten Limited, a British Virgin Islands limited liability company, (v) 6,078,571 ordinary shares directly held by Everest, and (vi) 373,557 ADSs (representing 859,181 ordinary shares) held by C-Bridge II Investment Thirteen Limited, a British Virgin Islands limited liability company. IBC Investment Seven Limited, CBC SPVII LIMITED, CBC Investment I-Mab Limited, C-Bridge II Investment Ten Limited, Everest, and C-Bridge II Investment Thirteen 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 Thirteen 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. Mr. Wei Fu is the sole director of C-Bridge Capital GP, Ltd. Everest is a public company listed on the Hong Kong Stock Exchange and controlled by funds which are under common control of the C-Bridge group, which, in turn, is controlled by Mr. Wei Fu. The business address of each of C-Bridge entities is Suite 3306-3307, Two Exchange Square, 8 Connaught Place, Central, Hong Kong.

(3) Represents (i) 6,367,410 ADSs (representing 14,645,043 ordinary shares), 1,229,741 ordinary shares issuable upon exercise of call options and 2,459,482 ordinary shares issuable upon exercise of warrants directly held by Gaoling Fund, L.P., or Gaoling, an exempted limited partnership organized under the laws of the Cayman Islands, (ii) 248,760 ADSs (representing 572,148 ordinary shares), 48,047 ordinary shares issuable upon exercise of call options and 96,094 ordinary shares issuable upon exercise of warrants directly held by YHG Investment, L.P., or YHG, an exempted limited partnership organized under the laws of the Cayman Islands, and (iii) 5 ordinary shares directly held by HH IMB Holdings Limited, or HH IMB, an exempted Cayman Islands company. Hillhouse Capital Advisors, Ltd., or HCA, an exempted Cayman Islands company, acts as sole management company of Gaoling and the sole general partner of YHG, and is deemed to be the beneficial owner of, and to control the voting power of, the ordinary shares held by Gaoling and YHG. HH IMB is wholly owned by Hillhouse Fund IV, L.P., whose sole management company is Hillhouse Capital Management, Ltd., or HCM. HCM is deemed to be the beneficial owner of, and to control the voting power of, the ordinary shares held by HH IMB. HCA and HCM are under common control and share certain policies, personnel and resources. Accordingly, each of HCA and HCM has shared voting and dispositive power of the ordinary shares beneficially owned by each of HCA and HCM. The business address of each of Gaoling, YHG and HH IMB is Suite 2202, 22nd Floor, Two International Finance Centre, 8 Finance Street, Central Hong Kong.

(4) Represents (i) 12,942,997 ordinary shares directly held by Tasly Biopharm Limited, a British Virgin Islands limited liability company, and (ii) 499,286 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 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 International BioInv One Limited is wholly-owned by Tasly International Capital Limited, whose sole shareholder is 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 entities. 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.

(5) Represents 8,677,996 ordinary shares, 1,132,249 ADSs (representing 2,604,173 ordinary shares) and 894,447 ordinary shares issuable upon exercise of warrants held by GIC Private Limited, a Singapore fund manager. GIC Private Limited only has two clients: the Government of Singapore, or GoS, and the Monetary Authority of Singapore, or MAS. Under the investment management agreement with GoS, GIC Private Limited has been given the sole discretion to exercise the voting rights attached to, and the disposition of, any shares managed on behalf of GoS. As such, GIC Private Limited has the sole power to vote and dispose of securities beneficially owned by it. GIC Private Limited shares the power to vote and dispose of securities beneficially owned by it with MAS. The business address of GIC Private Limited is 168 Robinson Road, #37-01 Capital Tower, Singapore 068912.

(6) Represents (i) 8,488,885 ordinary shares directly held by Genexine, Inc. (Genexine), and (ii) 570,000 ADSs (representing 1,311,000 ordinary shares) purchased by Genexine. Genexine is a Korean public company. The registered address of Genexine is 4th Fl., Bldg. B, Korea Bio Park, 700 Daewangpangyo-ro, Seongnam-si, Gyeonggi-do 13488, Republic of Korea.

(7) Represents 8,561,616 ordinary shares directly 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 Investment (Shanghai) Limited. The sole shareholder of Hony Investment (Shanghai) Limited is Beijing Hony Hezhong Enterprise Management Limited. Each of Yonggang Cao, Minsheng Xu and Wen Zhao holds 33.3% equity interests in Beijing Hony Hezhong Enterprise Management Limited. The registered address of Fortune Eight Jogging Limited is Kingston Chambers, PO Box 173, Road Town, Tortola, British Virgin Islands. Mr. Bing Yuan, our director, is a managing director of the sole director of the Hony entity.

To our knowledge, as of March 31, 2021, 73,412,688 of our ordinary shares were held by one record holder in the United States (including 2,982,401 ordinary shares issued to our depositary bank for bulk issuance of ADSs reserved for future issuances upon the exercising or vesting of awards granted under our share incentive plans) , representing approximately 44.1% of our total outstanding shares. The holder 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 the initial public offering (ii) after the initial public offering, 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 the initial public offering of our company 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 the initial public offering of our company (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.

Subscription Agreement with Hillhouse Entities

In September 2020, we entered into a Subscription Agreement with the Hillhouse Entities, as amended by an amendment to Subscription Agreement entered into between Hillhouse Entities and our company in December 2020. The Subscription Agreement, as amended, provides for (i) certain investors' rights, such as registration rights, board representation rights and anti-dilution rights and (ii) lock-up and other transfer restrictions. Set forth below is a description of certain rights and restrictions thereof.

Mandatory Registration after Initial Closing (September 11, 2020). We agree to file with the SEC a registration statement to register the resale of Hillhouse Entities' registrable securities, which include ordinary shares issued and issuable upon exercise of Investor Warrants under the Subscription Agreement, on Form F-3 or Form F-1, as applicable. We shall have the relevant registration statement declared effective by the SEC no later than ninety (90) calendar days after September 11, 2020, which period could be extended to one hundred and twenty (120) calendar days if the SEC reviews and comments on the registration statement. However, if the SEC prevents inclusion of the registrable securities in the registration statement pursuant to limitations under Rule 415 of the Securities Act, the number of registrable securities to be registered for each selling shareholder named in the registration statement shall be reduced pro rata among all such selling shareholders. We shall maintain the continuous effectiveness of the registration statement for a period of ninety (90) days after its effectiveness or such shorter period upon which the Hillhouse Entities have notified us that their registrable securities have actually been sold.

Mandatory Registration after Subsequent Closing (December 17, 2020). With respect to the registrable securities then held by the Hillhouse Entities which have not been previously registered and sold, we agree to file a prospectus supplement or a registration statement to register the resale of such registrable securities on a Form F-3 or Form F-3ASR registration statement (or, if Form F-3 or Form F-3ASR is not then available to us, on Form F-1 or such other form of registration statement as is then available to effect a registration for resale of such registrable securities), and have such registration statement declared effective by the SEC no later than (a) the ten (10) business days after the later of (i) the first date when we become eligible to use registration statement on F-3, or (ii) the expiration of the lock-up period with respect to the subsequent closing, or forty-five (45) calendar days after such lock-up period expiration date if the SEC reviews and comments on the registration statement. We shall maintain the effectiveness of such registration statement for a period ending on the date the registrable securities registered thereon have ceased to be registrable securities.

Demand Registration Rights. Upon written request from the Hillhouse Entities at any time after we have effected two registration statements abovementioned, with respect to the registrable securities then held by the Hillhouse Entities, and in no event later than the forty-five (45) calendar days following the delivery of such request, we shall file a prospectus supplement or a registration statement to register the resale of such registrable securities on a Form F-3 or Form F-3ASR registration statement (or, if Form F-3 or Form F-3ASR is not then available to us, on Form F-1 or such other form of registration statement as is then available to effect a registration for resale of such registrable securities), have such registration statement declared effective, and maintain the effectiveness of such registration statement for a period ending on the date the registrable securities registered thereon have ceased to be registrable securities. If the registrable securities are offered by means of an underwritten offering, and we or the underwriters determine that marketing factors require a limitation of the number of securities to be underwritten, the number of registrable securities that may be included in the underwriting shall be r educed and allocated (i) first, to us and each holder in accordance with the terms of the Shareholders Agreement; (ii) second, to investors in the private placements entered into in September 2020 (including the Hillhouse Entities) requesting inclusion of their registrable securities in such registration statement on a pro rata basis based on the total number of registrable securities then held by each such investor; and (iii) third, to other holders of registrable securities, if any.

Suspension of Registration. We may suspend the use of any registration statement for a period not exceeding thirty (30) consecutive trading days, if we (i) determine that we would be required to make disclosure of material information in the registration statement that we have a bona fide business purpose for preserving as confidential; (ii) determine that we must amend or supplement the registration statement so that it shall not include an untrue statement of a material fact or omit to state a material fact; or (iii) have experienced or are experiencing some other material non-public event, the disclosure of which at such time would adversely affect us. However, we cannot exercise the suspension right more than once in any twelve (12) month period and may not register any other securities during such suspension period.

Expenses. We will bear all registration expenses, except any (i) portions of fees and disbursements of counsel for the Hillhouse Entities exceeding US$30,000, (ii) underwriting discounts and selling commissions applicable to sale of registrable securities, and (iii) fees payable pursuant to the deposit agreement.

Ranking of Registration Rights. Registration rights granted to the Hillhouse Entities shall not be senior to, or on a parity with, those granted to holders under the Shareholders Agreement.

Board Representation Rights. As long as the Hillhouse Entities continue to jointly beneficially own at least five percent (5.0%) of our total issued and outstanding share capital, it is entitled to nominate and maintain one representative to our board of directors. We shall cause an individual jointly designated by the Hillhouse Entities to be appointed as the investor director with immediate effect no later than the fifteenth (15^{th}) business day after receiving written notice from Hillhouse Entities or such later date on which we receive necessary shareholder approval.

Lock-up. The Hillhouse Entities shall not dispose of any of the ordinary shares purchased by Hillhouse Entities on the applicable initial or subsequent closing date within a 90-day period following September 11, 2020 or a subsequent closing date set forth in the subscription agreement to any person other than affiliates of the Hillhouse Entities, who shall be bound by the Hillhouse Entities' lock-up obligations for the balance of each applicable lock-up period. Each of the Hillhouse Entities and their affiliates may directly or indirectly, place any charge, mortgage, lien, pledge, restrictions, security interest or other encumbrance in respect of the lock-up securities in connection with such Hillhouse Entity's (or any of its affiliates') margin loans, collars, derivative transactions or other such downside protection transactions to be entered into on or after the date of the subscription agreement.

Anti-dilution rights. We agree not to issue, offer, sell, or grant any option or right to purchase any new securities, without the prior written consent of the Hillhouse Entities, (i) during the 90-day period following each closing date; or (ii) at an effective purchase price per share lower than the purchase price under the Subscription Agreement with Hillhouse Entities during the 90-day period commencing from the expiration of each lock-up period.

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

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). For a detailed description of this assignment and license agreement, see "Item 4. Information on the Company—B. Business Overview—Licensing and Collaboration Arrangements—(a) In-Licensing Arrangements."

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 nil, RMB5.6 million and nil for the year ended December 31, 2018, 2019 and 2020, respectively.

In August 2017, we entered into a two-way master service agreement with Genexine, further amended in October 2019, whereby both parties agreed that we or Genexine will be engaged by the other party in the business of providing contract research and manufacturing services for biopharmaceutical in this agreement or following work statements. We had paid US$0.7 million, US$0.8 million and US$0.7 million to Genexine for their CMC relevant services for the year ended December 31, 2018, 2019 and 2020, respectively.

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 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 CMAB, this agreement was further amended in November 2019, with respect to the change of work scope of the original Service Proposal. Pursuant to these three 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 and RMB0.7 million (US$0.1 million) for the year ended December 31, 2020.

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. Everest had paid us prepayments of RMB178.7 million, RMB53.1 million (US$7.6 million) and nil for the year ended December 31, 2018, 2019 and 2020, 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 felzartamab in Greater China. Upon the termination, Everest will not retain any rights or entitlements to develop or commercialize felzartamab or any economic interest in its commercialization. All intellectual property rights in respect of felzartamab 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 felzartamab 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 felzartamab 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 November 2020, we entered into a product development and supply agreement with Jiangsu Taslydiyi Pharmaceutical Co., Ltd. ("Jiangsu Taslydidyi"), an affiliate of Tasly. Both parties agreed that Jiangsu Taslydiyi will supply temozolomide capsules to us free of charge in our efineptakin alfa (TJ107) Phase 2 and future Phase 3 clinical trials in GBM treatment. We agreed that when reaching the commercialization stage, we will grant the Right of First Negotiation (ROFN) to Jiangsu Taslydiyi for the commercialization of efineptakin alfa in mainland China. We incurred RMB2.4 million (US$0.4 million) in research and development expenses for the aforementioned drug supply services for the year ended December 31, 2020.

In July 2019, we entered into a loan agreement with I-Mab Hangzhou, pursuant to which I-Mab Hangzhou borrowed RMB2 million (US$0.3 million) from us for a term of 12 months with a free interest. In July 2020, we entered into another loan agreement with I-Mab Hangzhou, pursuant to which I-Mab Hangzhou borrowed RMB50 million (US$7.7 million) from us for a term of 4 months with a free interest. Under the terms of these two agreements, we provided loans to I-Mab Hangzhou to finance their daily operations. These loans were repaid to us in November 2020.

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. In April 2020, Tracon issued a notice of disputes with respect to the TJD5 Agreement and the BsAbs Agreement. As of the date of this annual report, these disputes have not been resolved. In February 2021, we sent Tracon a notice to terminate the TJD5 Agreement, which would result in a prespecified termination fee of US$9.0 million owing to Tracon. 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. 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 Act, 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 by the Companies Act 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 Act, 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 Act 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 Act 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 Act, 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 Act, 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 Act. The Companies Act 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 under this item, in "Item 4. Information on the Company", "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions," "Item 10. Additional Information—C. Material Contracts" or elsewhere in this annual report on Form 20-F.

Subscription Agreements with Certain Investors Other Than Hillhouse Entities

In September 2020, we entered into subscription agreements with various investors other than HillHouse Entities. The subscription agreements are of the same form and provide for certain investors' rights, such as registration rights and anti-dilution right. Set forth below is a description of certain rights and restrictions thereof.

Mandatory Registration. We agree to file with the SEC a registration statement to register the resale of such investors' registrable securities, which include ordinary shares issued and issuable upon exercise of Investor Warrants under the Subscription Agreement, on Form F-3 or Form F-1, as applicable. We shall have the relevant registration statement declared effective by the SEC no later than ninety (90) calendar days after the initial closing date, which period could be extended to one hundred and twenty (120) calendar days if the SEC reviews and comments on the registration statement. However, if the SEC prevents inclusion of the registrable securities in the registration statement pursuant to limitations under Rule 415 of the Securities Act, the number of registrable securities to be registered for each selling shareholder named in the registration statement shall be reduced pro rata among all such selling shareholders. We shall maintain the continuous effectiveness of the registration statement for a period of ninety (90) days after its effectiveness or such shorter period upon which such investors have notified us that their registrable securities have actually been sold.

Piggyback Registration. We agree to notify such investors at least thirty (30) days prior to filing any registration statement for purposes of effecting a public offering of ADSs (excluding registration statements relating to the mandatory registration described above). The Private Placement Investors has 20 days after receiving notice from us to notify us in writing of their desire to include their registrable securities in the registration statement. However, if the registrable securities in such registration statement are offered by means of an underwritten offering, and we or the underwriters determine that marketing factors require a limitation of the number of securities to be underwritten, the number of registrable securities that may be included in the underwriting shall be reduced and allocated (i) first, to us and each holder in accordance with the terms of the Shareholders Agreement; (ii) second, to investors in the private placements entered into in September 2020 requesting inclusion of their registrable securities in such registration statement on a pro rata basis based on the total number of registrable securities then held by each such investor; and (iii) third, to other holders of registrable securities, if any.

Suspension of Registration. We may suspend the use of any registration statement for a period not exceeding thirty (30) consecutive trading days, if we (i) determine that we would be required to make disclosure of material information in the registration statement that we have a bona fide business purpose for preserving as confidential; (ii) determine that we must amend or supplement the registration statement so that it shall not include an untrue statement of a material fact or omit to state a material fact; or (iii) have experienced or are experiencing some other material non-public event, the disclosure of which at such time would adversely affect us. However, we cannot exercise the suspension right more than once in any twelve (12) month period and may not register any other securities during such suspension period.

Expenses. We will bear all registration expenses, except any (i) portions of fees and disbursements of counsel for such investors, and (ii) underwriting discounts and selling commissions applicable to sale of registrable securities.

Ranking of Registration Rights. Registration rights granted to such investors shall not be senior to, or on a parity with, those granted to holders under the Shareholders Agreement.

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 the 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 the 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 are a party to a double tax treaty entered into with the United Kingdom in 2010 but otherwise is not party to any double tax treaties. 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 or ordinary shares and holds our ADSs or ordinary shares 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. There can be no assurance that the Internal Revenue Service, or 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, 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; 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.

We do not believe that we were a PFIC for the taxable year ended December 31, 2020. Although we do not believe we were a PFIC for the taxable year ended December 31, 2020, no assurance can be given with respect to our PFIC status 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. Furthermore, prior to the commercialization of any of our drug candidates, interest and other passive income could constitute more than 75% of gross income for any taxable year. 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 are listed on the Nasdaq Global Market. We believe that the ADSs are 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 believe that the ADSs, but not our ordinary shares, will be treated as marketable stock because the ADSs are listed on the Nasdaq Global Market. However, we cannot guarantee that 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, no assurances may be given in this regard.

Because a mark-to-market election cannot technically 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 2018, 2019 and 2020 were increases of 1.9%, 4.5% and 0.2%, 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 RMB1,680.9 million, RMB1,193.3 million and RMB4,758.8 million (US$729.3 million) as of December 31, 2018, 2019 and 2020, 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, 2020, we had RMB-denominated cash and cash equivalents, restricted cash and short-term investments of RMB483.1 million (US$74.0 million). A 10% depreciation of RMB against U.S. dollar based on the foreign exchange rate on December 31, 2020 would result in a decrease of US$7.4 million in cash and cash equivalents. A 10% appreciation of RMB against U.S. dollar based on the foreign exchange rate on December 31, 2020 would result in an increase of US$7.4 million in cash and cash equivalents.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Pursuant to the Subscription Agreements, we agree to issue and sell to the investors thereunder the Investor Warrants, exercisable at the election of the applicable investors within 12 months after the initial or subsequent closing dates set forth in the applicable Subscription Agreements. On September 11, 2020 and December 17, 2020, we issued and sold a portion of the Investor Warrants, allowing the applicable investors to purchase 3,744,032 ordinary shares and 1,597,235 ordinary shares, respectively. As of the date of this annual report, none of the Investor Warrants has been exercised.

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 amount 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. For the period from January 16, 2020, the date that the Form F-1 was declared effective by the SEC, to December 31, 2020, we used approximately US$86.3 million of the net proceeds from our initial public offering as follows:

- approximately US$45.2 million for research and development of our existing drug candidates;
- approximately US$18.4 million for potential investments in the establishment of our own manufacturing capacities, including the construction of our manufacturing facility in China and for expanding our U.S. presence by building research facilities, including a translational medicine laboratory, in the United States; and
- approximately US$22.7 million for general corporate purposes (including working capital needs).

ITEM 15. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, has performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual report, as required by Rule 13a-15(b) under the Exchange Act. Based upon that evaluation, our management, with the participation of our chief executive officer and chief financial officer, has concluded that, as of December 31, 2020, our disclosure controls and procedures were 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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our management, with the participation of our chief executive officer and principal financial officer, evaluated the effectiveness of our internal control over financial reporting based on criteria established in the framework in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2020.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Remediation of the Material Weaknesses in Internal Control over Financial Reporting Reported in 2019

As of December 31, 2020, based on an assessment performed by our management on the performance of certain remediation measures specified below, we determined that the material weaknesses in our internal control over financial reporting previously identified by us and our independent registered public accounting firm in connection with the audits of our consolidated financial statements as of and for the years ended December 31, 2018 and 2019 had been remediated.

The material weaknesses identified related 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 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.

We have implemented a number of measures to address the material weaknesses that were identified in connection with the audits of our consolidated financial statements as of and for the years ended December 31, 2018 and 2019. We have hired qualified financial and accounting staffs with working experience of U.S. GAAP and SEC reporting requirements, in addition, we have engaged an external consulting firm for accounting advisory service on U.S. GAAP and financial reporting. We have also conducted regular and continuous U.S. GAAP accounting and financial reporting training programs for our financial reporting and accounting personnel. We further established 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 have already engaged an external consulting firm to assist us to assess Sarbanes-Oxley Act compliance requirements and improve our overall internal controls. Furthermore, we have prepared comprehensive guidance on accounting policies, manuals and closing procedures to improve the quality and accuracy of our period end financial closing process.

Attestation Report of the Registered Public Accounting Firm

This annual report on Form 20-F does not include an attestation report of our independent registered public accounting firm because we qualified as an "emerging growth company" as defined under the JOBS Act as of December 31, 2020.

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,	
	2019	2020
	(in thousands of RMB)	
Audit fees[(1)]	4,260	8,631
Tax fees[(2)]	230	580
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

On July 15, 2020, we announced a share repurchase program, pursuant to which we were authorized to repurchase our own ordinary shares, in the form of ADSs, with an aggregate value of up to US$20.0 million during a twelve-month period effective upon and from the date on which a formal stock repurchase plan engagement agreement is signed with a qualified broker-dealer(s). As of the date of this annual report, we had not repurchased any ADSs in the open market under this program.

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. We follow home country practice with respect to adoption of the 2020 Plan. If we choose to follow any other 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 with the SEC on October 29, 2019)
2.1	Registrant's Specimen American Depositary Receipt (included in Exhibit 2.3)
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 with the SEC on October 29, 2019)
2.3	Deposit Agreement, dated as of January 22, 2020, among the Registrant, the depositary and holder of the American Depositary Receipt (incorporated herein by reference to Exhibit 4.3 to the registration statement on Form S-8 (File No. 333-239871), as amended, initially filed with the SEC on July 15, 2020)
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 with the SEC on October 29, 2019)
2.5	Description of American Depositary Shares of the Registrant (incorporated herein by reference to Exhibit 2.5 to the annual report on Form 20-F (File No. 001-39173), as amended, initially filed with the SEC on April 29, 2020)
2.6	Description of Ordinary Shares of the Registrant (incorporated herein by reference to Exhibit 2.6 to the annual report on Form 20-F (File No. 001-39173), as amended, initially filed with the SEC on April 29, 2020)
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 with the SEC 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 with the SEC 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 with the SEC on October 29, 2019)
4.4	2020 Share Incentive Plan (incorporated herein by reference to Exhibit 10.4 to the registration statement on Form S-8 (File No. 333-239871), as amended, initially filed with the SEC on July 15, 2020)

4.5	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 with the SEC on October 29, 2019)
4.6	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 with the SEC on October 29, 2019)
4.7	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 with the SEC on October 29, 2019)
4.8†	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 with the SEC on October 29, 2019)
4.9	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 with the SEC on October 29, 2019)
4.10	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 with the SEC on October 29, 2019)
4.11	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 with the SEC on October 29, 2019)
4.12†	Collaboration Agreement, dated as of July 9, 2019, between I-Mab US 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 with the SEC on October 29, 2019)
4.13†	License and Collaboration Agreement, dated as of July 26, 2018, between the Registrant and ABL Bio (incorporated herein by reference to Exhibit 4.12 to the annual report on Form 20-F (File No. 001-39173), as amended, initially filed with the SEC on April 29, 2020)
4.14	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 with the SEC on October 29, 2019)
4.15	Subscription Agreement, dated as of September 3, 2020, among the Registrant and certain affiliates of Hillhouse (incorporated herein by reference to Exhibit 2 of the Schedule 13D (File No. 005-91674) jointly filed by Hillhouse Capital Advisors, Ltd. and Hillhouse Capital Management, Ltd. with the SEC on September 14, 2020)
4.16	Amendment to Subscription Agreement, dated as of December 17, 2020, among the Registrant and certain affiliates of Hillhouse (incorporated herein by reference to Exhibit 5 of the Schedule 13D/A (File No. 005-91674) jointly filed by Hillhouse Capital Advisors, Ltd. and Hillhouse Capital Management, Ltd. with the SEC on December 21, 2020)
4.17	Form of Call Option granted to affiliates of Hillhouse (incorporated herein by reference to Exhibit 4 of the Schedule 13D (File No. 005-91674) jointly filed by Hillhouse Capital Advisors, Ltd. and Hillhouse Capital Management, Ltd. with the SEC on September 14, 2020)
4.18	Form of Subscription Agreement, dated as of September 3, 2020, between the Registrant and certain investors (other than Hillhouse) (incorporated herein by reference to Exhibit 10.17 to the registration statement on Form F-1 (File No. 333- 251050), as amended, initially filed with the SEC on December 1, 2020)

4.19	Form of Warrants to Purchase Ordinary Shares of the Registrant, between the Registrant and certain investors (incorporated herein by reference to Exhibit 10.18 to the registration statement on Form F-1 (File No. 333- 251050), as amended, initially filed with the SEC on December 1, 2020)
4.20†	License and Collaboration Agreement, dated as of September 3, 2020, among I-Mab Shanghai, I-Mab US and AbbVie Ireland Unlimited Company (incorporated herein by reference to Exhibit 10.19 to the registration statement on Form F-1 (File No. 333-251050), as amended, initially filed with the SEC on December 1, 2020)
4.21†	English translation of Equity Transfer and Investment Agreement, dated as of September 15, 2020, among I-Mab Biopharma (Hangzhou) Co., Ltd. and the other parties thereto (incorporated herein by reference to Exhibit 10.20 to the registration statement on Form F-1 (File No. 333- 251050), as amended, initially filed with the SEC on December 1, 2020)
4.22†	English translation of Shareholders Agreement, dated as of September 15, 2020, among I-Mab Biopharma (Hangzhou) Co., Ltd. and other parties thereto (incorporated herein by reference to Exhibit 10.21 to the registration statement on Form F-1 (File No. 333-251050), as amended, initially filed with the SEC on December 1, 2020)
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 with the SEC on October 29, 2019)
12.1*	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2*	Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1**	Certification by Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2**	Certification by Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1*	Consent of JunHe LLP
15.2*	Consent of PricewaterhouseCoopers Zhong Tian LLP
101.INS*	Inline XBRL Instance Document—this instance document does not appear in the Interactive Data File because its XBRL tags are not embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
** Furnished herewith.
† Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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 28, 2021

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, 2020 and 2019, and the related consolidated statements of comprehensive income (loss), of changes in shareholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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 28, 2021

We have served as the Company's auditor since 2018.

I-MAB
Consolidated Balance Sheets
As of December 31, 2019 and 2020
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	As of December 31, 2019 RMB	As of December 31, 2020 RMB	As of December 31, 2020 US$ (Note 2.5)
Assets				
Current assets				
Cash and cash equivalents		1,137,473	4,758,778	729,315
Restricted cash	10	55,810	—	—
Accounts receivable	3, 18	—	130,498	20,000
Contract assets	3, 18	—	227,391	34,849
Short-term investments	2.4, 2.9	32,000	31,530	4,832
Prepayments and other receivables	4	136,036	195,467	29,957
Total current assets		1,361,319	5,343,664	818,953
Property, equipment and software	5	30,069	25,272	3,873
Operating lease right-of-use assets	6	16,435	14,997	2,298
Intangible assets	7	148,844	120,444	18,459
Goodwill	8	162,574	162,574	24,916
Investment accounted for using the equity method	9	—	664,832	101,890
Other non-current assets		18,331	2,010	308
Total assets		**1,737,572**	**6,333,793**	**970,697**
Liabilities, mezzanine equity and shareholders' equity (deficit)				
Current liabilities				
Short-term borrowings	10	50,000	—	—
Accruals and other payables	11	273,553	560,558	85,909
Operating lease liabilities, current	6	6,807	8,058	1,235
Ordinary shares to be issued to Everest	23	258,119	—	—
Deferred subsidy income	2.15	—	7,509	1,151
Total current liabilities		588,479	576,125	88,295
Convertible promissory notes	15	68,199	—	—
Put right liabilities	2.4, 9	—	116,006	17,779
Operating lease liabilities, non-current	6	7,492	5,542	849
Deferred subsidy income	2.15	3,920	—	—
Other non-current liabilities	11	—	8,975	1,375
Total liabilities		**668,090**	**706,648**	**108,298**
Commitments and contingencies	22			
Mezzanine equity				
Series A convertible preferred shares (US$0.0001 par value, 30,227,056 shares authorized, issued and outstanding as of December 31, 2019, and nil authorized, issued and outstanding as of December 31, 2020)	14	687,482	—	—
Series B convertible preferred shares (US$0.0001 par value, 30,305,212 shares authorized, issued and outstanding as of December 31, 2019, and nil authorized, issued and outstanding as of December 31, 2020)	14	921,243	—	—
Series C convertible preferred shares (US$0.0001 par value, 31,046,360 shares authorized, issued and outstanding as of December 31, 2019, and nil authorized, issued and outstanding as of December 31, 2020)	14	1,306,633	—	—
Series C-1 convertible preferred shares (US$0.0001 par value, 3,857,143 shares authorized, issued and outstanding as of December 31, 2019, and nil authorized, issued and outstanding as of December 31, 2020)	14	188,819	—	—
Total mezzanine equity		**3,104,177**	**—**	**—**

I-MAB

Consolidated Balance Sheets (Continued)
As of December 31, 2019 and 2020
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	As of December 31, 2019 RMB	As of December 31, 2020 RMB	As of December 31, 2020 US$ (Note 2.5)
Shareholders' equity (deficit)				
Ordinary shares (US$0.0001 par value, 500,000,000 and 800,000,000 shares authorized as of December 31, 2019 and December 31, 2020, respectively; 8,363,719 and 164,888,519 shares issued and outstanding as of December 31, 2019 and December 31, 2020, respectively)	13	6	114	17
Additional paid-in capital		389,379	7,701,116	1,180,249
Accumulated other comprehensive income (loss)		70,127	(50,793)	(7,784)
Accumulated deficit		(2,494,207)	(2,023,292)	(310,083)
Total shareholders' equity (deficit)		**(2,034,695)**	**5,627,145**	**862,399**
Total liabilities, mezzanine equity and shareholders' equity (deficit)		**1,737,572**	**6,333,793**	**970,697**

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB
Consolidated Statements of Comprehensive Income (Loss)
For the Years Ended December 31, 2018, 2019 and 2020
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	Year Ended December 31, 2018 RMB	2019 RMB	2020 RMB	2020 US$ (Note 2.5)
Revenues					
Licensing and collaboration revenue	18	53,781	30,000	1,542,668	236,424
Expenses					
Research and development expenses	2.18	(426,028)	(840,415)	(984,689)	(150,910)
Administrative expenses		(66,391)	(654,553)	(402,409)	(61,672)
Income (loss) from operations		**(438,638)**	**(1,464,968)**	**155,570**	**23,842**
Interest income		4,597	30,570	24,228	3,713
Interest expense		(11,695)	(2,991)	(957)	(147)
Other income (expenses), net	19	(16,780)	(20,205)	412,892	63,278
Equity in loss of an affiliate	9	—	—	(108,587)	(16,642)
Fair value change of warrants	2.4	61,405	5,644	—	—
Income (loss) before income tax expense		**(401,111)**	**(1,451,950)**	**483,146**	**74,044**
Income tax expense	12	(1,722)	—	(12,231)	(1,874)
Net income (loss) attributable to I-MAB		**(402,833)**	**(1,451,950)**	**470,915**	**72,170**
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	20	—	(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	20	—	(27,768)	—	—
Net income (loss) attributable to ordinary shareholders		**(402,833)**	**(1,485,001)**	**470,915**	**72,170**
Net income (loss) attributable to I-MAB		**(402,833)**	**(1,451,950)**	**470,915**	**72,170**
Other comprehensive income (loss):					
Foreign currency translation adjustments, net of nil tax		53,689	10,747	(120,920)	(18,531)
Total comprehensive income (loss) attributable to I-MAB		**(349,144)**	**(1,441,203)**	**349,995**	**53,639**
Net income (loss) attributable to ordinary shareholders		**(402,833)**	**(1,485,001)**	**470,915**	**72,170**
Weighted-average number of ordinary shares used in calculating net income (loss) per share - basic	20	6,529,092	7,381,230	134,158,824	134,158,824
Weighted-average number of ordinary shares used in calculating net income (loss) per share - diluted	20	6,529,092	7,381,230	157,231,652	157,231,652
Net income (loss) per share attributable to ordinary shareholders					
—Basic	20	(61.70)	(201.19)	3.51	0.54
—Diluted	20	(61.70)	(201.19)	3.00	0.46
Net income (loss) per ADS attributable to ordinary shareholders					
—Basic		(141.91)	(462.74)	8.07	1.24
—Diluted		(141.91)	(462.74)	6.90	1.06

The accompanying notes are an integral part of these consolidated financial statements.

I-MAB
Consolidated Statements of Changes in Shareholders' Equity (Deficit)
For the Years Ended December 31, 2018, 2019 and 2020
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Ordinary share (Note 13) (US$0.001 par value)						
	Number of shares	Amount	Treasury stock	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity (deficit)
		RMB	RMB	RMB	RMB	RMB	RMB
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 of I-Mab	—	—	—	3,520	—	—	3,520
Transaction with redeemable non- controlling interests	—	—	—	(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 of I-Mab	—	—	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)**

I-MAB
Consolidated Statements of Changes in Shareholders' Equity (Deficit) (Continued)
For the Years Ended December 31, 2018, 2019 and 2020
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Ordinary share (Note 13) (US$0.001 par value)						
	Number of shares	Amount	Treasury stock	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity (deficit)
		RMB	RMB	RMB	RMB	RMB	RMB
Balance as of December 31, 2019	**8,363,719**	**6**	**—**	**389,379**	**70,127**	**(2,494,207)**	**(2,034,695)**
Foreign currency translation adjustments	—	—	—	—	(120,920)	—	(120,920)
Net income	—	—	—	—	—	470,915	470,915
Share-based compensation of I-Mab	—	—	—	402,413	—	—	402,413
Exercise of stock options	1,841,373	3	—	7,771	—	—	7,774
Issuance of ordinary shares for restricted share units (Note 17 (f))	7,000	—	—	46	—	—	46
Conversion from convertible promissory notes (Note 15)	900,000	1	—	58,825	—	—	58,826
Capital contribution from stock option surrender (Note 17 (h))	—	—	—	91,051	—	—	91,051
Conversion of preferred shares to ordinary shares upon the completion of initial public offering ("IPO")	99,760,129	69	—	3,104,108	—	—	3,104,177
Issuance of ordinary shares to Everest	6,078,571	4	—	254,844	—	—	254,848
Issuance of ordinary shares upon IPO and over-allotment, net of issuance cost	18,804,225	13	—	697,865	—	—	697,878
Issuance of ordinary shares upon private placement, net of issuance cost	29,133,502	18	—	2,543,908	—	—	2,543,926
Proportionate share of share-based compensation expenses recorded in an equity method affiliate (Note 9(a))	—	—	—	41,163	—	—	41,163
Issuance of warrants	—	—	—	109,743	—	—	109,743
Balance as of December 31, 2020	**164,888,519**	**114**	**—**	**7,701,116**	**(50,793)**	**(2,023,292)**	**5,627,145**

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, 2018, 2019 and 2020
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Year Ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
Cash flows from operating activities				
Net income (loss)	(402,833)	(1,451,950)	470,915	72,170
Adjustments to reconcile net income (loss) to net cash used in operating activities				
Depreciation of property, equipment and software	6,740	9,831	12,743	1,953
Amortization of intangible assets	—	—	1,556	238
Loss on disposal of property, equipment and software	—	—	8	1
Interest expenses of convertible promissory notes and onshore convertible loans	6,963	—	—	—
Fair value change of warrants	(61,405)	(5,644)	—	—
Fair value change of put right liabilities	—	—	(3,024)	(463)
Fair value change of other financial assets	—	(42)	—	—
Income from other financial assets	(13,622)	—	—	—
Equity in loss of an affiliate	—	—	108,587	16,642
Share-based compensation	3,520	366,895	493,464	75,627
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	—	—
Amortization of right-of use assets and interest of lease liabilities	—	5,803	8,837	1,354
Gains on deconsolidation of a subsidiary	—	—	(407,598)	(62,467)
Fair value change of short-term investments	—	(703)	(11,288)	(1,730)
Changes in operating assets and liabilities				
Accounts receivable	—	—	(130,498)	(20,000)
Contract assets	(11,000)	11,000	(227,391)	(34,849)
Prepayments and other receivables	(76,276)	(48,831)	(58,692)	(8,995)
Accruals and other payables	55,641	188,375	173,713	26,624
Contract liabilities	(15,803)	—	—	—
Advance from customers	14,151	(14,151)	—	—
Research and development funding received	178,715	53,148	—	—
Other non-current liabilities	—	—	7,474	1,145
Deferred subsidy income	2,500	1,420	3,589	550
Lease liabilities	—	(6,172)	(8,837)	(1,354)
Net cash generated from (used in) operating activities	**(280,705)**	**(867,982)**	**433,558**	**66,446**
Cash flows from investing activities				
Purchase of property, equipment and software	(14,409)	(12,241)	(8,008)	(1,227)
Proceeds from disposal of short-term investments	—	102,703	2,503,749	383,716
Purchase of short-term investments	—	(134,000)	(2,491,991)	(381,914)
Cash paid for investments in other financial assets	(30,000)	—	—	—
Cash disposed of resulting from deconsolidation of a subsidiary	—	—	(257,651)	(39,487)
Cash received from disposal of other financial assets	40,000	256,000	—	—
Cash received on income from other financial assets	13,909	—	—	—
Cash received from repayment of loans due from an affiliate	—	—	52,000	7,969
Net cash generated from (used in) investing activities	**9,500**	**212,462**	**(201,901)**	**(30,943)**

I-MAB
Consolidated Statements of Cash Flows (Continued)
For the Years ended December 31, 2018, 2019 and 2020
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Year Ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
Cash flows from financing activities				
Proceeds from issuance of convertible preferred shares, net of issuance cost	1,306,633	183,536	—	—
Proceeds from issuance of convertible promissory notes	59,704	—	—	—
Proceeds from initial public offering and over-allotment, net of underwriting discounts and commissions	—	—	726,300	111,310
Payment of issuance cost for initial public offering and over-allotment	—	(827)	(27,595)	(4,229)
Proceeds from private placement, net of payment of issuance cost	—	—	2,782,455	426,430
Proceeds from exercise of warrants	132,332	—	—	—
Proceeds from exercise of stock options	—	—	9,275	1,422
Proceeds from issuance of ordinary shares for restricted share units	—	—	46	7
Proceeds from bank borrowings	80,000	50,000	—	—
Repayment of bank borrowings	(99,000)	(80,000)	(50,000)	(7,663)
Prepayment for stock repurchase program	—	—	(34,859)	(5,342)
Cash received from collection of prepayment for stock repurchase program	—	—	34,859	5,342
Net cash generated from financing activities	**1,479,669**	**152,709**	**3,440,481**	**527,277**
Effect of exchange rate changes on cash and cash equivalents and restricted cash	59,754	15,163	(106,643)	(16,344)
Net increase (decrease) in cash and cash equivalents and restricted cash	1,268,218	(487,648)	3,565,495	546,436
Cash, cash equivalents, and restricted cash, beginning of year	412,713	1,680,931	1,193,283	182,879
Cash, cash equivalents, and restricted cash, end of the year	**1,680,931**	**1,193,283**	**4,758,778**	**729,315**

I-MAB
Consolidated Statements of Cash Flows (Continued)
For the Years ended December 31, 2018, 2019 and 2020
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Year Ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
Additional ASC 842 supplemental disclosures				
Cash paid for fixed operating lease costs included in the measurement of lease obligations in operating activities	—	6,172	8,837	1,354
Right-of-use assets obtained in exchange for operating lease obligations	—	8,595	7,459	1,143
Other supplemental cash flow disclosures				
Interest paid	4,862	2,991	957	147
Non-cash activities				
Exercise of warrants	1,314	—	—	—
Payables for in-licensed patent rights	5,970	—	—	—
Accrued initial public offering costs payable	—	17,504	—	—
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	—	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	—	—
Accrued private placement offering costs payable	—	—	128,786	19,737
Ordinary shares issued to Everest	—	—	254,848	39,057
Conversion of preferred shares to ordinary shares	—	—	3,104,177	475,736
Conversion of convertible promissory notes to ordinary shares	—	—	58,826	9,015

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 Act 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.

On January 17, 2020, the Company consummated its IPO on the Nasdaq Global Market, where 7,407,400 American Depositary Shares ("ADSs") were issued at the price of US$14.00 per ADS for 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$114.5 million. Each ten ADSs represents twenty-three ordinary shares of the Company.

As of December 31, 2020, 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 ("I-Mab Hong Kong")	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

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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.

The Group consolidates entities in which it has a controlling financial interest based on either the variable interest entity (VIE) or voting interest model. The Group is required to first apply the VIE model to determine whether it holds a variable interest in an entity, and if so, whether the entity is a VIE. If the Group determines it does not hold a variable interest in a VIE, it then applies the voting interest model. Under the voting interest model, the Group consolidates an entity when it holds a majority voting interest in an entity.

The Company accounts for investments in which it has significant influence but not a controlling financial interest using the equity method of accounting (see Note 9).

VIE Model

An entity is considered to be a VIE if any of the following conditions exist: (a) the total equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support, (b) the holders of the equity investment at risk, as a group, lack either the direct or indirect ability through voting rights or similar rights to make decisions that have a significant effect on the success of the entity or the obligation to absorb the entity's expected losses or right to receive the entity's expected residual returns, or (c) the voting rights of some equity investors are disproportionate to their obligation to absorb losses of the entity, their rights to receive returns from an entity, or both and substantially all of the entity's activities either involve or are conducted on behalf of an investor with disproportionately few voting rights.

Under the VIE model, limited partnerships are considered VIE unless the limited partners hold substantive kick-out or participating rights over the general partner. The Group consolidates entities that are VIEs when the Group determines it is the primary beneficiary. Generally, the primary beneficiary of a VIE is a reporting entity that has (a) the power to direct the activities that most significantly affect the VIE's economic performance, and (b) the obligation to absorb losses of, or the right to receive benefits from, the VIE that could potentially be significant to the VIE.

As of December 31, 2020, the Group determined that the one entity subject to the consolidation guidance is a VIE for which the Group is not the primary beneficiary.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

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 fair value measurements of wealth management products, warrants and put right liabilities, impairment of accounts receivables, contract assets, other receivables, long-lived assets, intangible assets and goodwill, useful lives of property, equipment and software, recognition of right-of-use assets and lease liabilities, variable consideration in collaboration revenue arrangements, determination of the standalone selling price of each performance obligation in the Company's revenue arrangements, valuation of share-based compensation arrangements and deferred tax assets valuation allowances. 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, accounts receivable, contract assets, other receivables, short-term borrowings, accruals and other payables, warrant liabilities and put right liabilities. As of December 31, 2019 and 2020, except for short-term investments, other financial assets and put right 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 put right liabilities at fair value at each balance sheet date and changes in fair value are reflected in the consolidated statements of comprehensive income (loss).

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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 measures its short-term investments, other financial assets, warrant liabilities, and put right liabilities at fair value on a recurring basis. As the Group's short-term investments, other financial assets, warrant liabilities and put right 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, warrant liabilities and put right 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, 2019 and 2020:

	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

	As of December 31, 2020			
	Active market (Level 1) RMB	Observable input (Level 2) RMB	Non-observable input (Level 3) RMB	Total RMB
Assets:				
Short-term investments	—	—	31,530	31,530
Liabilities				
Put right liabilities	—	—	116,006	116,006

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.4 Fair value measurements (continued)

The roll forward of major Level 3 financial assets and financial liabilities are as follows:

	Short-term investments	Other financial assets	Warrant liabilities	Put right liabilities
Fair value of Level 3 financial asset and liabilities 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	—	(256,000)	—	—
Fair value changes	703	42	5,644	—
Currency translation differences	—	—	(26)	—
Fair value of Level 3 financial assets and liabilities as of December 31, 2019	**32,000**	**—**	**—**	**—**
Purchase of short-term investments	2,491,991	—	—	—
Disposal of short-term investments	(2,503,749)	—	—	—
Grant of put right liabilities	—	—	—	124,321
Fair value changes	11,288	—	—	(3,024)
Currency translation differences	—	—	—	(5,291)
Fair value of Level 3 financial assets and liabilities as of December 31, 2020	**31,530**	**—**	**—**	**116,006**

See Note 9 for additional information about Level 3 put right liabilities measured at fair value on a recurring basis for the year ended December 31, 2020.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
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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 income (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 (loss). The exchange rates used for translation on December 31, 2019 and 2020 were US$1.00 = RMB6.9762 and RMB6.5249 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 income (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, 2020 are solely for the convenience of the readers and were calculated at the rate of US$1.00=RMB6.5250, representing the noon buying rate in The City of New York for cable transfers of RMB as certified for customs purposes by the Federal Reserve Bank of New York on December 31, 2020. No representation is made that the RMB amounts could have been, or could be, converted, realized or settled into US$ at that rate on December 31, 2020, 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 Group 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. The Group has presented restricted cash separately from cash and cash equivalents in the consolidated balance sheets.

Cash, cash equivalents and restricted cash as reported in the consolidated statement of cash flows are presented separately on the consolidated balance sheet as follows:

	As of December 31,	
	2019	2020
	RMB	RMB
Cash and cash equivalents	1,137,473	4,758,778
Restricted cash	55,810	—
Total	1,193,283	4,758,778

2.8 Accounts receivable

Accounts receivable are stated at amortized cost less allowance for credit losses. The allowance for credit losses reflects the best estimate of future losses over the contractual life of outstanding accounts receivable and is determined on the basis of historical experience, specific allowances for known troubled accounts, other currently available information including customer financial condition, and both current and forecasted economic conditions.

2.9 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 income (loss).

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.10 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 of any estimated residual value:

Laboratory equipment	3 to 10 years
Software	1 to 5 years
Office furniture and equipment	5 years
Leasehold improvements	Lesser of useful life or lease term

The Group recognizes the gain or loss on the disposal of property, equipment and software in the consolidated statements of comprehensive income (loss).

2.11 Intangible assets

Intangible assets acquired in a business combination that are used in research and development activities, or in-process research and development (IPR&D) intangible assets, are considered indefinite lived until the completion or abandonment of the associated research and development efforts. During the period that those assets are considered indefinite lived, they are not amortized but are tested for impairment annually and more frequently if events or changes in circumstances indicate that it is more likely than not that the asset is impaired. If after assessing the totality of events and circumstances and their potential effect on significant inputs to the fair value determination the Group determines that it is not more likely than not that the indefinite-lived intangible is impaired, then the entity shall calculate the fair value of the intangible asset and perform the quantitative impairment test by comparing the fair value of the asset with its carrying amount. If the carrying amount exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. For IPR&D assets, the impairment loss is recognized in research and development expenses in the consolidated statements of comprehensive income (loss).

Intangible assets with finite useful lives are amortized over their useful lives. The useful life of an intangible asset is the period over which the asset is expected to contribute directly or indirectly to the future cash flows of the Group. The Group uses the straight-line amortization method when the economic benefits of the intangible assets are consumed or otherwise used up cannot be reliably determined. In particular, the Group amortizes the IPR&D intangible assets with finite useful lives over 10 to 20 years on a straight-line basis. Intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an intangible asset may not be recoverable. If circumstances require an intangible asset be tested for possible impairment, the Group first compares undiscounted cash flows expected to be generated by that asset to its carrying amount. If the carrying amount is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. For IPR&D assets, the impairment loss is recognized in research and development expenses in the consolidated statements of comprehensive income (loss).

2.12 Impairment of long-lived assets

Long-lived assets, such as property, plant, and software, and intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying amount. If the carrying amount of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered necessary. For the years ended December 31, 2019 and 2020, there was no impairment of the value of the Group’s long-lived assets.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.13 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 is tested on at least an annual basis or whenever events or changes in circumstances indicate that the carrying value of the asset may not be recoverable.

The Group first assesses 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, 2019 and 2020, the Group determined that there were no indicators of impairment of the goodwill.

2.14 Long-term investments

The Group's long-term investments include equity investments in an affiliate in which it does not have a controlling financial interest, but has the ability to exercise significant influence over the operating and financial policies of the investee. The investment is accounted for using the equity method of accounting in accordance with ASC topic 323, Investments—Equity Method and Joint Ventures ("ASC 323"). Under the equity method, the Group initially records its investments at fair value. The Group subsequently adjusts the carrying amount of the investment to recognize the Group's proportionate share of the equity investee's net income or loss after the date of investment. When the liquidation rights and priorities as defined by an equity investment agreement differ from what is reflected by the underlying percentage ownership interests, applying the percentage ownership interest to U.S. GAAP net income in order to determine earnings or losses does not accurately represent the income allocation and cash flow distributions that will ultimately be received by the investors. As such, for this type of investments, the Group uses the Hypothetical Liquidation at Book Value ("HLBV") method for allocating earnings or losses of the equity method investee. The HLBV method is considered as a balance sheet approach. Specifically, a calculation is prepared at each balance sheet date to determine the amount that the Group would receive if an equity investment entity were to liquidate all of its assets (as valued in accordance with U.S. GAAP) and distribute that cash to the investors based on the contractually defined liquidation priorities. The difference between the calculated liquidation distribution amounts at the beginning and the end of the reporting period, after adjusting for capital contributions and distributions, is the Group's share of the earnings or losses from the equity investment for the period.

As it relates to the share-based compensation awarded by an equity method investee to its own employees, the Group recognizes its proportionate share of the compensation expense over the vesting period, included in the equity in loss of affiliate in the consolidated statements of comprehensive income (loss). As it relates to the share-based compensation awarded by the Group to the equity method investee employees that are based on the Group's stock, when the other investors do not provide proportionate value to the investee or the Group does not receive any consideration, the Group expenses the entire cost associated with the award in the same period the costs are recognized by the investee, to the extent that the Group's claim on the investee's book value has not been increased. The expenses recognized by the Group is included in the equity in loss of affiliate in the consolidated statements of comprehensive income (loss).

The Group evaluates the equity method investment for impairment under ASC 323. An impairment loss on the equity method investments is recognized in losses when the decline in value is determined to be other-than-temporary. No impairment charge was recognized for the year ended December 31, 2020.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.15 Deferred subsidy income

Deferred subsidy income consists of deferred income from government grants. Government grants mainly 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 as other income when all the obligations have been satisfied. If such obligations are not satisfied, the Group may be required to refund the subsidy. The Group recorded cash grants of RMB7,509 and RMB3,920 and in deferred subsidy income as of December 31, 2020 and 2019 respectively.

2.16 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.

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. An the entity performs the following five steps to account for the arrangements that an entity determines are within the scope of ASC 606: (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.

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, 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. For any units of account that are reflective of a vendor-customer relationship those units of account are accounted for within the scope of ASC 606. For any units of account that are not accounted for under ASC 606 and therefore accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.16 Revenue recognition (continued)

Collaboration revenue (continued)

The Group's collaborative arrangements may contain more than one unit of account, or performance obligation, such as grant of licenses of intellectual property rights, promises to provide research and development services and other deliverables. The collaborative arrangements do not include a right of return for any deliverable. When multiple units of account or performance obligations are identified within the 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.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.16 Revenue recognition (continued)

Collaboration revenue (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 the license that is determined to be distinct, the Group recognizes revenues in the amount of non-refundable, up-front fees allocated to the license at a point in time, upon which 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 revenue over time as delivery or performance of such services provided to the Group's customers 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 resulting adjustment is recorded on a cumulative catch-up basis, which would affect the Group's reported revenues and earnings in the period of the 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 sales-based royalties or milestone payments 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).

Contract assets and liabilities

Contract assets primarily represent revenue earnings over time that are not yet billable based on the terms of the contracts. The Group does not have impairment losses associated with contracts with customers for the years ended December 31, 2019 and 2020.

Contract liabilities consist of fees invoiced or paid by the Group's customers for which the associated performance obligations have not been satisfied and revenue has not been recognized based on the Group's revenue recognition criteria described above.

Contract assets and contract liabilities are reported in a net position on an individual contract basis at the end of each reporting period. Contract assets are classified as current in the consolidated balance sheet when the Group expects to complete the related performance obligations and invoice the customers within one year of the balance sheet date, and as long-term when the Group expects to complete the related performance obligations and invoice the customers more than one year out from the balance sheet date. Contract liabilities are classified as current in the consolidated balance sheet when the revenue recognition associated with the related customer payments and invoicing is expected to occur within one year of the balance sheet date and as long-term when the revenue recognition associated with the related customer payments and invoicing is expected to occur in more than one year from the balance sheet date.

2.17 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 12% of the value-added-tax depending on the tax-payer's location. The deductible input VAT balance is included in the prepayments and other receivables in the consolidated balance sheets, and VAT payable balance is recorded in the accruals and other payables in the consolidated balance sheets.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.18 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, and (5) other research and development expenses. Research and development expenses are charged to expenses as incurred when these expenditures are used for the Group's research and development activities 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 does 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 are capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. All development expenditures are recognized in profit or loss when incurred, as long as the conditions enabling capitalization of development expenses as an asset have not yet been met.

2.19 Leases

In accordance with ASC 842 adopted 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. The Group does not have any finance leases since the adoption date.

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 Group 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 Group's results of operations or cash flows.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.20 Comprehensive income (loss)

Comprehensive income (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 income (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 income (loss) includes net income (loss) and foreign currency translation adjustments, which are presented in the consolidated statements of comprehensive income (loss).

2.21 Share-based compensation

The Group 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, if equity-classified, are measured at the grant date fair value of the awards and are recognized as expenses over the requisite period of the award, which is generally the vesting term of share-based payment awards.

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. In addition, the forfeiture rate is estimated based on an analysis of the Group's actual forfeitures and the appropriateness of the forfeiture rate will continue to be evaluated based on the actual forfeiture experience, analysis of employee turnover and other factors. The fair value of these awards was determined with the assistance from an independent third-party valuation firm.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.22 Income taxes

The Group accounts for income taxes under the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the enacted tax rates that expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. 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.

2.23 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 as interest expense in the consolidated statements of comprehensive income (loss) over the period of the borrowings, using the effective interest method.

2.24 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.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.25 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.

2.26 Income (loss) per share

Basic income (loss) per share is computed by dividing net income (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 income (loss) is allocated between ordinary shares and other participating securities based on their participating rights. Net income (loss) is not allocated to other participating securities if based on their contractual terms they are not obligated to share in the income (loss). Diluted income (loss) per share is calculated by dividing net income (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 issuance of ordinary shares to be issued to Everest using the if-converted method, shares issuable upon the conversion of the convertible promissory notes using the if-converted method, shares issuable upon the exercise of share options using the treasury stock method, shares issuable upon the issuance of ordinary shares for restricted shares units using the treasury stock 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 income (loss) per share calculation when inclusion of such shares would be anti-dilutive.

2.27 Adopted 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. The Group elected to adopt this ASU and applied this guidance retrospectively to all periods presented.

In January 2017, the FASB issued ASU 2017-04, Intangibles—Goodwill and Other (Topic 350), which simplifies the subsequent measurement of goodwill by removing the second step of the two-step impairment test. The amendment requires an entity to perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. A goodwill impairment will be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. The Group adopted this ASU on January 1, 2020 and the adoption of this ASU does not have a material impact to its consolidated financial statements.

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.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.27 Adopted 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 the Group 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. Since the Group's all relevant units of accounts were accounted for under ASC 606, the adoption of this ASU does not have a material impact to the Group's consolidated financial statements, with no adjustment to its opening retained earnings.

2.28 Recent accounting pronouncements

In December 2019, the FASB issued ASU 2019-12-Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. The amendments in ASU 2019-12 simplify the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify U.S. GAAP for other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 is effective for the Company beginning on January 1, 2022. Early adoption of the amendments is permitted. The Company is currently evaluating the impact of ASU 2019-12 on its consolidated financial statements.

In January 2020, the FASB issued ASU 2020-01, Investments – Equity Securities (Topic 321), Investments – Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815): Clarifying Interactions between Topic 321, Topic 323, and Topic 815. ASU 2020-01addresses accounting for the transition into and out of the equity method and provides guidance on whether equity method accounting would be applied to certain purchased options and forward contracts upon settlement. ASU 2020-01 is effective for the Group's annual periods beginning after December 15, 2021. ASU 2020-01 will be applied prospectively. Early adoption is permitted. The Group is currently evaluating the effect the adoption of ASU 2020-01 will have on its consolidated financial statements.

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3. ACCOUNTS RECEIVABLE AND CONTRACT ASSETS

Accounts receivable and contract assets, net of allowance for credit losses, consisted of the following:

	As of December 31,		
	2019	2020	
	RMB	RMB	US$(Note 2.5)
Accounts receivable, gross	—	130,498	20,000
Allowance for credit losses	—	—	—
Accounts receivable, net	—	130,498	20,000

	As of December 31,		
	2019	2020	
	RMB	RMB	US$(Note 2.5)
Contract assets, gross	—	227,391	34,849
Allowance for credit losses	—	—	—
Contract assets, net	—	227,391	34,849

No allowance for credit losses was recorded as of December 31, 2019 and 2020.

4. PREPAYMENTS AND OTHER RECEIVABLES

	As of December 31,		
	2019	2020	
	RMB	RMB	US$ (Note 2.5)
Prepayments:			
- Prepayments to CRO vendors	78,740	83,140	12,742
- Prepayments for other services	880	2,550	391
Receivables due from employees [(1)]	16,201	—	—
Receivables due from an affiliate (Note 23)	—	21,212	3,251
Value-added tax recoverable	12,517	63,664	9,757
Rental deposits	546	1,766	271
Interest receivables	764	236	36
Others	26,388	22,899	3,509
	136,036	195,467	29,957

(1) The balance mainly represents the receivables due from certain employees, arose from the Group's obligation to pay the withholding individual income tax ("IIT") for those employees' stock option activities. The balance was collected by the Group in January 2020.

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5. PROPERTY, EQUIPMENT AND SOFTWARE

Property, equipment and software consist of the following:

	As of December 31, 2019	As of December 31, 2020	
	RMB	RMB	US$ (Note 2.5)
Cost			
Laboratory equipment	24,265	30,808	4,722
Leasehold improvement	11,856	13,842	2,121
Software	10,220	9,990	1,531
Office furniture and equipment	1,526	1,531	234
Total property, equipment and software	47,867	56,171	8,608
Less: accumulated depreciation and amortization	(18,221)	(30,899)	(4,735)
Net book value	29,646	25,272	3,873
Construction in progress	423	—	—
Total net book value of property, equipment and software	30,069	25,272	3,873

The total amounts charged to the consolidated statements of comprehensive income/(loss) for depreciation and amortization expenses amounted to approximately RMB6.7 million, RMB9.8 million and RMB12.7 million, for the years ended December 31, 2018, 2019 and 2020, respectively.

6. LEASES

As of December 31, 2020, the Company has operating leases recorded on its balance sheet for certain office spaces and facilities that expire on various dates through 2023. 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 and 2020 is as follows (in thousands, except for percentages and years).

	As of December 31,		
	2019	2020	
	RMB	RMB	US$ (Note 2.5)
Assets			
Operating lease right-of-use assets	16,435	14,997	2,298
Liabilities			
Operating lease liabilities, current	6,807	8,058	1,235
Operating lease liabilities, non-current	7,492	5,542	849
Weighted average remaining lease term (years)	2.4	1.7	1.7
Weighted average discount rate	5%	5%	5%

Information related to operating lease activity during the years ended December 31, 2019 and 2020 is as follows:

	For the Year Ended		
	2019	2020	
	RMB	RMB	US$ (Note 2.5)
Operating lease rental expense			
Amortization of right-of-use assets	5,260	8,158	1,250
Expense for short-term leases within 12 months	592	—	—
Interest of lease liabilities	543	679	104
	6,395	8,837	1,354

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6. LEASES (CONTINUED)

Maturities of lease liabilities were as follows:

	As of December 31, 2020	
	RMB	**US$ (Note 2.5)**
2020	—	—
2021	8,901	1,364
2022	5,464	837
2023	536	82
2024	—	—
Thereafter	—	—
Total undiscounted lease payments	14,901	2,283
Less: imputed interest	(1,301)	(199)
Total lease liabilities	**13,600**	**2,084**

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7. INTANGIBLE ASSETS

Intangible assets as of December 31, 2019 and 2020 are summarized as follows:

	As of December 31, 2020			
	Gross carrying amount RMB	Accumulated amortization RMB	Net carrying amount RMB	Net carrying amount US$ (Note 2.5)
Intangible assets				
IPR&D TJ103	11,670	(1,556)	10,114	1,550
IPR&D TJ101	110,330	—	110,330	16,909
Total intangible assets	122,000	(1,556)	120,444	18,459

	As of December 31, 2019			
	Gross carrying amount RMB	Accumulated amortization RMB	Net carrying amount RMB	Net carrying amount US$ (Note 2.5)
Intangible assets				
IPR&D TJ103	11,670	—	11,670	1,788
IPR&D TJ102	26,844	—	26,844	4,114
IPR&D TJ101	110,330	—	110,330	16,909
Total intangible assets	148,844	—	148,844	22,811

The three IPR&D assets (TJ103, TJ101, and TJ102) were acquired from the 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. The licensor of these IPR&D assets was Genexine, Inc. The gross carrying amounts represent the fair value assigned to the respective research and development assets. At the date of acquisition, all three assets had not reached technological feasibility. They were considered indefinite lived.

IPR&D related to TJ103 was subsequently determined to have a finite useful life as a result of an out-licensing arrangement. Consequently, the Group uses the straight-line method to amortize the asset. The amortization for the years ended December 31, 2018, 2019 and 2020 was nil, nil, and RMB1,556 respectively, recognized as research and development expenses in the consolidated statements of comprehensive income (loss). The estimated amortization expense for each of the five succeeding fiscal years is RMB778.

On September 15, 2020, I-Mab Hong Kong and Genexine, Inc. entered into amendments to Intellectual Property License Agreement with I-Mab Hangzhou to assign and transfer all the rights and obligations related to TJ102 to I-Mab Biopharma (Hangzhou) Limited ("I-Mab Hangzhou"), pursuant to an equity transfer and investment agreement entered into between I-Mab Hong Kong and various parties (see Note 9).

As of December 31, 2019 and 2020, there was no impairment of the value of the Group's intangible assets.

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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, 2019 and 2020, the goodwill of RMB162,574 (US$24,916) 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, 2019 and 2020, 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. INVESTMENT ACCOUNTED FOR USING THE EQUITY METHOD AND PUT RIGHT LIABILITIES

(a) Investment accounted for using the equity method

I-Mab Hangzhou, incorporated on June 16, 2019, was a wholly owned subsidiary of I-Mab Hong Kong with registered capital of US$30 million, which was paid up by I-Mab Hong Kong on September 14, 2020.

On September 15, 2020 (the "Closing Date"), I-Mab Hong Kong entered into an equity transfer and investment agreement (the "SPA") with (i) a limited partnership jointly established by the management of I-Mab Hangzhou to hold restricted equity of I-Mab Hangzhou issued to the management ("Management Holdco"), (ii) a limited partnership established to hold the shares of I-Mab Hangzhou for future equity incentive plan ("ESOP Holdco") and (iii) a group of domestic investors in China ("Domestic Investors").

In accordance with the terms of the SPA,

(i) I-Mab Hong Kong agreed to assign all rights and obligations/ownership of certain drug candidates in different stages of development ("Target Pipelines") to I-Mab Hangzhou as of the Closing Date as well as to transfer employment of a team of designated management/workforce to I-Mab Hangzhou. The Target Pipelines were evaluated by an independent valuer, with a total value of US$105 million as of the Closing Date;

(ii) Management Holdco would acquire 10% of the equity of I-Mab Hangzhou from I-Mab Hong Kong with no consideration. The 10% equity is represented by I-Mab Hangzhou's registered capital of US$3 million, and that after acquiring such equity, Management Holdco is committed to pay US$3 million in cash to I-Mab Hangzhou to fulfil its capital contribution obligations in a period of four years starting from the Closing Date;

(iii) ESOP Holdco would acquire 5% of the equity of I-Mab Hangzhou from I-Mab Hong Kong with no consideration. The 5% equity is represented by I-Mab Hangzhou's registered capital of US$1.5 million. All of such equity would be used for I-Mab Hangzhou's future equity incentive plan.

(iv) Domestic Investors would acquire a total of 40% of the equity of I-Mab Hangzhou from I-Mab Hong Kong with no consideration. The 40% equity is represented by I-Mab Hangzhou's registered capital of US$12 million, and after acquiring such equity of I-Mab Hangzhou, Domestic Investors would pay US$120 million collectively in cash to I-Mab Hangzhou to fulfil its capital contribution obligations.

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9. INVESTMENT ACCOUNTED FOR USING THE EQUITY METHOD AND PUT RIGHT LIABILITIES

(a) Investment accounted for using the equity method (continued)

Upon closing of the SPA, the registered capital of I-Mab Hangzhou remained to be US$30 million. As of December 31, 2020, among the total 25,500,000 outstanding shares of I-Mab Hangzhou, 13,500,000 shares were held by I-Mab Hong Kong while the remaining 12,000,000 shares was held by Domestic Investors. Shares subscribed by Management Holdco and ESOP Holdco, in the total number of 4,500,000, have not yet been purchased by or issued to Management Holdco and ESOP Holdco as of December, 31, 2020. Once all these 4,500,000 subscribed shares of I-Mab Hangzhou are purchased by or issued to Management Holdco and ESOP Holdco, the equity interest in I-Mab Hangzhou held by I-Mab Hong Kong, Domestic Investors, Management Holdco and ESOP Holdco would be 45%, 40%, 10% and 5% respectively.

On the same day, I-Mab Hong Kong also entered into a shareholders agreement with the aforementioned investors (the “SHA”). According to the SHA and I-Mab Hangzhou’s articles of association, the board of directors of I-Mab Hangzhou shall be composed of seven directors. The directors shall be elected in the following ways: I-Mab Hong Kong is entitled to appoint three directors, including the chairman of the board of directors, as well as nominate one independent director; the Management Holdco is entitled to appoint one director; two non-related entities of the Domestic Investors are entitled to appoint one director respectively (“Investors Directors”). Each director of the board of directors shall have one vote. I-Mab Hong Kong, Management Holdco and ESOP Holdco agree to act in concert, as long as each of Management Holdco and ESOP Holdco respectively holds equity in I-Mab Hangzhou, when exercising the rights as a shareholder.

As a result of the above transactions, I-Mab Hangzhou became an affiliate of the Group on the Closing Date in accordance with ASC 810 since I-Mab Hangzhou meets the definition of a business under ASC 805. In accordance with ASC 810-10, I-Mab Hangzhou is a variable interest entity, and no shareholder shall consolidate I-Mab Hangzhou under VIE model as neither party have the power to direct all the activities that most significantly impact the economic performance of I-Mab Hangzhou. Therefore, the Group deconsolidated I-Mab Hangzhou and retained significant influence in I-Mab Hangzhou. The investment was accounted for using the equity method. The retained investment in the common stock of I-Mab Hangzhou was initially measured at fair value in accordance with ASC 810-10-40.

The Group determined the fair value of its retained equity interest with the assistance of an independent third-party valuation firm. The Group used equity allocation model to estimate the fair value of the investment. The fair value as of the Closing Date was US$112,039 (equivalent to approximately RMB764,352), which reflected the fact that the shares subscribed by Management Holdco and ESOP Holdco were not issued and outstanding as of the Closing Date.

A gain of RMB407,598 million was recognized as a result of the deconsolidation. The gain represented the difference between:

i) The fair value of the retained noncontrolling investment in I-Mab Hangzhou at the Closing Date; and

ii) The aggregate of all of the following:

   a) the carrying amount of transferred intellectual property related to TJ102 at the Closing Date (see Note 7);

   b) the fair value of the put right liabilities written by I-Mab Hong Kong to Domestic Investors;

   c) the carrying amount of I-Mab Hangzhou’s net assets at the Closing Date.

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9. INVESTMENT ACCOUNTED FOR USING THE EQUITY METHOD AND PUT RIGHT LIABILITIES (CONTINUED)

(a) Investment accounted for using the equity method (continued)

Subsequently, pursuant to the I-Mab Hangzhou's articles of association, the Group applies the HLBV method to allocate earnings or losses of I-Mab Hangzhou because the liquidation rights and priorities sufficiently differ from what is reflected by the underlying percentage ownership interests. For the period from September 15, 2020 to December 31, 2020, the Group recognized RMB67,425 in equity in loss of an affiliate in the consolidated statements of comprehensive income.

The purchase price of US$3 million committed by Management Holdco under SPA, representing 10% of the equity of I-Mab Hangzhou, is significantly lower than the fair value of the corresponding subscribed shares as of the Closing Date. The excess is considered as share-based compensation to the I-Mab Hangzhou's management for the services to be used or consumed in the I-Mab Hangzhou's own operations. The share-based compensation is considered granted upon the Closing Date and cliff vests after five years of service since the Closing Date. Consequently, the Group recognizes its proportionate share of the compensation expense recorded by I-Mab Hangzhou. For the period from September 15, 2020 to December 31, 2020, the amount included in the equity in loss of an affiliate in the Group's consolidated statements of comprehensive income is RMB8,456.

Along with the equity transfer transaction, the team of designated management/workforce transferred from the Group to I-Mab Hangzhou consists of several grantees under the Group's 2020 Share Incentive Plan ("2020 Plan", see Note 17(f)). These individuals continued to qualify the definition of the eligible participants under the 2020 Plan after the Closing Date. Meanwhile, there has been no change to any of the award terms. The equity transfer transaction did not trigger the modification accounting to the share-based compensation. Additionally, given that I-Mab Hangzhou became an affiliate to the Group upon deconsolidation, and that the other shareholders of I-Mab Hangzhou are not providing proportionate value to sponsor the 2020 Plan nor is the Group receiving any consideration for the awards granted to employees of I-Mab Hangzhou, the Group is required, under Topic 323, to expense the full costs of share-based compensation as incurred at the same period as the costs are recognized by I-Mab Hangzhou. For the year ended December 31, 2020, such expenses of RMB32,707 and was recorded in the equity in loss of an affiliate in the consolidated statements of comprehensive income.

As of December 31, 2020, the carrying value of the Group's long-term investment measured under equity method was RMB664,832. The Group presented the summarized financial information of the Group's long-term investment measured under equity method below in accordance with Rule 4-08 of Regulation S-X (RMB in thousands).

	For the period from September 15, 2020 to December 31, 2020
Operating data:	
Revenue	271
Gross profit	271
Loss from operations	(85,945)
Net Loss	(85,945)

	As of December 31, 2020
Balance sheet data:	
Current assets	923,010
Non-current assets	810,623
Current liabilities	31,519
Non-current liabilities	10,933
Non-controlling interests	—

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9. INVESTMENT ACCOUNTED FOR USING THE EQUITY METHOD AND PUT RIGHT LIABILITIES (CONTINUED)

(b) Put right liabilities

Pursuant to the SHA, if I-Mab Hangzhou fails to close a public offering of I-Mab Hangzhou's shares on the China Stock Exchange's Science and Technology Innovation Board, Main Board, Small and Medium-Sized Enterprise Board, Growth Enterprise Board, or Hong Kong Stock Exchange, U.S. Stock Exchange, or other stock exchanges approved by the shareholders of I-Mab Hangzhou in accordance with provisions of the SHA within 4 years after September 15, 2020, I-Mab Hong Kong is obligated to repurchase the equity held by Domestic Investors in cash or in I-Mab's stock (subject to the approval procedures of I-Mab) within 3 years from the expiration of the 4-year period after the Closing Date of September 15, 2020.

The put right written by I-Mab Hong Kong to Domestic Investors is a freestanding equity-linked instrument, which is classified as a put right liability and is initially measured at fair value. Subsequent changes in fair value are recorded in other income (loss) in the consolidated statements of comprehensive income (loss).

The Group determined the fair value of the put right with the assistance of an independent third-party valuation firm. The Group used the option pricing model (finnerty model) to estimate the fair value of the put right using the following assumptions:

	As of September 15, and September 30, 2020	As of December 31, 2020
Expected terms (Year)	4	4
Estimated volatility	55.2%	55.9%
Spot price	US$ 143,401	US$143,804
Probability of triggering event for redemption option	65%	65%

The model requires the input of highly subjective assumptions including the expected terms, estimated volatility, spot price and probability of triggering event for redemption option. Expected terms is estimated based on the timing of a hypothetical redemption event which is assumed to be the earlier of expected redemption date or expected public offering date. Expected volatility is estimated based on daily stock prices of the comparable company for a period with length commensurate to the expected terms of redemption event. The spot price was determined with assistance from an independent third-party valuation firm. The Group's management is ultimately responsible for the determination of the spot price and probability of triggering event for redemption option.

Significant decreases in interval between valuation date and maturity date, estimated volatility, spot price and probability of triggering event for redemption option would result in a significantly lower fair value measurement.

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10. 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 was fully repaid in June 2020.

11. ACCRUALS AND OTHER PAYABLES

	As of December 31, 2019	As of December 31, 2020	
	RMB	RMB	US$ (Note 2.5)
Current:			
Staff salaries and welfare payables	30,166	94,133	14,427
Accrued external research and development activities related expenses	144,000	218,583	33,499
Accrued initial public offering costs payable	17,504	—	—
Accrued private placement offering costs payable	—	128,786	19,737
Withholding IIT payable related to stock options	16,201	—	—
Non-refundable incentive payment from depositary bank [(2)]	—	2,424	371
Accrued traveling expenses, office expenses and others	65,682	116,632	17,875
	273,553	560,558	85,909
Non-current:			
Non-refundable incentive payment from depositary bank [(2)]	—	7,474	1,145
Advance payment received from an employee for exercise of stock options	—	1,501	230
	—	8,975	1,375
Total	—	569,533	87,284

(2) The Group received a non-refundable incentive payment of US$1,857 (equivalent to approximately RMB12,982) from depositary bank in April 2020. The amount was recorded ratably as other gains over a five-year arrangement period. For the year ended December 31, 2020, the Group has recorded RMB2,348 as other income in the consolidated statements of comprehensive income.

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12. 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. I-Mab did business registration in Hong Kong and has a Hong Kong tax file number.

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, 2018, 2019 and 2020, 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 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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12. 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 corporate income taxes for corresponding tax residents has been made because the Group are in cumulative loss positions for all the periods presented. During the year ended December 31, 2020, the Group recorded withholding taxes with the amount of RMB12,231 in relation to research and development service and other supporting service charges made by its non-PRC tax resident subsidiaries to its PRC tax resident subsidiaries.

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, 2018, 2019 and 2020 are as follows:

	Year Ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
Income (loss) before income tax	(401,111)	(1,451,950)	483,146	74,044
Income tax computed at respective applicable tax rate	(56,093)	(148,871)	66,044	10,122
Non-deductible expenses	2,548	87,021	72,256	11,073
Research and development expenses plus deduction	(6,762)	(9,254)	(60,776)	(9,314)
Changes in valuation allowance	62,029	71,104	(65,293)	(10,007)
	1,722	—	12,231	1,874
Effect of tax holidays entitled by the PRC subsidiaries on basic income (loss) per share	3.07	9.55	0.34	0.05

The principal components of the deferred tax assets and liabilities are as follows:

	Year Ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
Deferred tax assets:				
Net operating loss carryforward	92,185	136,443	107,344	16,451
Depreciation and amortization of property, equipment, software and intangible asset, net	18,405	44,398	30,417	4,662
Accrual expense	21,132	21,867	10,568	1,620
Less: valuation allowance	(94,511)	(165,497)	(100,204)	(15,358)
Total deferred tax assets	37,211	37,211	48,125	7,375
Deferred tax liabilities:				
Acquired intangible assets	37,211	37,211	18,067	2,768
Contract assets	—	—	30,058	4,607
Total deferred tax liabilities	37,211	37,211	48,125	7,375
Deferred tax assets, net	—	—	—	—

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12. INCOME TAXES (CONTINUED)

Movement of the valuation allowance is as follows:

	Year Ended December 31			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
Balance as of January 1	(49,541)	(94,511)	(165,497)	(25,364)
Additions	(62,029)	(71,104)	(36,061)	(5,527)
Utilization and reversal of valuation allowances	—	—	89,154	13,663
Decrease due to the change of tax rate	17,059	118	12,200	1,870
Balance as of December 31	(94,511)	(165,497)	(100,204)	(15,358)

As of December 31, 2020, the Group had a majority of net operating losses of approximately RMB556,649 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 2030 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, 2019 and 2020.

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, 2019 and 2020, the Group did not have any significant unrecognized uncertain tax positions.

13. 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.

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13. ORDINARY SHARES (CONTINUED)

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.

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 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 net proceeds of US$101.3 million (equivalent to RMB697,788), netting of issuance cost from total gross proceeds of US$114.5 million. Each ten ADSs represent twenty-three ordinary shares of the Company.

On January 17, 2020, the Company also issued 6,078,571 ordinary shares to Everest (see Note 18 for details).

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.

On July 15, 2020, the Company's Board of Directors approved a share repurchase program to repurchase in the open market up to US$20 million worth of outstanding ADSs of the Group. The Company made a total prepayment of US$5,000 (equivalent to RMB34,051) for the share repurchase. The prepayment was collected subsequently in October 2020. No repurchase activity was taken place for the year ended December, 31, 2020.

On September 3, 2020, the Company entered into definitive subscription agreements with a consortium of institutional investors (the "Investors") to raise approximately US$418 million through a private placement. The consortium is led by Hillhouse Capital Group ("Hillhouse"), with significant participation by GIC Private Limited, and also includes certain other leading Asian and U.S. biotech investment funds, Hillhouse is entitled to nominate one representative to I-Mab's Board of Directors.

The private placement comprises (1) the sale to the Investors of the Group's 29,133,502 ordinary shares (equivalent to 12,666,740 ADSs) at a purchase price equivalent to US$33 per ADS amounting to approximately US$418 million; and (2) warrants (the "Investor Warrants", see Note 16(b)) to subscribe for an aggregate of 5,341,267 ordinary shares (equivalent to 2,322,290 ADSs) at an exercise price equivalent to US$45 per ADS, which may further increase the proceeds of approximately US$104.5 million if the Investor Warrants are fully exercised. The Investor Warrants will remain exercisable at the election of the Investors within 12 months after the closing of the private placement.

The subscription agreement with the Hillhouse entities contemplates two closings. The first closing occurred on September 11, 2020, and the second closing is conditioned upon an existing director of the Company having resigned to enable the Hillhouse entities to appoint a director to replace such director and the lemzoparlimab out-licensing agreement with AbbVie (see Note 18) being or remaining effective. Upon the first closing, 20,421,378 ordinary shares and 3,744,032 Investor Warrants were issued to the Investors for total gross proceeds of approximately US$293.0 million. On December 17, 2020, the Group entered into a written amendment made to the subscription agreement with the Hillhouse entities, which removed one of the two conditions for the second closing that an existing director of the Company having resigned to enable the Hillhouse entities to appoint a director to replace such director. The second closing occurred as the other condition was satisfied and 8,712,124 ordinary shares as well as 1,597,235 Investor Warrants were issued to the Hillhouse entities for total gross proceeds of approximately US$125.0 million. The total net proceeds, netting of issuance cost, from the private placement was US$397.2 million (equivalent to RMB2,653,669).

As of December 31, 2020, 1,841,373 stock options were exercised, and 7,000 restricted share units were issued as ordinary shares.

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14. 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").

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 Note 14) and 5,633,780 warrants to purchase its Series B-2 Preferred Shares ("Series B Warrant" and see Note 16).

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 15), 2) I-Mab Tianjin's issuance of convertible loans ("Onshore Convertible Loans" and see Note 15), 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 16).

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 15), 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 15) 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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14. 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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14. 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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14. 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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14. CONVERTIBLE PREFERRED SHARES (CONTINUED)

The Company's convertible preferred shares activities for the years ended December 31, 2019 and 2020 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, 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
Conversion to ordinary shares upon IPO	(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)
Balance as of December 31, 2020	—	—	—	—	—	—	—	—	—	—	—	—

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15. 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 14) 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 Genexine, Inc. 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. On December 17, 2020, the Group issued 900,000 ordinary shares to Genexine, Inc. upon the full conversion of the 2018 Notes with the conversion price of US$10 per share.

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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16. WARRANTS

(a) Warrants to purchase preferred shares

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 years ended December 31, 2019 and 2020 was amounting to RMB5,644 and nil, respectively.

Accounting of warrants for purchase preferred shares

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.

(b) Warrants to purchase ordinary shares

As mentioned in Note 13, on September 3, 2020, the Group entered into definitive subscription agreements with the Investors to raise approximately US$418 million through a private placement, which comprises the Investor Warrants to subscribe for an aggregate of 5,341,267 ordinary shares (equivalent to 2,322,290 ADSs) at an exercise price equivalent to US$45 per ADS.

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16. WARRANTS (CONTINUED)

(b) Warrants to purchase ordinary shares (Continued)

The Subscription Agreement with the Hillhouse entities contemplates two closings. In the first closing occurred on September 11, 2020 and second closing occurred on December 17, 2020, the Investor Warrants were issued with fixed exercise prices of US$45.00 per ADS (equivalent to US$19.57 per share) and lives of one year. The number of common share purchasable upon exercise of the Investor Warrants shall be proportionally adjusted to reflect any share dividend, share split, combination of shares or reverse share split, or other similar event affecting the number of outstanding common shares.

Accounting for warrants to purchase ordinary shares

The Investor Warrants are regarded as indexed to the Company's own stock and were classified as equity and initially measured at fair value and subsequent changes in fair value are not recognized as long as the Investor Warrants continue to be classified as equity. The estimated fair value of the Investor Warrants was shown below, which were used to determine the allocation of the total proceeds for the sale of ordinary shares between the Investor Warrants and ordinary shares.

	Terms	Exercise Price per share US$	Outstanding Units	Fair value at the closing date RMB'000
Warrants to purchase ordinary shares (first closing on September 11, 2020)	12 months	19.57	3,744,032	71,874
Warrants to purchase ordinary shares (second closing on December 17, 2020)	12 months	19.57	1,597,235	37,869

The Group determined the fair value of the warrants with the assistance of an independent third-party valuation firm. The Group used the binomial model to estimate the fair value of the warrant on September 11, 2020 and December 17, 2020 when the Investor Warrants were issued using the following assumptions:

	As of September 11, 2020	As of December 17, 2020
Risk-free rate of return	0.12%	0.08%
Maturity date	September 11, 2021	December 17, 2021
Estimated volatility rate	60.72%	59.56%
Exercise price	US$ 19.57	US$ 19.57

The model requires the input of assumptions including the risk-free rate of return, maturity date and estimated volatility rate. 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.

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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. As of December 31, 2019, all the restricted shares were fully vested.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(a) Restricted shares (continued)

The amounts of shared-based compensation expense in relation to the restricted shares recognized in the years ended December 31, 2018, 2019 and 2020 were RMB3,520, RMB1,566 and nil, respectively.

Share-based compensation expenses related to restricted shares were included in:

	Year Ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	1,056	470	—	—
Administrative expenses	2,464	1,096	—	—
	3,520	1,566	—	—

(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, 2018 and 2019, the Group granted 1,470,000 and 640,000 stock options respectively, to its employees (all with an exercise price of US$1). The Group did not grant any stock options to employees for the year ended December 31, 2020. No options were exercisable as of December 31, 2019 and 6,790,924 stock options were exercisable as of December 31, 2020. No options were exercised as of December 31, 2019 and 1,439,373 stock options were exercised as of December 31, 2020.

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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, 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
Forfeited	(338,876)	1.00	—	—
Exercised	(1,439,373)	0.72	—	—
Surrendered (Note 17(h))	(332,566)	1.00	—	—
Outstanding as of December 31 ,2020	7,702,066	0.97	6.75	150,415
Exercisable as of December 31, 2020	6,790,924	0.97	6.75	132,650

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,	
	2018	2019
Expected volatility	61.32%-62.13%	54.64%
Risk-free interest rate (per annum)	2.81%-3.06%	2.15%
Exercise multiple	2.80	2.80
Expected dividend yield	—	—
Contractual term (in years)	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.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(b) 2017 Employee Stock Option Plan ("2017 Plan") (continued)

A summary of non-vested stock option activities for the year ended December 31, 2020 is presented below:

	Number of shares	Weighted average Grant date fair value US$
Non-vested at December 31, 2019	9,812,881	2.10
Vested	(6,790,924)	1.90
Exercised	(1,439,373)	1.37
Forfeited	(338,876)	2.29
Surrendered	(332,566)	1.47
Non-vested at December 31, 2020	911,142	4.96

Since the exercisability was dependent upon the listing, and it was not probable that this performance condition could be achieved until a listing, no share-based compensation expense relating to the 2017 Plan was recorded for the year ended December 31, 2018 and 2019.

On January 17, 2020, the Group completed its IPO. After achieving this performance condition, the options continue to vest based only on service period completed according to the graded vesting schedule. The Group has begun recognizing share-based compensation expense for the options granted using the graded vesting method with a cumulative catch-up for the service period completed to date during the year ended December 31, 2020 and recognized RMB52,802, RMB69,213 and RMB4,277 share-based compensation expenses in administrative expenses, research and development expenses and equity in loss of an affiliate, respectively relating to options vested cumulatively. 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 Group's founders, namely Zheru Zhang, Lili Qian, Zhengyi Wang and Lei Fang surrendered 83,142 unvested stock options that were granted to him or her under 2017 Plan before, totally 332,566 unvested options, for no consideration, and these stock options were cancelled immediately.

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.

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.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(c) 2018 Employee Stock Option Plan ("2018 Plan")

The following table sets forth the stock options activities of 2018 Plan for the years ended December 31, 2019 and 2020:

	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
Exercised	(402,000)	1.00	—	—
Surrendered (Note 17 (h))	(2,544,917)	1.00	—	—
Outstanding as of December 31, 2020	10,589,671	1.00	8.15	206,499
Exercisable as of December 31, 2020	9,764,670	1.00	8.15	190,411

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

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.

A summary of non-vested stock option activities for the year ended December 31, 2020 is presented below:

	Number of shares	Weighted average grant-date fair value US$
Non-vested at December 31, 2019	3,098,500	5.57
Vested	(1,871,500)	5.57
Exercised	(402,000)	5.57
Non-vested at December 31, 2020	825,000	5.57

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17. SHARE-BASED COMPENSATION (CONTINUED)

(c) 2018 Employee Stock Option Plan ("2018 Plan")(continued)

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.

On January 17, 2020, the Group completed its IPO. After achieving this performance condition, the options continue to vest based only on service period completed according to the graded vesting schedule. The Group has begun recognizing share-based compensation expense for the options granted using the graded vesting method with a cumulative catch-up for the service period completed to date during the year ended December 31, 2020 and recognized RMB48,055, RMB65,656 and RMB226 share-based compensation expense in administrative expenses and research, development expenses and equity in loss of an affiliate, respectively relating to options vested cumulatively. 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 were granted to him under 2018 Plan, for no consideration, and these stock options were cancelled immediately.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(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.

The options shall vest when the Group completes a listing and the employee renders service to the Group in accordance with a stipulated service schedule starting from the employee's date of employment. Stock options granted to 3 independence directors under the 2019 Plan will be generally exercisable under the following terms:(a) a cliff vesting of 1/3 of the option on the first anniversary of the vesting commencement date (January 17, 2020); (b) a cliff vesting of 1/3 of the option on the second anniversary of the vesting commencement date (January 17, 2020); (c) a vesting of the remaining 1/3 of the option on the third anniversary of the vesting commencement date. In the last year of the grantee's service, the options shall vest on a prorated basis to reflect the portion of the year during which the grantee provided services to the Group.

For the year ended December 31, 2020, the Group granted 72,000 stock options to 3 independent directors (all with an exercise price of US$6.09) and recognized RMB1,171 share-based compensation expenses in administrative expenses according to the options' vesting schedule. No options were exercisable as of December 31, 2020.

The following table sets forth the stock options activities of 2019 Plan for the year ended December 31, 2020 presented:

	Number of shares	Weighted average exercise price US$	Weighted average remaining contractual term	Aggregate intrinsic value US$
Outstanding as of December 31, 2019	—	—	—	—
Granted	72,000	6.09	—	—
Outstanding as of December 31, 2020	72,000	6.09	9.33	1,038
Exercisable as of December 31, 2020	—	—	—	—

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17. SHARE-BASED COMPENSATION (CONTINUED)

(e) 2019 Share Incentive Plan ("2019 Plan") (Continued)

A summary of non-vested stock options activity for the year ended December 31, 2020 is presented below:

	Number of shares	Weighted average grant-date fair value US$
Non-vested at December 31, 2019	—	—
Granted	72,000	4.50
Non-vested at December 31, 2020	72,000	4.50

Stock options granted to the 3 independent directors were measured at fair value on the dates of grant using the Binomial Option Pricing Model with the following assumptions:

	Year Ended December 31, 2020
Expected volatility	54.88%
Risk-free interest rate (per annum)	0.79%
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 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.

(f) 2020 Plan

On July 15, 2020, the Group adopted 2020 Share Incentive Plan ("2020 Plan"). Under the 2020 Plan, the maximum aggregate number of shares authorized to be issued is 10,760,513 ordinary shares, provided that the maximum number of shares to be issued in the form of restricted share units shall not exceed 7,686,081 ordinary shares.

Stock options granted to employees under the 2020 Plan are graded vesting in four years with 25% vesting each year.

For the year ended December 31, 2020, the Group granted 1,068,733 stock options to its employees and recognized RMB4,357 RMB10,435 and RMB1,619 share-based compensation expenses in administrative expenses, research and development expenses and equity in loss of an affiliate, respectively, in the consolidated statement of comprehensive income. No option became exercisable as of December 31, 2020.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(f) 2020 Plan (Continued)

The following table sets forth the stock options activities of 2020 Plan for the year ended December 31, 2020:

	Number of shares	Weighted average exercise price US$	Weighted average remaining contractual term	Aggregate intrinsic value US$
Outstanding as of December 31, 2019	—	—	—	—
Granted	1,068,733	5.91	—	—
Forfeited	(24,365)	5.91	—	—
Outstanding as of December 31, 2020	1,044,368	5.91	9.62	15,237
Exercisable as of December 31, 2020	—	—	—	—

A summary of non-vested stock option activities for the year ended December 31, 2020 is presented below:

	Number of shares	Weighted average grant-date fair value US$
Non-vested at December 31, 2019	—	—
Granted	1,068,733	8.71
Forfeited	(24,365)	8.65
Non-vested at December 31, 2020	1,044,368	8.71

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, 2020
Expected volatility	56.51%
Risk-free interest rate (per annum)	0.86%
Exercise multiple	2.20-2.80
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 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.

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17. SHARE-BASED COMPENSATION (CONTINUED)

(f) 2020 Plan (Continued)

Restricted share units granted to employees under the 2020 Plan will be exercisable under the following items:

(a) 1/3 of the awarded restricted share units shall vest based on the following time attribution:(i) a vesting of 25% of the time attribution based restricted share units on the first anniversary of the applicable adoption date;(ii) a vesting of 25% of the time attribution based restricted share units on the second anniversary of the applicable adoption date;(iii) a vesting of 25% of the time attribution based restricted share units on the third anniversary of the applicable adoption date;(iv) a vesting of 25% of the time attribution based restricted share units on the fourth anniversary of the applicable adoption date.

(b) 1/3 of the awarded restricted share units shall vest based on the Group's weighted average market value during the last 30 days prior to the initial vesting date, the terms and conditions of which are set forth in the executed award agreements. In the event that dilution of additional share issuance occurs, the market value targets herein shall be adjusted accordingly with the proportion of additional share issuance. In the event that the average market value of Standard & Poor's 500 index falls by more than 20% from the date of grant, it shall be deemed as a decline of the market, and the board of the Group or a committee that board delegated its powers or authority to shall adjust the vesting schedule as appropriate.

(c) 1/3 of the awarded restricted share units shall vest based on certain performance conditions:(i) a vesting of 20% of the performance conditions based restricted share units if one of the performance conditions has been met at the initial vesting date;(ii) a vesting of 40% of the performance conditions based restricted share units if two of the performance conditions have been met at the initial vesting date;(iii) a vesting of 60% of the performance conditions based restricted share units if three of the performance conditions have been met at the initial vesting date;(iv) a vesting of 80% of the performance conditions based restricted share units if four of the performance conditions have been met at the initial vesting date; (v) a vesting of all of the performance conditions based restricted share units if five of the performance conditions or more have been met at the initial vesting date. As of December 31, 2020, it is probable that the 1/3 of the awarded restricted share units are fully vested because it is probable that at least five of the performance conditions will be met at the initial vesting date.

Notwithstanding the foregoing, if the Group's weighted average market value during the last 30 days prior to the initial vesting date reaches US$2 billion or above, and to the extent such restricted share units have been granted and outstanding, any such restricted share unit (except for those are based on time attribution) shall vest in full with immediate effect, inure to the benefit of the related grantees.

For the year ended December 31, 2020, the Group granted 4,093,079 restricted share units to employees and recognized RMB76,663 RMB71,945 and RMB7,500 share-based compensation expenses in administrative expenses, research and development expenses and equity in loss of an affiliate, respectively, in the consolidated statement of comprehensive income. No restricted share units became exercisable as of December 31, 2020.

The following table sets forth the restricted share units of 2020 Plan for the year ended December 31, 2020:

	Number of restricted share units	Weighted average exercise price US$	Weighted average remaining contractual term	Aggregate intrinsic value US$
Outstanding as of December 31, 2019	—	—	—	—
Granted	4,093,079	—	—	—
Forfeited	(13,461)	—	—	—
Outstanding as of December 31, 2020	4,079,618	—	9.70	83,632

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17. SHARE-BASED COMPENSATION (CONTINUED)

(f) 2020 Plan (Continued)

A summary of non-vested restricted share units activities for the year ended December 31, 2020 is presented below:

	Number of restricted share units	Weighted average grant-date fair value US$
Non-vested at December 31, 2019	—	—
Granted	4,093,079	13.99
Forfeited	(13,461)	11.73
Non-vested at December 31, 2020	4,079,618	14.00

Apart from the aforementioned restricted share units, up to 1,446,875 shares can be issued in the form of restricted share unit to eligible grantees that the board of the Group or a committee that board delegated its powers or authority determined appropriate with immediate effect of being fully vested, which are defined as special awards and are subject to terms and conditions under 2018 Plan.

For the year ended December 31, 2020, the Group granted 1,328,120 such restricted share units to employees and recognized RMB25,985 RMB67,182 and RMB19,085 share-based compensation expenses in administrative expenses, research and development expenses and equity in loss of an affiliate, respectively, in the consolidated statement of comprehensive incomes of December 31, 2020, 565,200 restricted share units were vested, among which 558,200 restricted share units were vested but not issued as ordinary shares as the employees will not be entitled to the rights of ordinary shares from the Group until they have the consideration for the transaction settled.

The following table sets forth the restricted share units subject to terms and conditions under 2018 Plan for the year ended December 31, 2020:

	Number of restricted share units	Weighted average exercise price US$	Weighted average remaining contractual term	Aggregate intrinsic value US$
Outstanding as of December 31, 2019	—	—	—	—
Granted	1,328,120	1.00	—	—
Vested	(565,200)	1.00	—	—
Outstanding as of December 31, 2020	762,920	1.00	9.65	14,877

A summary of non-vested restricted share units activities for the year ended December 31, 2020 is presented below:

	Number of restricted share units	Weighted average grant-date fair value US$
Non-vested at December 31, 2019	—	—
Granted	1,328,120	13.34
Vested	(565,200)	13.95
Non-vested at December 31, 2020	762,920	12.89

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17. SHARE-BASED COMPENSATION (CONTINUED)

(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 balance sheets.

(h) Surrender of stock options

On January 17, 2020, the Group completed its IPO. 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 were granted to him or her under 2017 Plan before, totally 332,566 unvested options, for no consideration, and these stock options were cancelled immediately. 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 were granted to him under 2018 Plan, for no consideration, and these stock options were cancelled immediately. Upon the completion of the Company's IPO in January 2020, the Group has recorded RMB91,051 share-based compensation expense related to these surrendered options.

The stock options surrendered by the founders should be accounted for as capital contribution. As the founders did not get the title of the stock options to be surrendered and the number of stock options would not be determined until listing, the capital contribution was not accounted for during the year ended December 31, 2019. For the year ended December 31, 2020, the Group has reclassified RMB91,051 from additional paid-in capital – share-based compensation to additional paid-in capital – capital contribution relating to the stock options surrendered in the consolidated statement of comprehensive income.

Share-Based Compensation Expense

The allocation of share-based compensation expense was as follows:

	Year Ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	1,056	470	284,431	43,591
Administrative expenses	2,464	514,733	209,033	32,036
Equity in loss of an affiliate	—	—	32,707	5,013
	3,520	**515,203**	**526,171**	**80,640**

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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, 2020.

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. No additional payments were made in 2018. Due to the uncertainty involved in meeting these developments 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. No additional payments were made for the year ended December 31, 2020 as no milestone has been achieved.

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
2020	—	—	—	—	—
2019	—	US$8,000	—	—	—
2018	—	—	—	—	—

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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 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 and 2020. 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, 2019 and 2020.

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
2020	—	—	—	—	—
2019	—	—	—	—	—
2018	US$12,000	—	—	—	—

In May 2020, the Group and Genexine entered into an amendment to this agreement whereby both parties desire to establish collaboration on TJ107 GBM Study in Greater China Under the terms of the expanded collaboration, the Group will be mainly responsible for using commercially reasonable efforts to conduct the Phase 2 GBM clinical trial in Greater China, and Genexine will share the development strategies, data and costs for success of this clinical trial. The Group shall undertake to bear two-thirds (2/3) proportion of the clinical development costs and Genexine shall undertake to bear one-third (1/3) proportion of these costs. As of December 31, 2020, the costs incurred for the development of this new indication was RMB4.3 million and thus RMB2.9 million expense was recorded in the consolidated statement of comprehensive income for the year ended December 31, 2020.

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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. In August 2020, the project achieved the first milestone and the Group paid US$1.0 million (equivalent to approximately RMB6.9 million) of milestone fees to Morphosys, which was recorded as research and development expenses in the consolidated statement of comprehensive income for the year ended December 31, 2020. 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, 2019 and 2020.

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
2020	—	US$1,000	—	—	—
2019	—	—	—	—	—
2018	US$ 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 the 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. No additional payments were made in the year ended December 31, 2020. 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 the Group participates, (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 and 2020.

	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
2020	—	—	—	—	—
2019	US$15,000	—	—	—	—

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

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. The Group additionally recorded US$3.1 million (equivalent to approximately RMB21.3 million) milestone payment during the year ended December 31, 2020. As of December 31, 2020, under the terms of the agreements, the licensors are eligible to receive from the Group up to an aggregate of approximately US$107.4 million (equivalent to approximately RMB740.4 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 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, in which the underlying intellectual property is significantly modified by the development activities being performed, 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.

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.

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

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 for the year ended December 31, 2019. Upon the completion of the IPO in January 2020, the Group issued 6,078,571 ordinary shares to Everest.

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. For the year ended December 31, 2020, US$0.04 million (equivalent to approximately RMB0.28 million) expenses were incurred by ABL Bio. Accordingly, the Group recorded US$0.02 million (equivalent to approximately RMB0.14 million) (50% cost sharing) of expenses in the Group's consolidated statement of comprehensive income for the year ended December 31, 2020.

Pursuant to the license and collaboration agreement that signed in July 2018 and memorandum of understanding that subsequently entered into 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 RMB690.3 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 RMB230.1 million) and sales milestones of up to US$65 million (equivalent to approximately RMB460.2 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 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. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Achievement of milestones that are not within the control of the Group or the licensee, such as regulatory approvals, are not considered probable until the approvals are achieved.

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. As of December 31, 2019 and 2020, no other milestone has been achieved. No revenue was recognized for the year ended December 31, 2019 and 2020.

On December 4, 2020, I-Mab Hong Kong, ABL Bio and I-Mab Hangzhou entered into an amendment, which is made effective as of September 15, 2020, that I-Mab Hong Kong, as the subject of the aforementioned licensing agreement, shall be replaced and substituted by I-Mab Hangzhou.

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 income (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. For the year ended December 31, 2020, RMB43.6 million expenses were incurred by the Group and RMB44.0 million expenses were incurred by ABL Bio. Accordingly, the Group recorded RMB43.8 million (50% cost sharing) of expenses in the Group’s consolidated statement of comprehensive income for the year ended December 31, 2020.

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

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. 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. 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. As of December 31, 2020, the Group has recorded US$0.03 million (equivalent to approximately RMB0.17 million) of research and development costs in the consolidated statement of comprehensive income for the year ended December 31, 2020.

In April 2020, Tracon issued a notice of disputes with respect to the TJD5 Agreement and the BsAbs Agreement. As of the date of this report, these disputes have not been resolved.

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.

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. No additional revenue was recognized in the year ended December 31, 2020 as no further milestone has been achieved.

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18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

Strategic Alliance Agreement with PT Kalbe Genexine Biologics ("KG Bio")

In March 2020, the Group entered into a strategic partnership with Kalbe Genexine Biologics ("KG Bio") to grant a right of first negotiation for an exclusive license for the development and commercialization of two I-Mab-discovered product candidates: uliledlimab, a highly differentiated anti-CD73 antibody in Phase 1 development for advanced solid tumors ("First Program"), and an I-Mab product candidate ("Second Program") to be agreed upon by both parties in certain regions. Through this agreement, both parties intend to negotiate the terms that will be reflected in definitive agreements for each prospective program covered under this agreement.

If and when the Group and KG Bio enter into the definitive licensing agreement, the Group will be eligible to receive from KG Bio an aggregate amount of up to approximately US$340 million, including an upfront payment and subsequent payments conditional upon achieving certain development and commercial milestones. KG Bio will pay the Group tiered royalties in the low to mid-teen percentages on net sales from certain regions. As the right of first negotiation has not been exercised and the definitive agreement has not been entered into as of December 31, 2020, no revenue was recognized during the year ended December 31, 2020.

Global Strategic Partnership with AbbVie

On September 3, 2020, the Group, through I-Mab Biopharma (Shanghai) Co., Ltd. and I-Mab Biopharma US Limited, each a wholly-owned subsidiary of the Group, entered into a broad global strategic partnership with AbbVie Ireland Unlimited Group ("AbbVie").

Pursuant to this collaboration, the Group will grant AbbVie a global license, excluding Mainland China, Macau, and Hong Kong, to develop and commercialize lemzoparlimab (also known as TJC4), an innovative anti-CD47 monoclonal antibody internally discovered and developed by I-Mab for the treatment of multiple cancers. The Group will retain all rights to develop and commercialize lemzoparlimab (as well as certain other compounds directed against CD47) in Mainland China, Macau, and Hong Kong. The Group is also responsible for performing the development activities at its sole cost and expense as outlined in the initial development plan. Such initial development activities consist of two studies, Study I and Study II. Study I is conducted in the United States evaluating lemzoparlimab in combination with pembrolizumab or rituximab in patients with relapsed or refractory solid tumors and lymphoma. Study II is conducted in Mainland China evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary efficacy of lemzoparlimab in patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). AbbVie will conduct further global clinical trials (which the Group may elect to co-fund) to evaluate lemzoparlimab in multiple cancers.

Potential collaboration on future CD47-related therapeutic agents is also allowed for under this arrangement, including CD47-based bispecific antibodies and combination therapies with lemzoparlimab and AbbVie's venetoclax (Venclexta®). Each party will have the opportunity, subject to rights of first negotiation to further licenses, to explore certain of each other's related CD47-antibody programs in their respective territories.

A joint governance committee was established as set forth in the agreement, functioning as an oversight and governance mechanism. Both parties will participate in the joint governance committee to facilitate decision-making during the terms of the collaborative endeavor. Furthermore, the Group and AbbVie will share manufacturing responsibilities, with AbbVie having the opportunity to manufacture supply outside of Mainland China, Hong Kong and Macau and the Group being the primary manufacturer for supply for Mainland China, Hong Kong and Macau.

18. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

Global Strategic Partnership with AbbVie (continued)

Upon the satisfaction of all the pre-effect date covenants, the collaborative agreement took effect on December 10, 2020, on which date the Group was entitled to a non-refundable upfront payment of US$180 million. In addition, the Group is eligible to receive up to US$1.76 billion in further success-based development, regulatory and sales milestone payments for lemzoparlimab, of which US$840 million are based on clinical development and regulatory approval milestones, with the remainder based on commercial milestones. Upon commercialization of lemzoparlimab, AbbVie will also pay tiered royalties from low-to-mid teen double-digit percentages on global net sales outside of Mainland China, Macau, and Hong Kong.

The Group identified three performance obligations: (1) grant of lemzoparlimab license upon the effective date, (2) delivering the Study I initial development services, and (3) delivering the Study II initial development services. The total transaction price under the agreement for the year ended December 31, 2020 is US$250 million consisting of (i) the upfront payment of US$180 million upon the effective date, (ii) the first milestone payment of US$20 million upon the achievement of the first milestone event in late December 2020, and (iii) the second milestone payment of US$50 million as of December 31, 2020 as the Group deemed that the achievement of the second milestone event is probable as of December 31, 2020 that a significant reversal of revenue would not occur. The achievements of the remaining development and regulatory based milestone events are constrained as of December 31, 2020, and will be included in the transaction price when uncertainty associated with the variable consideration is subsequently resolved. Sales-based milestones and royalties will be recognized when the subsequent sales occur.

The non-constrained consideration of US$250 million is then allocated to the three performance obligations based on the relative stand-alone selling price. For the grant of lemzoparlimab license, the Group adopted an income approach based on key assumptions and several factors including, but not limited to estimated market demand, stand-alone selling price by making reference to market comparable, development timeline, regulatory risks, future revenue potential and discount rate. The allocated price is US$228.8 million. The entire US$228.8 million (equivalent to approximately RMB1,502.9 million) was recognized as revenue at the point of the license transfer at the effective date. For the Study I and Study II initial development services, a cost-plus margin approach is utilized. The allocated price to Study I and Study II is US$11.0 million and US$10.2 million respectively. These two performance obligations are determined to be satisfied over time. The Group uses a cost-to-cost input method to measure progress as that method best depicts the transfer of the two performance obligations under the agreement. As of December 31, 2020, the cumulative percentages complete in the cost-to-cost input method for Study I and Study II were estimated to approximate 17 % and 41 % respectively. As a result, US$1.8 million (equivalent to approximately RMB12.0 million) and US$4.2 million (equivalent to approximately RMB27.8 million) were recognized as revenue for the year ended December 31, 2020 in the consolidated statement of comprehensive income for Study I and Study II respectively, resulting in a contract asset of US$34.8 million for this agreement as of December 31, 2020 in the consolidated balance sheets. As of December 31, 2020, the upfront payment of US$180 million was received by the Group. The 1st milestone payment of US$20 million was subsequently collected by the Group in March 2021.

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19. OTHER INCOME (EXPENSES), NET

The following table summarizes other income (expenses), net recognized for the years ended December 31, 2018, 2019 and 2020:

		Year Ended December 31			
		2018	2019	2020	
	Notes	RMB	RMB	RMB	US$ (Note 2.5)
Loss from conversion of 2017 Notes	15	(18,375)	—	—	—
Loss from conversion of Onshore Convertible Loans	15	(8,548)	—	—	—
Loss from issuance of 2018 Notes	15	(5,081)	—	—	—
Loss on termination agreement with Everest	18	—	(23,039)	—	—
Income of incentive payment from depository bank	11	—	—	2,348	360
Fair value change of short-term investments		—	703	11,288	1,730
Fair value change of put right liabilities		—	—	3,024	463
Income from other financial assets		13,622	—	—	—
Net foreign exchange gains (losses)		742	1,619	(22,126)	(3,391)
Subsidy income [(3)]		750	568	11,633	1,783
Gains on deconsolidation of a subsidiary	9	—	—	407,598	62,467
Fair value change of other financial assets		—	42	—	—
Others		110	(98)	(873)	(134)
		(16,780)	(20,205)	412,892	63,278

(3) For the year ended December 31, 2020, subsidy income consists primarily of the government grant of RMB10 million. The government grant was granted by the project management office of Shanghai Zhangjiang Science City to support the research and development activities in the local region.

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20. NET INCOME (LOSS) PER SHARE

Basic and diluted net income (loss) per share for each of the periods presented are calculated as follows:

	Year Ended December 31			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
	(in thousands, except for share and per share data)			
Numerator:				
Net income (loss) attributable to I-Mab	(402,833)	(1,451,950)	470,915	72,170
Deemed dividend to Series C-1 preferred shareholders at extinguishment of Series C-1 Preferred Shares	—	(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)	—	—
Net income (loss) attributable to ordinary shareholders	(402,833)	(1,485,001)	470,915	72,170
Denominator:				
Denominator for basic calculation-weighted average number of common shares outstanding	6,529,092	7,381,230	134,158,824	134,158,824
Dilutive effect of convertible preferred shares	—	—	4,373,047	4,373,047
Dilutive effect of ordinary shares to be issued to Everest	—	—	266,458	266,458
Dilutive effect of convertible promissory notes	—	—	865,479	865,479
Dilutive effect of restricted shares units	—	—	778,130	778,130
Dilutive effect of stock options	—	—	16,789,714	16,789,714
Denominator for diluted income (loss) per share calculation	6,529,092	7,381,230	157,231,652	157,231,652
Net income (loss) per share - basic	(61.70)	(201.19)	3.51	0.54
Net income (loss) per share - diluted	(61.70)	(201.19)	3.00	0.46

The effects of all outstanding convertible preferred shares, restricted shares and certain stock options have been excluded from the computation of diluted loss per share for the years ended December 31, 2018 and 2019 as their effects would be anti-dilutive. For the years ended December 31, 2018 and 2019, the Company also has certain dilutive potential stock options. These stock options which cannot be exercised until the Company completed 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	
	2018	2019
Convertible preferred shares	64,389,968	92,238,119
Restricted shares	1,134,058	—
Stock options	not applicable	11,388,776

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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 income (loss) for such employee benefits amounted to approximately RMB9,294, RMB14,152 and RMB10,049 for the years ended December 31, 2018, 2019 and 2020, respectively.

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 (see Note 18). In April 2020, Tracon issued a notice of disputes with respect to the TJD5 Agreement and the BsAbs Agreement. As of the date of this report, these disputes have not been resolved (see Note 18). As of December 31, 2020, the Group did not record any liabilities for these disputes. Information available prior to issuance of the financial statements did not indicate that it is probable that a liability had been incurred at the date of the financial statements and the Company is also unable to reasonably estimate the range of any liability or possible loss, if any.

The Group did not have significant capital and other commitments, long-term obligations, or guarantees as of December 31, 2019 and 2020.

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, 2019 and 2020:

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
Jiangsu Taslydiyi Pharmaceutical Co., Ltd.	Controlled by the ultimate controlling party of a principal shareholder of the Group
I-Mab Biopharma (Hangzhou) Co., Limited	Subsidiary of the Group before September 15, 2020; Affiliate of the Group after September 15, 2020

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23. RELATED PARTY BALANCES AND TRANSACTIONS (CONTINUED)

Details of related party balances as of December 31, 2019 and 2020 are as follows:

Ordinary Shares to be issued to Everest

	As of December 31,		
	2019	2020	
	RMB	RMB	US$ (Note 2.5)
Everest (Note 18)	258,119	—	—

Other receivables

	As of December 31,		
	2019	2020	
	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou	—	21,212	3,251

Accruals and other payables

	As of December 31,		
	2019	2020	
	RMB	RMB	US$ (Note 2.5)
Jiangsu Taslydiyi Pharmaceutical Co., Ltd.	—	2,395	367

Details of related party transactions for the years ended December 31, 2018, 2019 and 2020 are as follows:

Receipt of CRO services—recognized in research and development expenses

	For the year ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
CMAB Biopharma (Suzhou) Inc.	2,786	—	681	104
Jiangsu Taslydiyi Pharmaceutical Co., Ltd.	—	—	2,395	367
Tasly Pharmaceutical Group Co., Ltd.	—	5,590	—	—

Receipt of research and development funding

	For the year ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
Everest (Note 18)	178,715	53,148	—	—

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23. RELATED PARTY BALANCES AND TRANSACTIONS (CONTINUED)

Collection of loan to an affiliate

	For the year ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou [4]	—	—	52,000	7,969

(4) In July 2019 and July 2020, I-Mab Shanghai provided an interest free loan to I-Mab Hangzhou of RMB2,000 and RMB50,000 respectively to finance I-Mab Hangzhou's operation. These loans were repaid in November 2020.

Expenses paid on behalf of an affiliate

	For the year ended December 31,			
	2018	2019	2020	
	RMB	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou	—	—	21,212	3,251

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, accounts receivable, 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, 2019 and 2020, 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 accounts receivable, contract assets, other receivables and other financial assets, the Group performs on-going credit evaluations of the financial condition of its customers and counterparties.

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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts in thousands, except for share and per share data, unless otherwise noted)

25. SUBSEQUENT EVENTS

In February 2021, the Group sent Tracon a notice to terminate the TJD5 Agreement, which would result in a prespecified termination fee of US$9.0 million owing to Tracon.

In March 2021, the Group entered into two collaboration agreements with Complix, an EU-based biotech company (the "Complix Agreement"), and Affinity, a Shanghai-based biotech company (the "Affinity Agreement"), respectively, allowing the Group to access cutting edge technology platforms to create next generation of novel and highly differentiated drug candidates, including Cell Penetrating Alphabodies ("CPAB") for otherwise intractable intracellular drug targets and masked antibodies for targeted tumor-site activation. Under the Complix Agreement, both parties will collaborate to discover, develop and commercialize novel therapeutics for mutually agreed targets based on the Complix's proprietary technology. Under the Affinity Agreement, both parties will collaborate to develop lead compounds for mutually agreed targets based on Affinity's Tumor MicroEnvironment Activated body ("TMEAbody") platform technology.

In March 2021, the Group entered into a license and collaboration agreement with Genbase, a Shanghai-based biotech company to develop bi-specific antibodies or/and multi-specific antibodies using antibody sequences from both companies. Under this agreement, Genbase granted to the Group a non-transferable, sublicensable, and royalty-bearing license under Genbase parental antibody technology and Genbase parental antibody improvements owned and controlled by Genbase to make, develop and commercialize the licensed compounds and licensed products in all uses and indications worldwide.

26. 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, 2018, 2019 and 2020, 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.

As of December 31, 2020, the net asset base for purposes of calculating the proportionate share of restricted net assets of consolidated subsidiaries should be zero, while the Group has a consolidated shareholders' equity. Therefore, as the restricted net assets of consolidated subsidiaries do not exceed 25% of consolidated net assets as of the most recent fiscal year end, the Group is not required to provide parent company financial information.

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 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 (the "Company");

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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 this annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

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 28, 2021

By: /s/ Joan Huaqiong Shen
Name: Joan Huaqiong Shen
Title: 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 (the "Company");

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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 this annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

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 28, 2021

By: /s/ Jielun Zhu
Name: Jielun Zhu
Title: 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, 2020 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, as amended; 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 28, 2021

By: /s/ Joan Huaqiong Shen
Name: Joan Huaqiong Shen
Title: 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, 2020 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, as amended; 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 28, 2021

By: /s/ Jielun Zhu
Name: Jielun Zhu
Title: Chief Financial Officer

EXHIBIT 15.1

April 28, 2021
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.D. Key Information—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, 2020 (the "**Annual Report**"), which will be filed with the Securities and Exchange Commission (the "**SEC**") on the date hereof, and further consent to the incorporation by reference into the Registration Statements on Form S-8 (No. 333-239871) and Form F-3 (No. 333-252793) of I-Mab of the summary of our opinions under the headings "Item 3.D. Key Information—Risk Factors—Risks Related to Doing Business in China" and "Item 10. Additional Information—E. Taxation—PRC Taxation" in the Annual Report. 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

Exhibit 15.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-239871) and Form F-3 (No. 333-252793) of I-Mab of our report dated April 28, 2021 relating to the financial statements, which appears in this Form 20-F.

/s/PricewaterhouseCoopers Zhong Tian LLP
Shanghai, the People's Republic of China
April 28, 2021