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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, 2022.

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)

55th Floor, New Bund Center, 555 West Haiyang Road, Pudong District
Shanghai, 200124
People's Republic of China
(Address of Principal Executive Offices)

Richard Yeh, Interim Chief Financial Officer
55th Floor, New Bund Center, 555 West Haiyang Road, Pudong District
Shanghai, 200124
People's Republic of China
Phone: +86 21-6057-8000
Email: Richard.Yeh@i-mabbiopharma.com
(Name, Telephone, Email and/or Facsimile number and Address of Company Contact Person)

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:

190,879,919 ordinary shares outstanding, par value of US$0.0001 per share, excluding 2,961,319 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, as of December 31, 2022.

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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

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 consummate the listings of our securities on other stock exchanges;
- 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; and
- changes to regulatory and operating conditions in our industry and markets.

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 RMB6.8972 to US$1.00, the exchange rate in effect as of December 30, 2022 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

Our Holding Company Structure

I-Mab is not an operating company but a Cayman Islands holding company with operations primarily conducted by its subsidiaries based in China and the United States. We and our subsidiaries face various legal and operational risks and uncertainties related to doing business in China. A significant part of our business operations in China are conducted through our PRC subsidiaries, and we and our subsidiaries are subject to complex and evolving PRC laws and regulations. For example, the PRC government has recently issued statements and regulatory actions relating to areas such as the regulatory approvals on offshore offerings and listings by, and foreign investment in, China-based users, anti-monopoly actions and oversight on cybersecurity and data privacy. In addition, we also face risks arising from the prospective uncertainties associated with the ability of the Public Company Accounting Oversight Board (United States), or the PCAOB, to completely inspect registered public accounting firms headquartered in mainland China (including our independent auditor). These risks and uncertainties may impact our ability to conduct certain businesses, accept foreign investments, or list or conduct offerings on a United States or other foreign exchange, and could result in a material adverse change in our operations and the value of our ADSs, significantly limit or completely hinder our ability to offer or continue to offer securities to investors, or cause such securities to significantly decline in value. For a detailed description of risks related to doing business in China, see "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China."

The PRC government has significant authority in regulating our operations and may influence our operations. It may exert more oversight and control over offerings conducted overseas by, and foreign investment in, China-based issuers, which could significantly limit or completely hinder our ability to offer or continue to offer securities to investors. Implementation of industry-wide regulations, including data security or anti-monopoly related regulations, in this nature may cause the value of such securities to significantly decline. For more details, see "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—The PRC government's significant oversight and discretion over our business operations could result in a material adverse change in our operations and the value of our ADSs."

Risks and uncertainties arising from the legal system in China, including risks and uncertainties regarding the enforcement of laws and quickly evolving rules and regulations in China, could result in a material adverse change in our operations and the value of our ADSs. For more details, see "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—Uncertainties with respect to the PRC legal system could materially and adversely affect us."

Permissions Required from the PRC Authorities

We conduct our business in China primarily through our subsidiaries in China. Our operations in China are governed by PRC laws and regulations. As of the date of this annual report, our PRC subsidiaries have obtained the requisite licenses and permits from the PRC government authorities that are material for their business operations in China. Given the uncertainties of interpretation and implementation of relevant laws and regulations and the enforcement practice by relevant government authorities, we may be required to obtain additional licenses, permits, filings or approvals for the functions and services of our platform in the future, or renew our current licenses, permits, filings or approvals. For more detailed information, see "Item 3. Key Information—D. Risk Factors—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."

Furthermore, the PRC government has recently promulgated certain regulations and rules to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers. In connection with the nature and scale of data processed or handled by us in our business operations and our historical issuance of securities to foreign investors, under the current PRC laws, regulations and regulatory rules, as of the date of this annual report, we and our PRC subsidiaries, (i) are not required to go through the filing procedures with regard to the listing and historical issuance of securities by our company to foreign investors with the China Securities Regulatory Commission, or the CSRC, under the Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (the "Overseas Listing Trial Measures"), (ii) are not required by the Cyberspace Administration of China, or the CAC, or any of its local counterparts, to go through the cybersecurity review under the Cybersecurity Review Measures, and (iii) have not received or were denied such permissions by the CSRC or the CAC. Nevertheless, in the event that we conduct any securities offerings in the future that will be captured by the Overseas Listing Trial Measures, we will have to go through the filing procedures with the CSRC within three business days following the closing of the securities issuance or offering. For more detailed information, see "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—The approval of and filing with relevant PRC government authorities may be required in connection with our offshore offerings under PRC law, and, if required, we cannot predict whether or for how long we will be able to obtain such approval or complete such filing."

If (i) we do not receive or maintain any requisite permissions or approvals, (ii) we inadvertently concluded that certain permissions or approvals have been acquired or are not required, or (iii) applicable laws, regulations or interpretations thereof change and we become subject to the requirement of additional permissions or approvals in the future, we cannot assure you that we will be able to obtain such permissions or approvals in a timely manner, or at all, and such approvals may be rescinded even if obtained. Any such circumstance could subject us to penalties, including fines, suspension of business and revocation of required licenses, which could materially and adversely affect our business, financial condition and results of operations.

The Holding Foreign Companies Accountable Act

Pursuant to the Holding Foreign Companies Accountable Act, or the HFCAA, if the SEC determines that we have filed audit reports issued by a registered public accounting firm that has not been subject to inspections by the PCAOB for two consecutive years, the SEC will prohibit our shares or the ADSs from being traded on a national securities exchange or in the over-the-counter trading market in the United States. On December 16, 2021, the PCAOB issued a report to notify the SEC of its determination that the PCAOB was unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong, including our auditor. In May 2022, the SEC conclusively listed us as a Commission-Identified Issuer under the HFCAA following the filing of this annual report on Form 20-F for the fiscal year ended December 31, 2021. On December 15, 2022, the PCAOB issued a report that vacated its December 16, 2021 determination and removed mainland China and Hong Kong from the list of jurisdictions where it is unable to inspect or investigate completely registered public accounting firms. For this reason, we do not expect to be identified as a Commission-Identified Issuer under the HFCAA after we file this annual report on Form 20-F. Each year, the PCAOB will determine whether it can inspect and investigate completely audit firms in mainland China and Hong Kong, among other jurisdictions. If the PCAOB determines in the future that it no longer has full access to inspect and investigate completely accounting firms in mainland China and Hong Kong and we continue to use an accounting firm headquartered in one of these jurisdictions to issue an audit report on our financial statements filed with the Securities and Exchange Commission, we would be identified as a Commission-Identified Issuer following the filing of the annual report on Form 20-F for the relevant fiscal year. There can be no assurance that we would not be identified as a Commission-Identified Issuer for any future fiscal year, and if we were so identified for two consecutive years, we would become subject to the prohibition on trading under the HFCAA. For more details, see "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—The PCAOB had historically been unable to inspect our auditor in relation to their audit work performed for our financial statements and the inability of the PCAOB to conduct inspections of our auditor in the past has deprived our investors with the benefits of such inspections" and "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—Our ADSs may be prohibited from trading in the United States under the HFCAA in the future if the PCAOB is unable to inspect or investigate completely auditors located in China. The delisting of the ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment."

Cash and Asset Flows through Our Organization

I-Mab is a holding company with no operations of its own. We conduct our business primarily through our subsidiaries in China and the United States. As a result, although other means are available for us to obtain financing at the holding company level, our ability to pay dividends to the shareholders and investors of the ADSs and to service any debt it may incur may depend upon dividends paid by our subsidiaries. If any of our subsidiaries incurs debt on its own behalf in the future, the instruments governing such debt may restrict its ability to pay dividends to I-Mab. In addition, our PRC subsidiaries are permitted to pay dividends to I-Mab only out of their retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. Further, our PRC subsidiaries are required to make appropriations to certain statutory reserve funds or may make appropriations to certain discretionary funds, which are not distributable as cash dividends except in the event of a solvent liquidation of the companies. For more details, see "Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources—Holding Company Structure."

Under PRC laws and regulations, our PRC subsidiaries are subject to certain restrictions with respect to paying dividends or otherwise transferring any of their net assets to us. Remittance of dividends by a wholly foreign-owned enterprise out of China is also subject to examination by the banks designated by SAFE. The amounts restricted include the paid-up capital and the statutory reserve funds of our PRC subsidiaries, totaling RMB455.0 million, RMB486.9 million and RMB490.0 million (US$71.0 million) as of December 31, 2020, 2021 and 2022, respectively. Furthermore, cash transfers from our PRC subsidiaries to entities outside of China are subject to PRC government control of currency conversion. Shortages in the availability of foreign currency may temporarily delay the ability of our PRC subsidiaries to remit sufficient foreign currency to pay dividends or other payments to us, or otherwise satisfy their foreign currency denominated obligations. For the years ended December 31, 2020, 2021 and 2022, no dividends or distributions were made to I-Mab by our subsidiaries. For risks relating to the fund flows of our operations in China, see "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China—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."

Under PRC law, I-Mab may provide funding to our PRC subsidiaries only through capital contributions or loans, subject to satisfaction of applicable government registration and approval requirements. In the years ended December 31, 2020, 2021 and 2022, I-Mab extended loans with outstanding principal amount of RMB776.2 million, RMB1,079.6 million and RMB898.6 million (US$130.3 million), respectively, to our intermediate holding companies and subsidiaries.

I-Mab has not declared or paid any cash dividends, nor does it 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. See "Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Dividend Policy." For PRC and United States federal income tax considerations of an investment in our ADSs, see "Item 10. Additional Information—E. Taxation."

Selected Financial Data

As of December 31, 2022, we had cash, cash equivalents, restricted cash, and short-term investments of RMB3.5 billion (US$514.2 million), compared with RMB4.3 billion as of December 31, 2021. Our cash balance provides us with adequate funding to support our key business for at least the next three years based on our current estimation, taking our current cash position together with the expected upcoming milestone payments from the previous out-licensing deals and collaborations.

The following selected consolidated statements of comprehensive income (loss) data for the years ended December 31, 2020, 2021 and 2022, selected consolidated balance sheet data as of December 31, 2021 and 2022 and selected consolidated statements of cash flow data for the years ended December 31, 2020, 2021 and 2022 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 years ended December 31, 2018 and 2019, selected consolidated balance sheet data as of December 31, 2018, 2019 and 2020, and selected consolidated statements of cash flow data for the years ended December 31, 2018 and 2019 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.

	For the Year Ended December 31,					
	2018	2019	2020	2021	2022	
	RMB	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[1]	53,781	30,000	1,542,668	40,115	(249,665)	(36,198)
Supply of investigational products	—	—	—	47,911	28,102	4,074
Total revenues	53,781	30,000	1,542,668	88,026	(221,563)	(32,124)
Cost of revenues	—	—	—	(46,432)	(27,237)	(3,949)
Expenses						
Research and development expenses [2]	(426,028)	(840,415)	(984,689)	(1,212,958)	(904,901)	(131,198)
Administrative expenses [2]	(66,391)	(654,553)	(402,409)	(899,943)	(815,766)	(118,275)
Income (loss) from operations	(438,638)	(1,464,968)	155,570	(2,071,307)	(1,969,467)	(285,546)
Interest income	4,597	30,570	24,228	21,333	26,908	3,901
Interest expense	(11,695)	(2,991)	(957)	—	(9)	(1)
Other income (expenses), net	(16,780)	(20,205)	412,892	83,162	(126,587)	(18,353)
Equity in loss of affiliates [2]	—	—	(108,587)	(367,883)	(437,465)	(63,426)
Fair value change of warrants	61,405	5,644	—	—	—	—
Income (loss) before income tax expense	(401,111)	(1,451,950)	483,146	(2,334,695)	(2,506,620)	(363,425)
Income tax benefit (expense)	(1,722)	—	(12,231)	3,154	(697)	(101)
Net income (loss) attributable to I-Mab	(402,833)	(1,451,950)	470,915	(2,331,541)	(2,507,317)	(363,526)
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	(2,331,541)	(2,507,317)	(363,526)
Other comprehensive income (loss)						
Foreign currency translation adjustments, net of nil tax	53,689	10,747	(120,920)	(135,717)	400,304	58,039
Total comprehensive income (loss) attributable to I-Mab	(349,144)	(1,441,203)	349,995	(2,467,258)	(2,107,013)	(305,487)
Net income (loss) attributable to ordinary shareholders	(402,833)	(1,485,001)	470,915	(2,331,541)	(2,507,317)	(363,526)
Weighted-average number of ordinary shares used in calculating net income (loss) per share						
Basic	6,529,092	7,381,230	134,158,824	174,707,055	189,787,292	189,787,292
Diluted	6,529,092	7,381,230	157,231,652	174,707,055	189,787,292	189,787,292
Net income (loss) per share attributable to ordinary shareholders						
Basic	(61.70)	(201.19)	3.51	(13.35)	(13.21)	(1.92)
Diluted	(61.70)	(201.19)	3.00	(13.35)	(13.21)	(1.92)
Net income (loss) per ADS attributable to ordinary shareholders						
Basic	(141.91)	(462.74)	8.07	(30.71)	(30.38)	(4.41)
Diluted	(141.91)	(462.74)	6.90	(30.71)	(30.38)	(4.41)

Notes:

(1) The licensing and collaboration revenue of RMB-249.7 million (US$-36.2 million) was primarily due to a non-cash adjustment of US$-48.0 million (equivalent to RMB-314.2 million) recorded in the second half of 2022 following the amendment to the original license and the overall collaboration arrangement with AbbVie Ireland Unlimited Company ("AbbVie") in August 2022. This overall amendment led to a lowered probability of achieving a key milestone that was included in the consideration of revenue recognition in prior years. For more details, see "Item 5. Operating and Financial Review and Prospects."

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

	For the Year Ended December 31,					
	2018	2019	2020	2021	2022	
	RMB	RMB	RMB	RMB	RMB	US$
	(in thousands)					
Research and development expenses	1,056	470	284,431	201,926	117,876	17,090
Administrative expenses	2,464	514,733	209,033	406,683	239,272	34,691
Equity in loss of affiliates	—	—	32,707	13,267	13,852	2,008
Total	**3,520**	**515,203**	**526,171**	**621,876**	**371,000**	**53,789**

The following table presents our selected consolidated statements of balance sheet data as of the dates indicated:

	As of December 31,					
	2018	2019	2020	2021	2022	
	RMB	RMB	RMB	RMB	RMB	US$
	(in thousands)					
Selected Consolidated Statements of Balance Sheet Data:						
Current assets:						
Cash and cash equivalents	1,588,278	1,137,473	4,758,778	3,523,632	3,214,005	465,987
Restricted cash	92,653	55,810	—	—	96,764	14,029
Accounts receivable	—	—	130,498	33,081	—	—
Contract assets	11,000	—	227,391	253,780	—	—
Short-term investments	—	32,000	31,530	753,164	235,429	34,134
Inventories	—	—	—	27,237	—	—
Prepayments and other receivables	88,972	136,036	195,467	190,824	80,278	11,639
Other financial assets	255,958	—	—	—	—	—
Total current assets	2,036,861	1,361,319	5,343,664	4,781,718	3,626,476	525,789
Property, equipment and software	27,659	30,069	25,272	45,716	60,841	8,821
Operating lease right-of-use assets	—	16,435	14,997	112,781	63,125	9,152
Intangible assets	148,844	148,844	120,444	119,666	118,888	17,237
Goodwill	162,574	162,574	162,574	162,574	162,574	23,571
Investment accounted for using the equity method	—	—	664,832	352,106	30,850	4,473
Other non-current assets	—	18,331	2,010	26,634	10,911	1,582
Total assets	**2,375,938**	**1,737,572**	**6,333,793**	**5,601,195**	**4,073,665**	**590,625**
Total liabilities	**415,684**	**668,090**	**706,648**	**1,041,635**	**1,163,763**	**168,729**
Total mezzanine equity	**2,915,358**	**3,104,177**	**—**	**—**	**—**	**—**
Shareholders' deficit						
Ordinary shares (US$0.0001 par value, 800,000,000 shares authorized as of December 31, 2021 and 2022; 183,826,753 and 190,879,919 shares issued and outstanding as of December 31, 2021 and 2022, respectively)	6	6	114	126	132	19
Treasury stock	(1)	—	—	—	(21,249)	(3,081)
Additional paid-in capital	—	389,379	7,701,116	9,100,777	9,579,375	1,388,879
Accumulated other comprehensive income (loss)	59,380	70,127	(50,793)	(186,510)	213,794	30,997
Accumulated deficit	(1,014,489)	(2,494,207)	(2,023,292)	(4,354,833)	(6,862,150)	(994,918)
Total shareholders' equity/(deficit)	**(955,104)**	**(2,034,695)**	**5,627,145**	**4,559,560**	**2,909,902**	**421,896**
Total liabilities, mezzanine equity and shareholders' equity/(deficit)	**2,375,938**	**1,737,572**	**6,333,793**	**5,601,195**	**4,073,665**	**590,625**

The following table presents our selected consolidated statements of cash flow data for the years indicated:

	For the Year Ended December 31,					
	2018	2019	2020	2021	2022	
	RMB	RMB	RMB	RMB	RMB	US$
	(in thousands)					
Selected Consolidated Statements of Cash Flow Data:						
Net cash (used in) generated from operating activities	(280,705)	(867,982)	433,558	(973,093)	(1,102,805)	(159,892)
Net cash generated from (used in) investing activities	9,500	212,462	(201,901)	(727,206)	458,382	66,459
Net cash generated from financing activities	1,479,669	152,709	3,440,481	593,924	42,357	6,141
Effect of exchange rate changes on cash and cash equivalents and restricted cash	59,754	15,163	(106,643)	(128,771)	389,203	56,429
Net increase (decrease) in cash, cash equivalents and restricted cash	1,268,218	(487,648)	3,565,495	(1,235,146)	(212,863)	(30,863)
Cash, cash equivalents and restricted cash, beginning of the year	412,713	1,680,931	1,193,283	4,758,778	3,523,632	510,879
Cash, cash equivalents and restricted cash, end of the year	1,680,931	1,193,283	4,758,778	3,523,632	3,310,769	480,016

A. Reserved

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Summary of Risk Factors

An investment in our ADSs or ordinary shares involves significant risks. Below is a summary of material risks we face, organized under relevant headings. These risks are discussed more fully in "Item 3. Key Information—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 have incurred net losses in the past and we may not be able to maintain profitability in the future.
- 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.

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.

- 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 banned.

- 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.

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.

- 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 failure to obtain patent term extension and data exclusivity for approved pharmaceutical products could increase the risk of generic competition with our products.

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.

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

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 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.

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.

- 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.

- 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.

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

Risks Related to Doing Business in China

- The PRC government's significant oversight and discretion over our business operations could result in a material adverse change in our operations and the value of our ADSs.
- The PCAOB had historically been unable to inspect our auditor in relation to their audit work performed for our financial statements and the inability of the PCAOB to conduct inspections of our auditor in the past has deprived our investors with the benefits of such inspections.
- Our ADSs may be prohibited from trading in the United States under the HFCAA in the future if the PCAOB is unable to inspect or investigate completely auditors located in China. The delisting of the ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment.
- The approval of and filing with relevant PRC government authorities may be required in connection with our offshore offerings under PRC law, and, if required, we cannot predict whether or for how long we will be able to obtain such approval or complete such filing.

General Risks Related to Our ADSs

- The trading price of our ADSs may be volatile, which could result in substantial losses to you.
- We may face an increased risk of securities class action litigation.

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 the sales of our commercial products. 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 public and private placements. While we have generated revenue from licensing and collaboration deals, we have only started to generate revenue from supply of investigational products since 2021, and we may continue to incur significant research and development expenses and other expenses related to our ongoing operations. As a result, we had generated a net income of RMB470.9 million in 2020 primarily due to contributions from licensing and collaboration deals, incurred a net loss of RMB2,331.5 million in 2021 and a net loss of RMB2,507.3 million (US$363.5 million) in 2022, respectively. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We cannot assure you that we will be able 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 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 and received total net proceeds of approximately US$105.3 million from our initial public offering. We generated RMB433.6 million in net cash from our operations in 2020 primarily due to collection of upfront payment from licensing and collaboration deals, and spent RMB973.1 million and RMB1,102.8 million (US$160.0 million) in net cash to finance our operations in 2021 and 2022, respectively.

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

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

The 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(s), will be sufficient to meet our present anticipated working capital requirements and capital expenditures. However, if the volatility in the financial markets continues (including the impact that may arise from the COVID-19), 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. For example, in July 2022, due to an unexpected high incidence of fatal bleeding, MacroGenics terminated a phase 2 study of enoblituzumab as a combination therapy with PD-1 antibody or PD-1/LAG3 bispecific antibody in patients with head and neck cancers. As a result of such incident, we exercised our right to terminate the collaboration agreement with MacroGenics by serving a termination notice on August 29, 2022 and the termination came into effect in February 2023. In addition, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, differences in individual patient conditions, including genetic differences, and other compounding factors, such as other medications or pre-existing medical conditions.

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

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

Our business will depend on the successful development, regulatory approval and commercialization of our drug candidates for the treatment of patients with our targeted indications, all of which are still in pre-clinical or clinical development, and other new drug candidates that we may identify and develop. As of the date of this annual report, we have obtained investigational new drug (IND) approvals from the NMPA for seven of our drug candidates, felzartamab, efineptakin alfa, lemzoparlimab, ulilediimab, eftansomatropin alfa, TJ210 and givastomig. In addition, we have obtained IND approvals from the FDA for five of our drug candidates, lemzoparlimab, ulilediimab, TJ210, TJ-L14B and givastomig and from the Taiwan Food and Drug Administration (the "TFDA") for felzartamab. 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 efineptakin alfa and eftansomatropin alfa in China, for felzartamab in Greater China, for TJ210 and TJ-L14B in the United States, for lemzoparlimab, uliledlimab and givastomig 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;
- our partners identify safety concerns in the clinical assets that we licensed, which lead to the termination of the collaboration and development of the underlying clinical assets with our partners;
- 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 fail to timely and effectively address the above challenges, 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 seven of our drug candidates, felzartamab, efineptakin alfa, lemzoparlimab, uliledlimab, eftansomatropin alfa, TJ210 and givastomig. In addition, we have obtained IND approvals from the FDA for five of our drug candidates, lemzoparlimab, uliledlimab, TJ210, TJ-L14B and givastomig; from the TFDA for felzartamab. 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 ("GMP"), 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 failure to obtain patent term extension and data exclusivity for approved pharmaceutical products could increase the risk of generic competition with our products.

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, the PRC Patent Law, which was most recently amended by the Standing Committee of the National People's Congress on October 17, 2020, and became effective on June 1, 2021, for the first time, generally provides for patent term compensation and patent linkage system. Under the PRC Patent Law, patent term compensation can be obtained for regulatory delays in the review and approval of new drugs but are limited to no more than five years and the total post-marketing patent term of the new drug cannot exceed 14 years, which is similar to the provisions of Hatch-Waxman. However, to be implemented, the patent term compensation requires further promulgation of detailed implementation measures. Depending upon the timing, duration and specifics of any NMPA marketing approval process for any drug candidates we may develop, one or more of our China patents, if issued, may not be eligible for or only be eligible for limited patent term compensation. The PRC Patent Law, for the first time, introduces a system for the early resolution of patent disputes concerning generic drug applications, which is similar to the U.S. patent linkage system. The Implementation Measures for Early Resolution Mechanism of Pharmaceutical Patent Disputes (for Trial Implementation) jointly issued by the NMPA and the China National Intellectual Property Administration (the "CNIPA") on July 4, 2021 and the Administrative Ruling Measures on the Early Resolution Mechanism for Drug Patent Dispute issued by the CNIPA on July 5, 2021 collectively set forth, for the first time, details of how such patent linkage system would be implemented. As the China trial version of patent linkage system was just implemented commencing from July 2021, substantial uncertainties remain as to whether this trial system can effectively block early generic competition with our products. Although the Regulations for Implementation of the Drug Administration Law of the People's Republic of China has provided six-year data exclusivity for a new chemical entity, and Chinese regulators have proposed a framework for integrating data exclusivity into the Chinese regulatory regime in 2018, the system of data exclusivity was not really implemented in practice. Consequently, the absence of currently implemented data exclusivity may result in weaker protection for us against generic competition in China than could be available to us in the United States. 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 GMPs, 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 sourcing 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. We have invested in a comprehensive biologics manufacturing facility in Hangzhou, China (the "Hangzhou Facility") held by I-Mab Biopharma (Hangzhou) Limited ("I-Mab Hangzhou"), an unconsolidated affiliate of our company, as part of our strategic plan to become a global biopharma company. Concrete steps have been taken 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 construction of the Hangzhou Facility commenced in April 2021. The Hangzhou Facility has established a pilot capacity of two production lines (one line configured with 2 x 2,000L and the other line with 1 x 2,000L). However, the investment for building the new biologics manufacturing facility that is compliant with cGMP regulations will be a significant upfront cost for I-Mab Hangzhou and its shareholders. 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 and our third-party collaborators 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 will 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 will also 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. The following sets forth the major provisions of the ACA that may affect our drug candidates:

- 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 could utilize 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 secure a facility that we can control for clinical-scale manufacturing and processing of our drug candidates, 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 Ireland Unlimited Company ("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 retain all rights to develop and commercialize lemzoparlimab in mainland China, Hong Kong and Macau. On August 15, 2022, we and AbbVie Global Enterprises Ltd. (as an assignee of AbbVie) entered into an amendment to the original licensing and collaboration agreement (as amended, the "AbbVie Collaboration Agreement"). The parties are collaborating on the global development of anti-CD47 antibody therapy under the AbbVie Collaboration Agreement. AbbVie discontinued the global Phase 1b study of lemzoparlimab combination therapy with AZA and venetoclax, in patients with MDS and AML and a Phase 1b study of lemzoparlimab in patients with relapsed/refractory multiple myeloma. These discontinuations were not related to any specific or unexpected safety concerns. This change led to a lowered probability of achieving a key milestone that was included in the consideration of revenue recognition in prior years. We recorded a reduction in the revenue of approximately US$48.0 million in the second half of 2022. For a more detailed discussion, please see "Item 4. Information on the Company—B. Business Overview—Licensing and Collaboration Arrangements—B. Out-Licensing Arrangements—License and Collaboration Agreement with AbbVie" and "Item 5. Operating and Financial Review and Prospects."

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 address the risks mentioned above and successfully integrate these agreements or partnerships with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. For example, disputes have arisen between Tracon Pharmaceuticals, Inc. ("Tracon") and us in relation to the collaboration agreements to co-develop our proprietary CD73 antibody, TJD5 (the "TJD5 Agreement") and to co-develop up to five bispecific antibodies (the "BsAbs Agreement"). The disputes relating to the TJD5 Agreement and the BsAbs Agreement were presented to a binding arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce before an arbitration tribunal. On April 25, 2023, the arbitration award determined that the TJD5 Agreement has been terminated for a pre-agreed termination fee of US$9.0 million plus interest payable pursuant to the original agreement, and therefore Tracon has no rights to share any future economics with I-Mab. The arbitration award completely denied Tracon's damages claim of over US$200 million for any breach and awarded no damages to Tracon. The tribunal also confirmed the termination of the BsAb Agreement. Based on the arbitration award, I-Mab will bear a portion of Tracon's legal fees and costs, totaling approximately US$13.5 million. See "Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Legal Proceedings" for details. We cannot assure you that similar disputes will not occur again and we cannot assure you that no lawsuits will be initiated by other companies in the future. Also, these legal proceedings may be expensive, time-consuming and disruptive to our operations and divert our management's attention. We cannot predict the possible outcome of the legal proceedings of such nature in the future and there can also be no assurance that we will prevail in those legal proceedings.

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, 2022, our owned patent portfolio consisted of 113 issued patents and 185 patent applications primarily in connection with the drug candidates in our Global Portfolio, including 19 Patent Cooperation Treaty ("PCT") patent applications, 21 U.S. patent applications, 30 PRC patent applications and 228 patent applications in other jurisdictions. In addition, as of December 31, 2022, we in-licensed the Greater China and Korea rights relating to 35 issued patents and 26 pending patent applications primarily in connection with felzartamab, eftansomatropin alfa, efineptakin alfa and TJ210. 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, CNIPA, 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. For example, due to Tracon's wrong-doing during the confidential arbitration process, we are pursuing a trade secret misappropriation lawsuit case against a competitor of us and seeking remedies, including potentially substantial monetary damages. Regardless of the outcome, litigations or arbitrations can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. 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.

Although patent regulations in respect of patent term compensation and patent linkage system have been introduced by the PRC Patent Law taking effective on June 1, 2021, the patent term compensation requires further promulgation of detailed implementation measures to be implemented. Thus, patents that we expect to obtain in China may not be eligible for or only be eligible for limited patent term compensation. In the meantime, the PRC Patent Law, for the first time, introduces a system for the early resolution of patent disputes concerning generic drug applications. On July 4, 2021, the NMPA and the CNIPA jointly issued the Implementation Measures for Early Resolution Mechanism of Pharmaceutical Patent Disputes (for Trial Implementation) which sets forth, for the first time, details of how such patent linkage system would be implemented. Since the China trial version of patent linkage system was just implemented commencing from July 4, 2021, substantial uncertainties remain as to whether this trial system can effectively block early generic competition with our products. Although the Regulations for Implementation of the Drug Administration Law of the People's Republic of China has provided six-year data exclusivity for a new chemical entity, and the Chinese regulators have proposed a framework for integrating data exclusivity into the Chinese regulatory regime in 2018, the system of data exclusivity was not really implemented in practice. Consequently, these factors may result in weaker protection for us against generic competition in China than could be available to us in some jurisdictions such as the United States.

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.

Any failure to comply with the various applicable laws and regulations related to data security, cybersecurity and personal information and privacy protection could affect our offshore offerings and lead to liabilities, penalties or other regulatory actions, which could have a material and adverse effect on our business, financial condition and results of operations.

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.

In China, regulatory authorities 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. 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.

On June 10, 2021, the Standing Committee of the National People's Congress promulgated the PRC Data Security Law, which came into effect on September 1, 2021. The Data Security Law, among other things, provides for a security review procedure for the data activities that may affect national security. In addition, the Civil Code of the PRC ("the Civil Code"), which came into effect on January 1, 2021, expressly provides the right of privacy and personal information protection. The PRC Cyber Security Law, the Data Security Law and Civil Code are relatively new and subject to interpretation by the regulators. Although we only gain access to user information that is necessary for, and relevant to, the businesses conducted, the data we obtain and use may include information that is deemed as "personal information" or "important data" under the PRC Cyber Security Law, the Civil Code and related data privacy and protection laws and regulations.

On August 20, 2021, the Standing Committee of the National People's Congress promulgated the Personal Information Protection Law, which came into effect on November 1, 2021. The Personal Information Protection Law requires, among others, that the processing of personal information should have a specific and reasonable purpose, and must be conducted in a way that has the least impact on personal rights and interests, and should be limited to the minimum scope necessary to achieve the processing purpose. On November 4, 2022, the CAC and the SAMR jointly issued the Notification on the Implementation of Personal Information Protection Certification, which implemented the personal information protection certification mechanism in response to the requirements under the Personal Information Protection Law regarding the outbound transfer of personal information.

The Data Security Management Measures (Draft for Comments) was published by the CAC for public comments on November 14, 2021, which proposed that a data processor shall apply for a cybersecurity review under any of the following circumstances: (i) merger, reorganization, or division of internet platform operators with significant data resources concerning national security, economic development or public interest that affects or may affect national security; (ii) a data processor processing personal information of more than one million users while listing on foreign stock markets; (iii) a data processor listing in Hong Kong that affects or may affect national security; or (iv) other data processing activities that affect or may affect national security. The Data Security Management Measures (Draft for Comments) further required the data processors processing important data or listing on foreign stock markets to carry out annual data security self-assessment and submit an evaluation report to the CAC. However, as the Data Security Management Measures (Draft for Comments) was released only for public comment, there are still uncertainties regarding the final version and the effective date thereof.

In December 2021, the CAC and several other authorities jointly promulgated the revised Cybersecurity Review Measures, which came into effect in February 2022. Pursuant to the Cybersecurity Review Measures, where the relevant activity affects or may affect national security, a critical information infrastructure operator, or a CIIO, that purchases network products and services, or an internet platform operator that conducts data processing activities, shall be subject to the cybersecurity review. In addition, internet platform operators processing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review. As of the date of this annual report, (i) no detailed rules or implementation relating to the Cybersecurity Review Measures has been issued by any PRC regulatory authorities, (ii) we have not been informed of being identified as a CIIO or an internet platform operator, nor have we been required to go through the cybersecurity review procedures, by any PRC governmental authorities, and (iii) we have not been involved in any investigations on cybersecurity review on such basis, nor have we received any inquiry, notice, warning, or sanctions in such respect, by any PRC governmental authorities. Taking into consideration the above and that (i) the preclinical and clinical data processed or handled by us in our business operations, either by its nature or in scale, do not and will not directly or indirectly affect or potentially affect national security in any respect, and (ii) we have not possessed, and do not anticipate to possess, in the foreseeable future, personal information of more than one million users or persons, based on our understanding of the Cybersecurity Review Measures, we do not expect that we will be subject to cybersecurity review by the CAC in connection with our offering of securities to foreign investors and listing on the Nasdaq. Nevertheless, the exact scope of CIIO and "internet platform operator" under the current regulatory regime remains unclear, and the PRC governmental authorities may have wide discretion in the interpretation and enforcement of the Cybersecurity Review Measures and the relevant laws, regulations, implementation rules etc. Therefore, it is uncertain whether we would be deemed as a CIIO or an internet platform operator thereunder.

On July 7, 2022, the CAC promulgated the Security Assessment Measures for Outbound Data Transfers (the "Security Assessment Measures"), which came into effect on September 1, 2022. Pursuant to the Security Assessment Measures, a data processor shall apply for the security assessment before any data can be transferred outbound if (i) the data transferred out of China is important data, (ii) the data processor is a CIIO or the data processor has processed personal information of more than one million people, (iii) the data processor has made outbound transfer of personal information of 100,000 people or sensitive personal information of 10,000 people cumulatively since January 1 of the previous year, or (iv) the security assessment for outbound data transfers is otherwise required by the CAC. For outbound data transfers conducted before the implementation of the Security Assessment Measures which failed to comply therewith, rectification shall be completed within six months from the implementation thereof. On August 31, 2022, the CAC promulgated the first edition of the Guide to Applications for Security Assessment of Outbound Data Transfers, which provided guidance to the implementation of the Security Assessment Measures, and clarified the specific timeline and procedures for security assessment for outbound data transfers under the Security Assessment Measures.

On February 22, 2023, the CAC published promulgated the Measures for the Standard Contract for Outbound Transfer of Personal Information (the "Measures for Standard Contract"), which clarified the terms and conditions to be agreed on between personal information processors as a data exporter and an overseas data importer regarding the outbound data transfers of personal information. The Measures for Standard Contract will come into effect on June 1, 2023. Under the Measures for Standard Contract, a personal information processor may enter into the PRC Standard Contract and provide it with other required materials to the relevant governmental authorities for filing to ensure the legality of an outbound data transfer of personal information provided the personal information processor (i) is not a CIIO, (ii) processes personal information of less than one million individuals, (iii) has cumulatively transferred abroad personal information of less than 100,000 individuals since January 1 of the previous year, and (iv) has cumulatively transferred abroad sensitive personal information of less than 10,000 individuals since January 1 of the previous year.

The PRC laws and regulations concerning these subject matters are continually evolving and not always clear, and the measures we take to comply with these laws, regulations and industry standards may not always be effective. We cannot assure you that we will comply with such laws and regulations regarding cybersecurity, information security, privacy and data protection in all respects and any failure or perceived failure to comply with these laws, regulations or policy may result in inquiries, penalties and other proceedings or actions against us by governmental authorities, such as warnings, fines, making certain required rectification, service suspension and/or other sanctions, as well as negative publicity and damage to our reputation. It also remains uncertain whether the future regulatory changes would impose additional restrictions on companies like us. We cannot predict the impact of the future regulatory changes, including impact of any draft measures, at this stage, and we will closely monitor and assess any development in the rule-making process. If additional requirements are imposed to companies like us, such as the clearance of cybersecurity review, we face uncertainties as to whether we can fulfill those requirements in a timely manner, or at all. If we are not able to comply with the cybersecurity and data privacy requirements in a timely manner, or at all, we may be subject to government enforcement actions and investigations, fines, penalties or suspension of our non-compliant operations, which could materially and adversely affect our business and results of operations.

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.

In Europe, regulatory authorities 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 laws, 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 business may continue to be materially and adversely affected by the effects of the COVID-19 pandemic.

The outbreaks of COVID-19, a novel strain of coronavirus, has created significant business disruption which could materially and adversely affect our business and operations. Beginning in 2020, outbreaks of COVID-19, resulted in the temporary closure of many corporate offices, retail stores, and manufacturing facilities across China. Normal economic life throughout China was sharply curtailed. The COVID-19 outbreaks led to temporary closure of our offices in the first quarter of 2020 and from March through May 2022, causing cancellation of in-person attendance at meetings, restrictions on employee travels, and a significant portion of our employees working from home, which resulted in lower work efficiency and productivity, and disruptions to our business operations and clinical trials. The operations of our suppliers were also impacted.

Most of the travel restrictions and quarantine requirements in mainland China were lifted in December 2022. There were surges of cases in many cities during this time which caused disruption to our and our suppliers' operations, and there remains uncertainty as to the future impact of the virus, especially in light of this change in policy. The extent to which the pandemic impacts our results of operations going forward will depend on future developments which are highly uncertain and unpredictable, including the frequency, duration and extent of outbreaks of COVID-19, the appearance of new variants with different characteristics, the effectiveness of efforts to contain or treat cases, and future actions that may be taken in response to these developments. China may experience lower domestic consumption, higher unemployment, severe disruptions to exporting of goods to other countries and greater economic uncertainty, which may materially and adversely impact our business, including 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 coping with 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. Consequently, the COVID-19 pandemic may continue to materially and adversely affect our business, financial condition and results of operations in the future. 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.

In addition to the impact of COVID-19, global pandemics, natural catastrophes or other disasters in the locations in which we, our suppliers, CROs, CMOs and other contractors operate, or fear of spread of contagious diseases, such as avian influenza, severe acute respiratory syndrome (SARS), influenza A (H1N1), Ebola or another epidemic could disrupt the business operations of our company, our suppliers, CROs, CMOs and other contractors. The occurrence of any of the foregoing events is beyond our control but may result in regional or global economic distress, which may materially and adversely affect our business, financial condition and results of operations.

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. Pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to include a report by our management on our internal control over financial reporting and our independent registered public accounting firm must include an attestation report on internal control over financial reporting in our annual reports. 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 acting chief executive officer and interim chief financial officer, and our independent registered public accounting firm 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, 2022. See also "Item 15. Controls and Procedures" for a detailed description.

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 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, contractual agreements, employment related cases and other matters in the ordinary course of our business. For details of the material legal proceedings that we are subject to, see "Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Legal Proceedings." 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 Bio-tech (Tianjin) Co., Ltd ("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. An impairment loss of goodwill is recognized for the amount by which the carrying amount of the reporting unit exceeds its fair value, 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 PRC government's significant oversight and discretion over our business operations could result in a material adverse change in our operations and the value of our ADSs.

We conduct our businesses in China primarily through our PRC subsidiaries. Our operations in China are governed by PRC laws and regulations. The PRC government has significant oversight and discretion over the conduct of our business and may intervene or influence our operations as the government deems appropriate to advance regulatory and societal goals and policy positions. The PRC government has recently published new policies that significantly affected certain industries and we cannot rule out the possibility that it will in the future release regulations or policies that directly or indirectly affect our industry or require us to seek additional permission to continue our operations, which could result in a material adverse change in our operation and/or the value of our ADSs. Therefore, investors of our company and our business face potential uncertainty from actions taken by the PRC government affecting our business.

The PCAOB had historically been unable to inspect our auditor in relation to their audit work performed for our financial statements and the inability of the PCAOB to conduct inspections of our auditor in the past has deprived our investors with the benefits of such inspections.

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. The auditor is located in mainland China, a jurisdiction where the PCAOB was historically unable to conduct inspections and investigations completely before 2022.

As a result, we and investors in the ADSs were deprived of the benefits of such PCAOB inspections. The inability of the PCAOB to conduct inspections of auditors in China in the past has made 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. On December 15, 2022, the PCAOB issued a report that vacated its December 16, 2021 determination and removed mainland China and Hong Kong from the list of jurisdictions where it is unable to inspect or investigate completely registered public accounting firms. However, if the PCAOB determines in the future that it no longer has full access to inspect and investigate completely accounting firms in mainland China and Hong Kong, and we use an accounting firm headquartered in one of these jurisdictions to issue an audit report on our financial statements filed with the Securities and Exchange Commission, we and investors in our ADSs would be deprived of the benefits of such PCAOB inspections again, which could cause investors and potential investors in the ADSs to lose confidence in our audit procedures and reported financial information and the quality of our financial statements.

Our ADSs may be prohibited from trading in the United States under the HFCAA in the future if the PCAOB is unable to inspect or investigate completely auditors located in China. The delisting of the ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment.

Pursuant to the HFCAA, if the SEC determines that we have filed audit reports issued by a registered public accounting firm that has not been subject to inspections by the PCAOB for two consecutive years, the SEC will prohibit our shares or ADSs from being traded on a national securities exchange or in the over-the-counter trading market in the United States.

On December 16, 2021, the PCAOB issued a report to notify the SEC of its determination that the PCAOB was unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong and our auditor was subject to that determination. In May 2022, the SEC conclusively listed us as a Commission-Identified Issuer under the HFCAA following the filing of our annual report on Form 20-F for the fiscal year ended December 31, 2021. On December 15, 2022, the PCAOB removed mainland China and Hong Kong from the list of jurisdictions where it is unable to inspect or investigate completely registered public accounting firms. For this reason, we do not expect to be identified as a "Commission Identified Issuer" under the HFCAA after we file this annual report on Form 20-F for the fiscal year ended December 31, 2022.

Each year, the PCAOB will determine whether it can inspect and investigate completely audit firms in mainland China and Hong Kong, among other jurisdictions. If the PCAOB determines in the future that it no longer has full access to inspect and investigate completely accounting firms in mainland China and Hong Kong and we use an accounting firm headquartered in one of these jurisdictions to issue an audit report on our financial statements filed with the Securities and Exchange Commission, we would be identified as a Commission-Identified Issuer following the filing of the annual report on Form 20-F for the relevant fiscal year. In accordance with the HFCAA, our securities would be prohibited from being traded on a national securities exchange or in the over-the-counter trading market in the United States if we are identified as a Commission-Identified Issuer for two consecutive years in the future. If our shares and ADSs are prohibited from trading in the United States, there is no certainty that we will be able to list on a non-U.S. exchange or that a market for our shares will develop outside of the United States. A prohibition of being able to trade in the United States would substantially impair your ability to sell or purchase our ADSs when you wish to do so, and the risk and uncertainty associated with delisting would have a negative impact on the price of our ADSs. Also, such a prohibition would significantly affect our ability to raise capital on terms acceptable to us, or at all, which would have a material adverse impact on our business, financial condition, and prospects.

The approval of and filing with relevant PRC government authorities may be required in connection with our offshore offerings under PRC law, and, if required, we cannot predict whether or for how long we will be able to obtain such approval or complete such filing.

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, requires an overseas special purpose vehicle formed for listing purposes through acquisitions of PRC domestic companies and controlled by PRC persons or entities to obtain the approval of the CSRC prior to the listing and trading of such special purpose vehicle's securities on an overseas stock exchange. The interpretation and application of the regulations remain unclear, and our offshore offerings may ultimately require approval of the CSRC. If the CSRC approval is required, it is uncertain whether we can or how long it will take us to obtain the approval and, even if we obtain such CSRC approval, the approval could be rescinded. Any failure to obtain or delay in obtaining the CSRC approval for any of our offshore offerings, or a rescission of such approval if obtained by us, may subject us to sanctions imposed by the CSRC or other PRC regulatory authorities, which may include fines and penalties on our operations in China, restrictions or limitations on our ability to pay dividends outside of China, and other forms of sanctions that may materially and adversely affect our business, financial condition, and results of operations.

On July 6, 2021, the relevant PRC government authorities issued Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law. These opinions emphasized the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies and proposed to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies.

On February 17, 2023, the CSRC promulgated the Overseas Listing Trial Measures and relevant five guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and regulate both direct and indirect overseas offering and listing of PRC domestic companies' securities by adopting a filing-based regulatory regime. Pursuant to the Overseas Listing Trial Measures, an overseas offering and listing by a domestic company, whether directly or indirectly, must be filed with the CSRC. Specifically, the examination and determination of an indirect overseas offering and listing shall be conducted on a substance-over-form basis, and an offering and listing will be considered as an indirect overseas offering and listing by a domestic company if the issuer meets the following both conditions: (i) the operating income, gross profit, total assets or net assets of such domestic company in the most recent fiscal year was more than 50% of the relevant line items in the issuer's audited consolidated financial statements for that year; and (ii) the main part of operating activities is conducted in the PRC or the main place of business is located in the PRC, or the senior management personnel responsible for business operations and management are mostly PRC citizens or are ordinarily resident in the PRC. According to the Overseas Listing Trial Measures, in the case of an indirect overseas offering and listing by a domestic company, the issuer shall designate a main domestic operating entity to file with the CSRC. Particularly, (i) with respect to the issuer's overseas initial public offering or listing, the filing application shall be submitted to the CSRC within three business days after the submission by the issuer of its initial listing application; (ii) with respect to the issuer's follow-on offering on the same overseas market, the filing application shall be submitted to the CSRC within three business days after the completion of the follow-on offering. The Overseas Listing Trial Measures also require subsequent reports to be filed with the CSRC on material events, such as a change-of-control event, or voluntary or forced delisting of the issuer who has completed the overseas offering and listing. If the issuer fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, it may be subject to administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines. Furthermore, the Overseas Listing Trial Measures also set forth certain regulatory red lines for overseas offerings and listings by domestic enterprises.

On the same day, the CSRC also issued the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies, which, among others, clarified that, a domestic company that has completed the overseas offering and listing upon implementation of the Overseas Listing Trial Measures shall be regarded as an existing company, and is not required to file with the CSRC until its follow-on refinancing or the occurrence of other filing matters.

On February 24, 2023, the CSRC, jointly with other relevant governmental authorities, promulgated the revised Provisions on Strengthening Confidentiality and Archives Management of Overseas Securities Issuance and Listing by Domestic Enterprises, or the Confidentiality and Archives Management Provisions, which came into effect on March 31, 2023. According to the Confidentiality and Archives Management Provisions, in the overseas offering and listing by domestic companies, directly or indirectly, such domestic companies, as well as the securities companies and securities service agencies providing relevant services, shall strictly abide the relevant laws and regulations, and the Confidentiality and Archives Management Provisions. If a domestic company provides or publicly discloses, either directly or through its overseas listed entity, to entities and individuals such as securities companies, securities service agencies and overseas regulatory authorities, the documents and materials which contain state secrets or government work secrets, such domestic company shall obtain the approval from competent governmental authorities, and file with the secrecy administrative department at the same level with the approving governmental authority.

In addition, we cannot assure you that any new rules or regulations promulgated in the future will not impose additional requirements on us. If it is determined in the future that approval or filing from any regulatory authorities or other procedures, including the cybersecurity review under the Cybersecurity Review Measures, are required for our offshore offerings, it is uncertain whether we can or how long it will take us to obtain such approval or complete such filing procedures and any such approval or filing could be rescinded or rejected. Any failure to obtain or delay in obtaining such approval or completing such filing procedures for our offshore offerings, or a rescission of any such approval or filing if obtained by us, may subject us to sanctions by relevant regulatory authorities. These regulatory authorities may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operating privileges in China, delay or restrict the repatriation of the proceeds from our offshore offerings into China or take other actions that could materially and adversely affect our business, financial condition, results of operations, and prospects, as well as the trading price of our listed securities. These regulatory authorities also may take actions requiring us, or making it advisable for us, to halt our offshore offerings before settlement and delivery of the shares offered. Consequently, if investors engage in market trading or other activities in anticipation of and prior to settlement and delivery, they do so at the risk that settlement and delivery may not occur. In addition, if any regulatory authorities later promulgate new rules or explanations requiring that we obtain their approvals or accomplish the required filing or other regulatory procedures for our prior offshore offerings, we may be unable to obtain a waiver of such approval requirements, if and when procedures are established to obtain such a waiver. Any uncertainties or negative publicity regarding such approval requirement could materially and adversely affect our business, prospects, financial condition, reputation, and the trading price of our listed securities.

Uncertainties with respect to the PRC legal system could materially and adversely affect us.

The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investments in China. However, China has not developed a fully integrated legal system, and recently enacted laws and regulations may not sufficiently cover all aspects of economic activities in China. Since these laws and regulations are relatively new and may be amended from time to time, and the PRC legal system continues to rapidly evolve, and because of the limited number of published decisions and the nonbinding nature of such decisions, and because the laws and regulations often give the relevant regulator significant discretion in how to enforce them, the interpretations of many laws, regulations and rules may not be uniform and enforcement of these laws, regulations and rules involves uncertainties. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or tort claims. Besides, the PRC is geographically large and divided into various provinces and municipalities and, as such, different laws, rules, regulations and policies may have different and varying applications and interpretations in different parts of the PRC. Legislation or regulations, particularly in local applications, may be enacted without sufficient prior notice or announcement to the public. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions or threats in attempts to extract payments or benefits from us. Furthermore, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis, or at all, and may have a retroactive effect. As a result, we may not be aware of our violation of any of these policies and rules until sometime after the violation. Agreements that are governed by PRC laws may be more difficult to enforce by legal or arbitral proceedings in the PRC than that in other countries with different legal systems. In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention.

The ability of U.S. authorities to bring actions for violations of U.S. securities law and regulations against us, our directors or executive officers may be limited. Therefore, you may not be afforded the same protection as provided to investors in U.S. domestic companies.

The SEC, the U.S. Department of Justice, or the DOJ, and other U.S. authorities often have substantial difficulties in bringing and enforcing actions against non-U.S. companies and non-U.S. persons. Due to jurisdictional limitations, matters of comity and various other factors, the SEC, the DOJ and other U.S. authorities may be limited in their ability to pursue bad actors, including in instances of fraud, in emerging markets such as China. We conduct our operations mainly in China and our assets are mainly located in China. In addition, a majority of our directors and executive officers reside within China. There are significant legal and other obstacles for U.S. authorities to obtain information needed for investigations or litigation against us or our directors or executive officers in case we or any of these individuals engage in fraud or other wrongdoing. In addition, local authorities in China may be constrained in their ability to assist U.S. authorities and overseas investors in connection with legal proceedings. As a result, if we, our directors or executive officers commit any securities law violation, fraud or other financial misconduct, the U.S. authorities may not be able to conduct effective investigations or bring and enforce actions against us, our directors, executive officers or other gatekeepers. Therefore, you may not be able to enjoy the same protection provided by various U.S. authorities as it is provided to investors in U.S. domestic companies.

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 mainly 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 China's economic, political or social conditions or government policies could have a material and adverse effect on our business, financial condition and results of operations.

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, social 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 "—General 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, as I-Mab does not meet all of the above conditions and given that neither I-Mab nor any of its PRC subsidiaries has received any notice from the PRC tax authorities confirming, directly or indirectly, that I-Mab is a PRC resident enterprise for PRC tax income purposes as of the date of this annual report, 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"), the 2020 Share Incentive Plan (the "2020 Plan"), the 2021 Share Incentive Plan (the "2021 Plan") and the 2022 Share Incentive Plan (the "2022 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 March 31, 2023, the awards that had been granted to our directors, officers, employees and consultants and remained outstanding included (i) options to purchase an aggregate of 1,748,628 ordinary shares, 1,354,384 ordinary shares, 72,000 ordinary shares, 2,586,302 ordinary shares, 4,142,040 ordinary shares, and 6,672,944 ordinary shares under the 2017 Plan, the 2018 Plan, the 2019 Plan, the 2020 Plan, the 2021 Plan and the 2022 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 808,792 ordinary shares under the 2020 Plan, an aggregate of 1,752,194 ordinary shares under the 2021 Plan and an aggregate of 4,883,452 ordinary shares under the 2022 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—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 and was revised in 2022, requires that the anti-monopoly enforcement body of the State Council must be notified of transactions which are deemed concentrations (i) reaching the standard for notification as prescribed for by the State Council, or (ii) not reaching the standard for notification but proved by evidence that such concentrations will or may preclude or restrict competition and thus required by the anti-monopoly enforcement body of the State Council to undertake the notification, 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 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 can only use its capital pursuant to the principle of authenticity and self-use within its business scope. The capital of a foreign-invested enterprise cannot 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 unless expressly permitted in the business license. 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 Bulletin 7, 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: (i) whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; (ii) 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; (iii) 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; (iv) the duration of existence of the shareholders, business model and organizational structure of the overseas enterprise; (v) the income tax payable overseas for the transaction of indirect transfer of PRC taxable assets; (vi) the replicability of the transaction by direct transfer of PRC taxable assets; and (vii) 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.

For the period from January 1, 2022 to the date of this annual report, the trading price of our ADSs ranged from US$2.73 to US$47.75 per ADS. 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.

Our board of directors has historically authorized several share repurchase programs, pursuant to which we were authorized to repurchase our own ordinary shares, in the form of ADSs, with an aggregate value of up to certain amount during certain period. We implemented share repurchases pursuant to those authorized share repurchase programs from time to time. Our board of directors will review the implementation of share repurchases periodically and may authorize adjustment of its terms and size. In addition, certain senior management members and executive personnel also executed share purchases from the open market in the first quarter of 2022. For details of the purchase of equity securities by us and affiliated purchasers, see "Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers." The timing and dollar amount of share repurchase and share purchase transactions could affect the price of our ADSs and increase volatility. Nevertheless, there can be no assurance that any of our share repurchase program will be fully consummated or that such share repurchase program could enhance long-term shareholder value.

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. 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 (File 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. On March 31, 2022, we filed another prospectus supplement as part of a registration statement on Form F-3 (File No. 333-252793), under which the selling shareholders identified therein may offer, from time to time, up to 37,749,951 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, 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.

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 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. Additionally, our home country practices provide that shareholder approval may not be required when a plan or other equity compensation arrangement is established or materially amended and that we are not required to hold an annual general meeting of shareholders no later than one year after the end of its fiscal year-end. As we have chosen, or may from time to time to choose, to follow home country practice exemptions with respect to certain corporate matters, such as the ones mentioned above, 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. See also "Item 16G. Corporate Governance."

We believe that we were a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for the taxable year ended December 31, 2022, 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. Based upon the nature and composition of our assets (in particular, the retention of substantial amounts of cash and investments), and the market price of our ADSs, we believe that we were a PFIC for the taxable year ended December 31, 2022 and we will likely be a PFIC for our current taxable year unless the market price of our ADSs increases and/or we invest a substantial amount of the cash and other passive assets we hold in assets that produce or are held for the production of active income.

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") will generally be subject to reporting requirements and may incur significantly increased United States 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 United States federal income tax rules and such U.S. 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, unless we were to cease to be a PFIC and the U.S. Holder were to make a "deemed sale" election with respect to the ADSs or ordinary shares. For more information see "Item 10. Additional Information—E. Taxation—United States Federal Income Tax Considerations" and "Item 10. Additional Information—E. Taxation—United States Federal Income Tax Considerations—Passive Foreign Investment Company Rules."

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. We were an "emerging growth company" as defined in the U.S. Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we historically took advantage of certain exemptions from various requirements applicable to other public companies that are not emerging growth companies including, most significantly, 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.

As we no longer qualify as an emerging growth company, we are no longer able to take advantage of any reduced disclosure and other requirements that are available to emerging growth companies. 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 invest in a comprehensive biologics manufacturing facility in Hangzhou, China (the "Hangzhou Facility") as part of our strategic plan to become a specialty biopharma company. The construction of the Hangzhou Facility commenced in April 2021. The Hangzhou Facility has established a pilot capacity of two production lines (one line configured with 2 x 2,000L and the other line with 1 x 2,000L). The project has been 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, 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. I-Mab Hangzhou became an affiliate of our company on the closing date. On July 16, 2022, I-Mab Hangzhou entered into a definitive financing agreement with a group of domestic investors in China to raise approximately US$46 million (in RMB equivalent). Upon closing of the financing, we, through our wholly-owned subsidiary, will remain the largest shareholder. Upon the occurrence of certain triggering events as specified in the shareholders agreement among I-Mab Hangzhou, we, through our wholly-owned subsidiary, and other domestic investors, including, but not limited to, I-Mab Hangzhou's failure to accomplish certain public offering condition, we may be obligated to repurchase the equity held by other domestic investors in cash or in our securities in the period beyond 12 months. See Note 10 to our consolidated financial statements included elsewhere in this annual report for additional information of our investment in I-Mab Hangzhou.

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. In August 2022, we and AbbVie Global Enterprises Ltd., the assignee of AbbVie, entered into an amendment to the original collaboration agreement. Pursuant to the currently effective collaboration agreement, as amended, the parties are collaborating on the global development of anti-CD47 antibody therapy. As of the date of this annual report, AbbVie has paid us an upfront payment of US$180 million and milestone payment of US$20 million, and we will be eligible to receive, and AbbVie and its assignee will pay, up to US$1.295 billion in the development, regulatory and sales milestone payments, and the tiered royalties at rates from mid-to-high single digit percentages on global net sales outside of Greater China for certain new anti-CD47 antibodies currently in development, or the original milestone payments and tiered royalties previously disclosed in our annual report in Form 20-F for the fiscal year 2021 for other licensed products. We have the exclusive right to develop and commercialize all licensed products under the amended collaboration agreement in Greater China. AbbVie discontinued the global Phase 1b study of lemzoparlimab combination therapy with AZA and venetoclax, in patients with MDS and AML, and a Phase 1b study of lemzoparlimab in patients with relapsed/refractory multiple myeloma. These discontinuations were not related to any specific or unexpected safety concerns.

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, which were fully exercised in 2021 and further generated proceeds of approximately US$104.5 million.

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 (File 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. On March 31, 2022, we filed another prospectus supplement as part of a registration statement on Form F-3 (File No. 333-252793), under which the selling shareholders identified therein may offer, from time to time, up to 37,749,951 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.

On July 27, 2021, our board of directors approved a preliminary proposal for the potential dual listing of our newly issued shares on the Science and Technology Innovation Board of the Shanghai Stock Exchange (the "STAR Board"). Our board also authorized certain officers to execute the Listing Tutoring Agreement between us and the Sponsor China International Capital Corporation Limited (the "Tutoring Agreement"). The completion of the proposed dual listing on the STAR Board is conditional upon and subject to, among other things, market conditions, further approval of our board of directors and potentially of our shareholders at a general meeting of our company, and the obtaining of the necessary regulatory approvals.

In December 2021, our board of directors approved a motion to pursue the listing of our ordinary shares on The Main Board of The Stock Exchange of Hong Kong Limited (the "Hong Kong Dual Listing"). The board also authorized our senior management to proceed with the relevant preparatory work and undertake the necessary procedures to complete the Hong Kong Dual Listing. The Hong Kong Dual Listing is conditional upon and subject to, among other things, market conditions, further approval of the Board, and the obtaining of the necessary regulatory approvals.

Our principal executive offices are located at 55th Floor, New Bund Center, 555 West Haiyang 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

In 2022, we faced a series of risks, including macroeconomic and geopolitical headwinds, which prompted us to re-position our overall business in response to these challenges, while focusing on re-prioritizing the pipeline development to deliver on key clinical milestones. These measures resulted in a streamlined workforce and R&D activities focusing on five key clinical assets, significantly reducing the cash burn rate in 2022 and beyond. Today, the risks imposed by the HFCAA and the COVID-19 pandemic are largely mitigated. Collectively, we are now in a strong position to continue to deliver the expected key catalysts and value through pipeline progress and global partnerships with a more prudent expenditure strategy to support our key business operations for the next three years.

More specifically, we made significant progress in our pipeline development by focusing on five key clinical assets: eftansomatropin alfa, felzartamab, lemzoparlimab, uliledlimab, and givastomig (TJ-CD4B). The major achievements in 2022 included: (1) positive Phase 2 data readout for lemzoparlimab and regulatory approval to initiate a Phase 3 clinical trial in China; (2) positive Phase 2 data readout for uliledlimab - an encouraging clinical dataset for CD73 and PD-1 combination therapy in advanced non-small cell lung cancer (NSCLC) to date, which is enabled by CD73 expression as a predictive biomarker. The clinical development plan is being finalized to initiate a biomarker-guided pivotal trial in the second half of 2023 in advanced NSCLC. In addition, we expect that the recent Phase 2 data could contribute to the ongoing discussions for a potential global partnership; (3) encouraging Phase 1 data for givastomig, which will potentially enable the initiation of a Phase 2 trial in the second half of 2023, and a potential global partnership; and (4) significant progress on eftansomatropin alfa and felzartamab, leading to Phase 3 data readout expected in the second half of 2023 and potential NDA submission in China by the end of 2023 or early 2024 for eftansomatropin alfa, and at a later time for felzartamab.

The five prioritized clinical assets include three Phase 3 assets (eftansomatropin alfa, felzartamab and lemzoparlimab), one end-of-phase 2 (EOP2) asset (uliledlimab) and one Phase 1 asset (givastomig). As the studies progress, we expect to have two potential near-term NDA submissions in China (by the end of 2023 or early 2024 for eftansomatropin alfa and at a later time for felzartamab), two key assets entering into Phase 3 or pivotal trials in China (lemzoparlimab for myelodysplastic syndromes (MDS) in Phase 3 and uliledlimab for NSCLC in a pivotal clinical trial) and one asset entering into Phase 2 (givastomig) in 2023.

As of December 31, 2022, we had a total cash position, consisting of cash, cash equivalents, restricted cash and short-term investments, of RMB3.5 billion (US$514.2 million), which we estimate to be sufficient to fund our key business operations for over three years.

Our Drug Pipeline

Our innovative and advanced drug pipeline is led by five key clinical assets, followed by the next-generation bi-specific antibody assets. The section below describes the development status of the key clinical assets and selected pre-clinical assets.

Five Key Clinical Assets

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

Summary

Eftansomatropin alfa is a differentiated long-acting recombinant human growth hormone (rhGH) developed for pediatric growth hormone deficiency (PGHD), being the only rhGH in its proprietary fusion protein format and is not chemically linked with PEG or other linkers. Its safety, tolerability, and efficacy have been well demonstrated in Phase 1 and Phase 2 clinical trials. We are currently progressing towards the end of a Phase 3 registrational trial (“TALLER”) of eftansomatropin alfa as a weekly treatment for PGHD patients in China, with plans to submit an NDA by the end of 2023 or early 2024. We obtained the rights from Genexine for the development, manufacturing and commercialization of eftansomatropin alfa in China. In November 2021, we entered into a strategic commercial partnership with Jumpcan, a leading domestic pharmaceutical company specializing in and committed to pediatric medicines, to accelerate the commercialization of eftansomatropin alfa.

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 kilodaltons) is expected to reduce renal clearance.

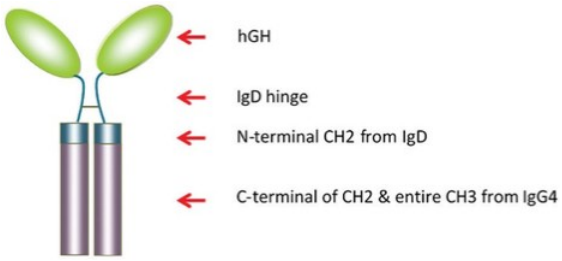


Figure: Schematic presentation of the structure of eftansomatropin alfa. CH2 & CH3: Constant regions 2 & 3 of antibody heavy chains, respectively; HGH: human growth hormone. (Source: Genexine)

Advantages of Eftansomatropin alfa

We believe that eftansomatropin alfa has the following advantages: (1) when compared with 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.

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 the 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 in Healthy Adult Subjects

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

The Phase 2 trial in PGHD was a randomized, open-label, active-controlled study to assess the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of weekly and twice-monthly doses of eftansomatropin alfa, as compared with a daily injection of Genotropin, the current standard of care for PGHD. 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.

Data from the trial showed that 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. In an extension study, 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 the patients who received eftansomatropin alfa throughout or in subjects who switched from the Genotropin cohort. The tolerability of eftansomatropin alfa was consistent with the known properties of marketed products.

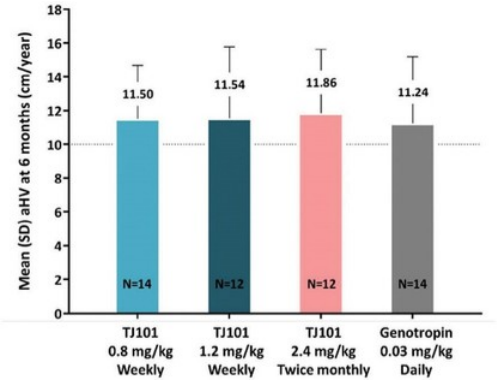


Figure: The aHV at six months indicated comparable growth rates between all doses of eftansomatropin alfa (both weekly and twice-monthly treatment) and the active comparator, Genotropin. (Source: Genexine)

Registrational Phase 3 Clinical Trial

The registrational Phase 3 trial of eftansomatropin alfa in PGHD ("TALLER") is on track in China. In May 2022, we announced the completion of patient enrollment in the TALLER study for treatment of PGHD. TALLER is a multi-center, randomized, open-label, active-controlled clinical study designed to assess the efficacy, safety, and pharmacokinetics of eftansomatropin alfa in PGHD (NCT04633057). The primary objective is to demonstrate non-inferiority of 1.2 mg/kg/week of eftansomatropin alfa administered SC, compared with the active control Norditropin, a daily rhGH marketed in China. Following the completion of the patient enrollment, the final dataset from the TALLER study is anticipated in the second half of 2023, which is expected to be followed by an NDA submission by the end of 2023 or early 2024.

In November 2021, we announced a strategic commercial partnership with Jumpcan, a leading domestic pharmaceutical company specializing in and committed to pediatric medicines, to accelerate the commercialization of eftansomatropin alfa. We will be the marketing authorization holder (MAH) of the product and supply the product at an agreed cost to Jumpcan. Jumpcan will be responsible for commercializing the product and developing new indications in collaboration with us in mainland China. Jumpcan has made an upfront payment to us of RMB224 million. Upon achievement of development, registration, and sales milestones, certain milestone payments of up to RMB1.79 billion will be made, with total non-royalty payments up to RMB2.02 billion. In addition, I-Mab and Jumpcan will share profits generated from the commercialization of the product in mainland China on a 50/50 basis, pursuant to which we will be entitled to receive tiered low double-digit royalties on net sales. This partnership deal represents one of the largest in China's biopharma market to date. Both companies have been working together to prepare for the future product launch of eftansomatropin alfa in China.

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

Summary

Felzartamab is a differentiated CD38 antibody for the treatment of relapsed and refractory multiple myeloma (MM) and potentially autoantibody-mediated autoimmune diseases. We obtained the rights from MorphoSys to develop, manufacture, and commercialize felzartamab in Greater China. Clinical data available from MorphoSys and I-Mab confirmed the advantages of felzartamab in its lower infusion-related reaction rates and a shorter infusion time, making felzartamab's use in an out-patient clinic setting possible, along with other potential benefits. Felzartamab required only a short infusion time of 30 minutes (as subsequent infusions) to two hours (as an initial infusion), compared with 3.5 to 6.5 hours for the currently marketed CD38 antibody. Moreover, the IRR of felzartamab was 7%, compared with 48% for the currently marketed CD38 antibody.

The third-line (3L) MM registrational trial of felzartamab has been completed, and the topline data have met the preset primary and secondary endpoints. The clinical data confirmed the clinical advantages of felzartamab in terms of aforementioned lower infusion-related reaction rate and shorter infusion time, which has made it feasible and practical for its use in an out-patient clinic setting. We are on track with the registrational trial of felzartamab in combination with lenalidomide and dexamethasone as a second-line (2L) MM treatment. The topline data package, when fully matured, is expected to support our NDA submission.

In January 2022, we signed a partnership agreement with the government of Qiantang District of Hangzhou in China to manufacture felzartamab locally to accelerate our commercialization of felzartamab. The local manufacturing plan is expected to significantly reduce the cost of goods and render felzartamab more commercially competitive.

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.

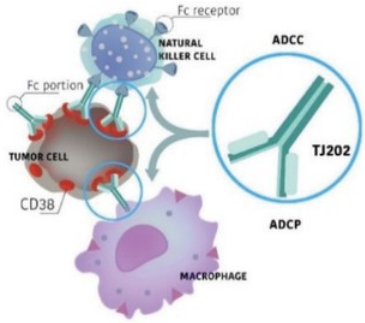


Figure: Felzartamab kills CD38-bearing tumor cells by inducing ADCC and ADCP.

Advantages of Felzartamab

We believe that felzartamab has the following advantages compared with the currently marketed CD38 antibody: (1) felzartamab demonstrated a lower infusion-related reaction rate and shorter infusion time, which could make it possible for use in an out-patient clinic setting; and (2) felzartamab treatment does not down-regulate CD38 expression on the surface of bone marrow myeloma cells *in vitro,* maintaining the sensitivity of malignant myeloma cells to repeated felzartamab treatments.

Summary of Clinical Results

Phase 1/2a Trial in patients with r/r MM by MorphoSys

A Phase 1/2a, open-label, multicenter, dose-escalation study in adult patients with relapsed or refractory MM was conducted by MorphoSys in Austria and Germany. The results concluded that felzartamab was well-tolerated as a single agent and in combination with dexamethasone (DEX), pomalidomide (POM)/DEX, or lenalidomide (LEN)/DEX. Felzartamab was administered as a two-hour IV infusion at the first dose, and infusion time could be reduced to as short as 30 minutes at subsequent doses without obvious safety concerns. The maximal tolerable dose (MTD) of felzartamab was not reached.

Preliminary efficacy results were based on 56 patients from three groups treated with felzartamab combination therapies. 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 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.

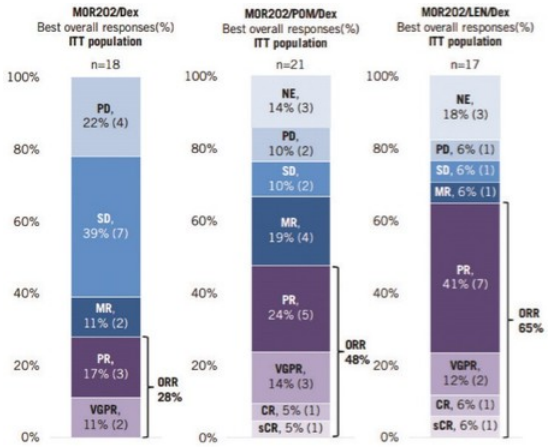


Figure: Best overall response and ORR. Patients were treated with felzartamab in combination with a low dose of DEX (40 mg for 75 years old and younger, or 20 mg for patients over 75 years old), POM (4 mg)/Dex, or LEN (25 mg)/Dex. Dex: dexamethasone; POM: pomalidomide; LEN: lenalidomide; ITT: intent 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)

Clinical Development Status

The third-line MM registrational trial has been completed, and the topline data have met the preset primary and secondary endpoints. More importantly, the clinical data have confirmed the clinical advantages of felzartamab in terms of lower infusion-related reaction rate and shorter infusion time, which makes it feasible and practical for its use in an out-patient clinic setting.

For the registrational trial of felzartamab and lenalidomide/dexamethasone as a 2L MM treatment, we completed patient enrollment in September 2021. The topline data package, when fully matured in 2023, is expected to support an NDA submission.

We plan to position felzartamab as the first and only locally manufactured CD38 antibody in China to facilitate its potential NDA submission and to be more commercially competitive. With the support of the local government in China, our plan is to manufacture felzartamab locally for increased affordability and commercial competitiveness. In parallel, we are exploring commercial partnerships in China for felzartamab, with the goal of enabling us to quickly gain and scale up market share for felzartamab without investing significant resources in our own commercialization capabilities.

Lemzoparlimab (TJC4): A Novel CD47 Antibody for Immuno-Oncology with First-in-Class Potential in China

Summary

Lemzoparlimab is a fully human CD47 monoclonal antibody discovered and developed internally by our company for cancer immunotherapy. CD47 has emerged as one of the most promising immuno-oncology targets in recent years. Lemzoparlimab is among the global front-runners after magrolimab. As one of the most promising drug classes in immuno-oncology, the development of CD47 antibodies is primarily hampered by their on-target binding to red blood cells (RBCs). Therefore, various CD47 antibodies in their clinical development are found to be susceptible to severe anemia and other hematologic side effects. As a result, many CD47 antibody programs have been either terminated in early clinical trials or faced drug safety challenges in clinical trials. For example, in January 2022, Gilead announced that the U.S. FDA had placed a partial clinical hold on studies evaluating the combination of magrolimab plus azacitidine due to an apparent imbalance in investigator-reported suspected unexpected serious adverse reactions (SUSARs) between study arms, which was later lifted for the study in acute myeloid leukemia (AML)/myelodysplastic syndromes (MDS) but remained in diffuse large B cell lymphoma (DLBCL) and multiple myeloma (MM).

Lemzoparlimab is a novel CD47 antibody by design. It was originally selected from antibody screen campaigns designed to identify CD47 antibody leads with minimal binding to RBCs while maintaining strong binding to tumor cells. In terms of its differentiation in drug safety, the preclinical, Phase 1, and Phase 2 clinical studies we conducted so far have supported a good safety profile without the need for a priming dosing regimen. In terms of treatment efficacy, our Phase 1 and Phase 2 clinical trials have demonstrated encouraging efficacy signals, mostly in hematologic malignancies. In September 2022, we presented the Phase 2 clinical data (NCT04202003) of lemzoparlimab in combination with AZA in patients with newly diagnosed higher risk myelodysplastic syndrome (HR-MDS) at the European Society for Medical Oncology (ESMO) Congress. Furthermore, we will provide the updated data from the Phase 2 MDS trial in the second half of 2023.

Our clinical development plan is aimed to prioritize hematologic malignancies with the first-line (1L) MDS combination therapy with azacitidine (AZA) as a lead indication. A Phase 3 clinical trial for 1L MDS combination therapy has been initiated in April 2023. Additionally, we are progressing towards the end of a Phase 2 AML trial in combination with AZA, and continue to evaluate lemzoparlimab in combination with rituximab in patients with non-Hodgkin's lymphoma (NHL) and with PD-1 therapy in patients with selected solid tumors.

Molecular Differentiation of Lemzoparlimab

Lemzoparlimab exhibits high-affinity binding to human CD47 protein and CD47-expressing tumor cells at the nanomolar level and effectively blocks the 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 anti-tumor activity in the HL-60 cell line in leukemia and Raji xenograft models (see Figure B below). Moreover, when combined with rituximab, lemzoparlimab exhibited a markedly enhanced inhibition of tumor growth in a diffuse large B cell lymphoma (DLBCL) animal model through the synergistic effect of both agents (see Figure C below).

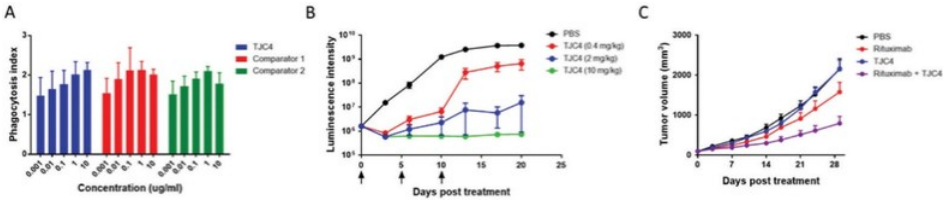


Figure: In vitro and in vivo anti-tumor activity of lemzoparlimab (TJC4). (A) In vitro phagocytosis of Raji cells by primary human macrophages in the presence of different doses of lemzoparlimab or comparator CD47 antibodies. (B) In vivo anti-tumor activity of lemzoparlimab mono-treatment in Raft xenograft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

The key differentiation of lemzoparlimab is its minimal binding to RBCs which is highlighted in a series of preclinical studies, thus potentially avoiding or minimizing inherent hematologic adverse effects typically seen in other CD47 antibodies in clinical trials. 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. The minimal binding of lemzoparlimab to RBCs was confirmed when compared with other CD47 antibodies across multiple concentrations in another experiment (see Figure B below).

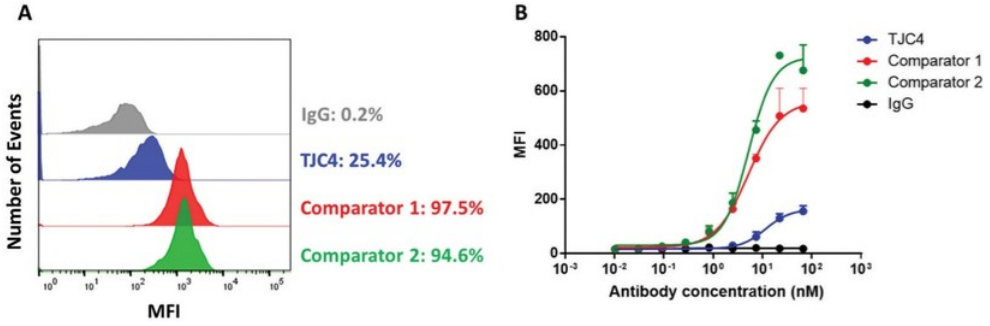


Figure: Binding of CD47 monoclonal antibodies to RBCs. (A) Representative graph of the staining of human RBCs with CD47 monoclonal antibodies or control IgG (1 µg/ml); (B) Dose dependent binding of CD47 monoclonal antibodies with human RBCs from different healthy donors (n = 3). MFI: mean fluorescence 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. In contrast, a comparator antibody caused significant hemagglutination starting at a concentration of 0.3 µg/ml.

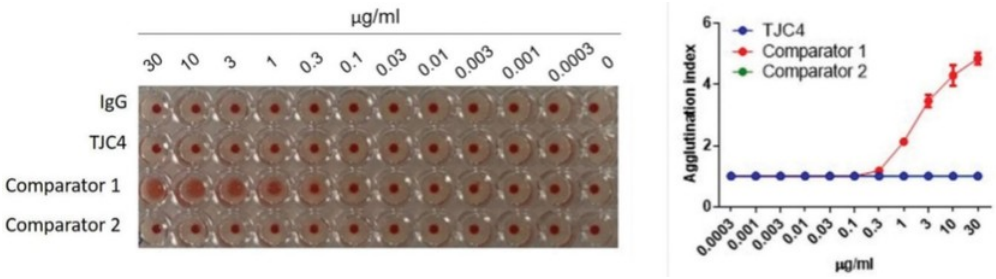


Figure: Hemagglutination by CD47 monoclonal antibodies. Left: representative graph of hemagglutination (haze appearance) or lack thereof (precipitate) by different concentrations of control IgG, lemzoparlimab (TJC4), and comparator antibodies. Right: quantification through an index determined by the 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). A following four-week GLP toxicology study further confirmed that lemzoparlimab treatment did not induce significant overall toxicologic changes. Only mild decreases in the number of RBCs, HGB, and hematocrit were found, which reached a nadir on Day 4 post-first administration and then gradually recovered to the normal range following administration. 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).

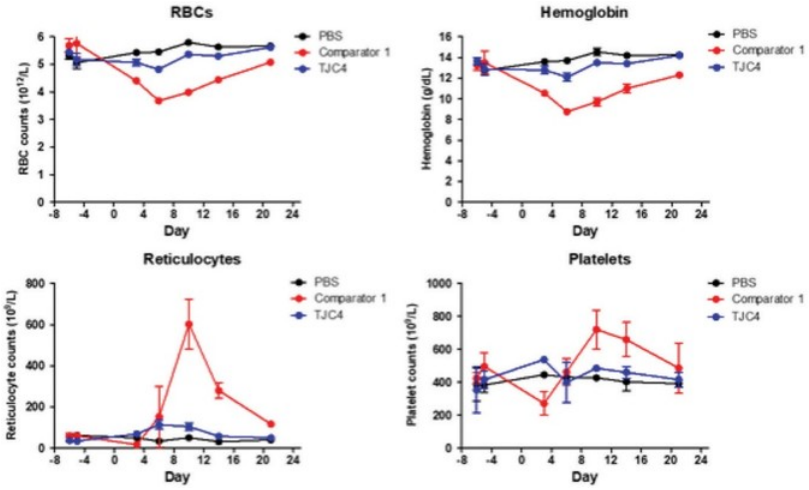


Figure: Hematological parameters in non-human primates treated with a single dose of CD47 antibodies. On Day 0, naive cynomolgus monkeys were IV injected with PBS control (n=2), lemzoparlimab (TJC4) (n=2, 10 mg/kg) or a comparator antibody (n=2, 10 mg/kg). Blood cells were counted twice before drug injection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

The Underlying Mechanism for Lemzoparlimab's Differentiation

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

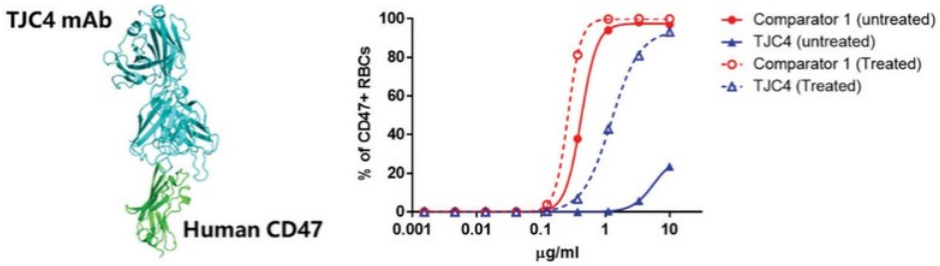


Figure: The left. Crystal structure of the complex of the Fab of lemzoparlimab (TJC4, Cyan) binding with the extracellular domain (ECD) of human CD47 (Green). The right. In a representative experiment, human RBCs were treated with PNGase for 1 hr, followed by the addition of lemzoparlimab (TJC4) ore 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.

In summary, the underlying mechanism is attributable to a unique binding site of lemzoparlimab or so-called glyco-epitope on RBCs. That is, the unique glycosylation integrated with the binding site of lemzoparlimab serves as a natural molecular barrier to prevent lemzoparlimab from engaging RBCs. Therefore, RBCs are only minimally accessible by lemzoparlimab. In contrast, the binding site on tumor cells does not have the same glycosylation pattern and is fully exposed to and accessible by lemzoparlimab. Therefore, lemzoparlimab can uniquely distinguish tumor cells from RBCs to avoid severe anemia that is commonly seen with other CD47 antibodies while retaining strong anti-tumor activity.

Amendment to the Global Partnership with AbbVie

In August 2022, we entered into an amendment with AbbVie Global Enterprises Ltd. (as assignee of AbbVie) to the original collaboration agreement (as amended, the "AbbVie Collaboration Agreement"). The parties are collaborating on the global development of certain new anti-CD47 antibodies under the AbbVie Collaboration Agreement. Accordingly, we will be eligible to receive, and AbbVie and its assignee will pay, up to US$1.295 billion in the development, regulatory and sales milestone payments, and the tiered royalties at rates from mid-to-high single digit percentages on global net sales outside of Greater China for the new anti-CD47 antibodies currently in development, or the original milestone payments and tiered royalties previously disclosed in our annual report in Form 20-F for the fiscal year 2021 for other licensed products. We have the exclusive right to develop and commercialize all licensed products under the AbbVie Collaboration Agreement in Greater China. Meanwhile AbbVie discontinued the global Phase 1b study of lemzoparlimab combination therapy with AZA and venetoclax, in patients with MDS and AML, and a Phase 1b study of lemzoparlimab in patients with relapsed/refractory multiple myeloma. These discontinuations were not related to any specific or unexpected safety concerns.

Summary of Clinical Results

Drug Safety

In terms of lemzoparlimab's safety profile, after the announcement of magrolimab's partial clinical hold in 2022, we conducted a systemic review of the safety data collected from nearly 200 patients, including solid tumors and hematologic malignancies treated in various combinations. The safety data from both the U.S. and China studies are consistent with our expected safety profile without the need of a priming dose regimen. As a result, there is no change in our strategy and plans for the development of lemzoparlimab.

For the studies in solid tumors and NHL in the U.S., lemzoparlimab was well tolerated up to 30 mg/kg on a weekly infusion schedule without priming dosing either in mono- or combination therapy. A 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 in the single-agent dose-escalation study in solid tumors and one Grade 3 TRAEs from the same patient, including pleural effusion, tachycardia, cough, pruritis, fatigue, rash, and dyspnea, at 20 mg/kg dose in a combination study with rituximab in NHL. No clinical or laboratory evidence of hemolytic anemia was observed throughout. The hematological data from both studies in solid tumors and NHL showed a transient reduction in the hemoglobin levels during the first cycle. The average drop was approximately 10% and was not dose-dependent. This finding is consistent with the results of preclinical GLP toxicity studies. None of the drug-related anemia reported was considered to be severe or hemolytic in nature.

For the Phase 2 clinical trial in AML/MDS, over 90 patients were dosed with lemzoparlimab at 30 mg/kg in combination with AZA in China. The safety data are being analyzed for a subsequent topline data release.

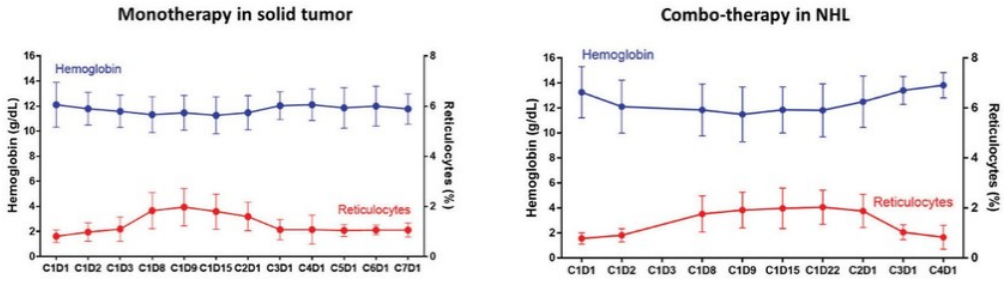


Figure: Time course of hemoglobulin level following lemzoparlimab treatment in phase 1 single-agent dose escalation study across all the cohorts (n=20) and phase 1b combination study with rituximab in NHL (n=9). Each cycle (C) is 21 days (D) for monotherapy and 28 days (D) for combination therapy. Mean+SD is shown.

Clinical Efficacy

Across multiple completed and ongoing clinical trials, encouraging efficacy signals were observed and described below.

For lemzoparlimab monotherapy in patients with solid tumors, one confirmed Partial Response (PR) was observed in the 30 mg/kg monotherapy cohort (1/3). 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 of 1 mg/kg, 10 mg/kg, and 30 mg/kg. Two patients with squamous cell carcinoma of the head and neck (SCCHN) and renal cell carcinoma (RCC), respectively, failed nivolumab and the other with ovarian cancer received no prior PD-(L)1 inhibitor treatment.

For lemzoparlimab combination therapy with rituximab in patients with NHL, we presented interim dose escalation data of lemzoparlimab in combination with rituximab in relapsed and refractory (r/r) NHL at the 2021 American Society of Hematology (ASH) Annual Meeting. The preliminary data were generated from nine patients with r/r NHL who received at least two prior lines of therapies, with a median of four lines. Safety findings of lemzoparlimab at doses of 20 mg/kg and 30 mg/kg weekly, without a priming dose, are consistent with what was observed at lower doses, and no dose-limiting toxicity (DLT) was observed. Positive clinical activity was observed in heavily pretreated patients who had progressed on prior anti-CD20 therapies. Among seven efficacy-evaluable patients, four achieved complete responses (CR) (1 transformed FL-DLBCL +3 FL), one partial response (PR) of FL were observed (ORR = 71%); two reported stable disease (SD), and the disease control rate (DCR) was 100%. Tumor shrinkage was observed in all evaluable patients. The median time to response was 50 days, and the response lasted from 61 to 236 days. A high level (80% and 90%) of intra-tumoral distribution measured by IHC of tumor biopsy was reached at 20 mg/kg and 30mg/kg weekly.

For lemzoparlimab combination therapy with AZA in patients with MDS, over 90 patients with newly diagnosed MDS and AML were dosed in the Phase 2 clinical trial of lemzoparlimab at 30 mg/kg in combination with AZA in China (NCT04202003). This patient cohort had a more severe disease at baseline due to disease conditions and clinical practice patterns in China. In September 2022, we announced encouraging data from this Phase 2 clinical trial in patients with newly diagnosed higher-risk myelodysplastic syndrome (HR-MDS), presented in an oral presentation at ESMO 2022. A total of 53 patients were enrolled as of March 31, 2022, receiving lemzoparlimab at a weekly dose of 30 mg/kg intravenously (IV) and AZA at 75 mg/m2 subcutaneously (SC) on Days 1–7 in a 28-day cycle. Top-line data showed that for patients who began treatments 6 months or longer prior to the analysis (n=15), the overall response rate (ORR) and complete response rate (CRR) were 86.7% and 40%, respectively. While the study enrolled more patients with worse baseline conditions due to underlying disease (74% of patients had grade ≥3 anemia, and 51% of patients had grade ≥3 thrombocytopenia), the results showed that lemzoparlimab combined with AZA was well-tolerated and the safety profile was comparable with that of AZA monotherapy. Updated results from the most recent data analysis of 62 patients in the study have demonstrated consistent clinical efficacy including ORR and CRR with no new safety signals identified. We plan to present the updated data at a major scientific meeting in the second half of 2023.

Clinical Development Plan

Leukemia. We are advancing our Phase 3 registrational trial of lemzoparlimab combination therapy for potential 1L treatment of newly diagnosed HR-MDS after approval by the CDE in September 2022. We presented the full dataset of our Phase 2 clinical trial in patients with newly diagnosed HR-MDS at the ESMO 2022 in September 2022 and expect to present the updated data readout of this study in the second half of 2023.

Lymphoma and Solid Tumors. We previously presented the encouraging clinical data at the 2021 American Society of Hematology (ASH) annual meeting for lemzoparlimab combination therapy with rituximab in patients with NHL. We continue to evaluate lemzoparlimab in combination with rituximab in patients with NHL and with PD-1 therapy in patients with selected solid tumors. More data will be reported as the studies progress.

Uliledlimab (TJD5): A Highly Differentiated CD73 Antibody for Solid Tumors

Summary

Uliledlimab is an internally discovered, highly differentiated CD73 neutralizing antibody. CD73 is a homodimeric enzyme widely expressed in multiple tumors and plays a critical role in the generation of adenosine to contribute to an immuno-suppressive tumor microenvironment. The key differentiation of uliledlimab, when compared to some of the other clinical-stage CD73 antibodies, is related to its novel epitope, which works through a unique intra-dimer binding mode, resulting in complete inhibition of the enzymatic activity and avoiding the aberrant pharmacological property known as the “hook effect.” In addition, 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. Preclinical studies have shown that uliledlimab could completely reverse the AMP-or tumor cell-mediated suppression of T cells *in vitro.* When combined with a PD-(L)1 antibody *in vivo,* uliledlimab exhibited a superior and synergistic inhibitory effect on tumor growth compared to PD-(L)1 monotherapy.

Uliledlimab is globally competitive and is among the front-runners after oleclumab, with significant progress made in its global clinical development. 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 combining with atezolizumab (Tecentriq ®) in patients with solid tumors. Topline results from this study showed that uliledlimab is safe and well-tolerated across all the dose cohorts evaluated. The data demonstrated a favorable linear PK and steep PK/PD relationship with complete receptor occupancy as expected based upon the normal dose-response property of uliledlimab without the hook effect. Furthermore, encouraging clinical efficacy signals from this study were observed in NSCLC and ovarian patients with higher CD73 and PD-L1 co-expression in the tumor, indicating a potential correlation between the clinical activity of uliledlimab and tumor CD73 expression as a potential predictive biomarker that warrants further investigation.

Based on the results of the Phase 1 study, we were able to determine the recommended phase 2 dose (RP2D) and further evaluated the efficacy and safety of uliledlimab in combination with checkpoint inhibitor in Stage IV NSCLC and other select tumor types in Phase 2 trials. The most encouraging results came from our Phase 2 trial of uliledlimab in combination with toripalimab (TUOYI®) in patients with Stage IV NSCLC. Since the initial presentation at the 2022 American Society of Clinical Oncology (ASCO) annual meeting, we have completed the enrollment of 70 patients in December 2022. Similar efficacy data in relation to CD73 expression were obtained with increased follow-up time in more patients, showing a consistent trend of efficacy signals with an overall ORR >30% in all patients and, noticeably, an ORR ~50% in CD73 high expression patients. The results have demonstrated that the higher clinical response of uliledlimab and PD-1 combination therapy correlates with high tumor CD73 expression in patients with advanced NSCLC. We plan to present the data at the ASCO 2023 annual meeting. With the availability of the new data, we have been actively discussing with potential global partners and aim to accelerate the ongoing business discussion for a potential global partnership.

Competitive Landscape

The most advanced CD73 antibody currently is oleclumab (MEDI-9447) from Medimmune/AstraZeneca, which has initiated a Phase 3, double-blinded, placebo-controlled, randomized study of durvalumab plus oleclumab in patients with locally advanced (Stage III), unresectable NSCLC who have not progressed following definitive, platinum-based concurrent chemoradiation therapy. Data from the COAST Phase 2 trial and NeoCOAST Phase 2 trials showed that the addition of oleclumab to durvalumab enhanced anti-tumor immune responses in patients with NSCLC. NZV-930 (from Novartis) and AK119 (from AkesoBio) were in Phase 1 clinical development for solid tumors. Arcus Biosciences had also reported promising results in their Phase 1b/2 trial of quemliclustat, a small molecule CD73 inhibitor, in combination with zimberelimab plus chemotherapy in patients with pancreatic cancer.

Molecular Differentiation 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 as a rate-limiting enzyme to generate adenosine. Thus, the CD73 antibody is expected to block adenosine generation more completely than other related targets. The key advantages of uliledlimab when compared with other CD73 antibodies or small molecule inhibitors can be summarized as follows: (1) uliledlimab exhibits a typical dose-response curve without the “hook effect” to achieve the 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.

Biochemically, 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. The recent structural data revealed by cryo-EM showed that uliledlimab binds to a unique epitope located at the C-terminus of CD73 dimer distinct from other CD73 antibodies, including oleclumab, all of which bind to the N-terminus of CD73. With this unique epitope, uliledlimab adopts a differentiated intra-dimer binding mode to prevent the conformational change of CD73 from inactive to the active form, resulting in the complete inhibition of CD73 enzymatic activity without causing a “hook effect.”

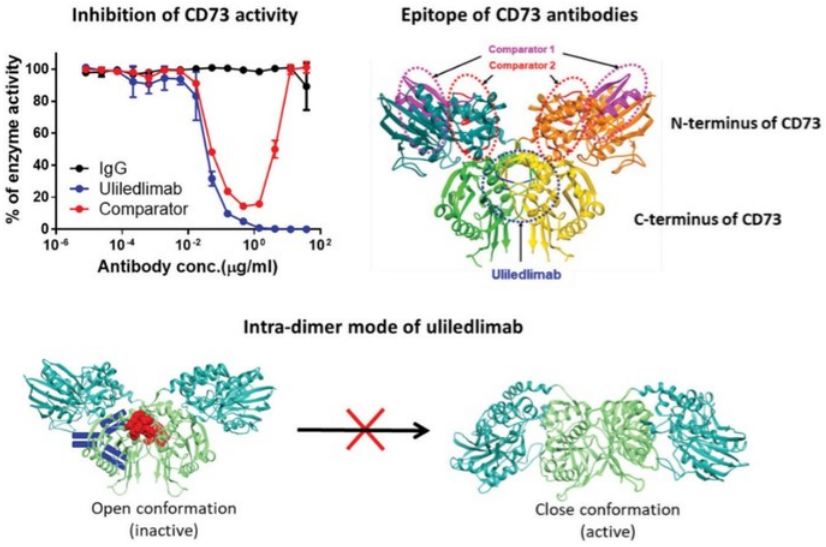


Figure: Inhibition of soluble CD73 enzymatic activity and the binding epitope of CD73 antibodies.

Immunologically, AMP inhibited interferon-gamma (IFN-γ) 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, the addition of uliledlimab restored T cell activity as measured by IFN-γ production in a concentration-dependent manner. In addition to the restoration of AMP-mediated T cell suppression, we found that uliledlimab treatment could activate human B cells, as evidenced by the up-regulation of activation markers CD69 and CD83, as well as antigen presentation markers CD86 and HLA-DR. Compared with T cells, the effects of uliledlimab on B cells were adenosine independent.

Consistent with the *in vitro* results, *in vivo* monotherapy of ulilediimab dose-dependently 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 antibodies, we evaluated the therapeutic effects of ulilediimab in combination with a PD-1 antibody in the MC38 model using CD73 humanized mouse and PD-L1 antibody in the A375 xenograft model, respectively. The combination treatments resulted in more potent inhibition of tumor growth than monotherapy of PD-(L)1 antibody or ulilediimab.

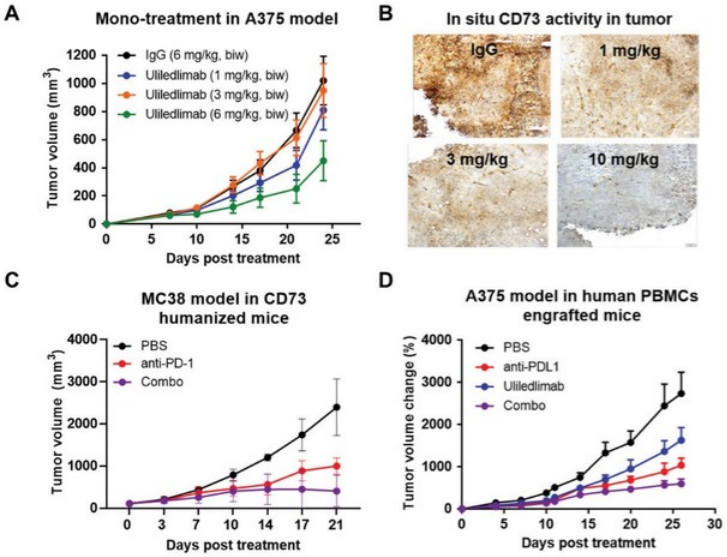


Figure: Inhibition of tumor growth and in situ CD73 activity by ulilediimab alone or in combination with a PD-1 or PD-L1 antibody.

Summary of Clinical Results

Phase 1 dose-escalation study in combination with atezolizumab

Data from the U.S. Phase 1 dose-escalation study of ulilediimab in combination with atezolizumab, which were presented at the 2021 ASCO annual meeting, showed that ulilediimab is safe and well-tolerated with no dose-limiting toxicity across all the dose cohorts in combination with atezolizumab. All treatment-related adverse events were either Grade 1 or Grade 2. Ulilediimab demonstrated a linear PK profile and reached full receptor occupancy on B cells at the middle and high dose levels with no “hook effect,” confirming a normal PK/PD relationship and sigmoid dose-activity response.

Patients who participated in the study had advanced cancers and had exhausted other cancer therapies. Among the 13 efficacy-evaluable patients dosed at 10 mg/kg or higher, three patients had complete or partial responses (ORR = 23%) and three had stable disease (DCR = 46%). The range of time on treatment for the six patients with a response and SD was from 187 to 485 days. The clinical activity was observed in both PD-(L)1 treatment naïve and refractory cancer patients, including one partial response patient who previously failed nivolumab. More importantly, all three responders were identified to exhibit higher co-expression of tumor CD73 and PD-L1 as compared to non-responders, indicating a correlation between higher CD73 expression and clinical activity of ulilediimab and a potential role of CD73 as a predictive biomarker to warrant further investigation.

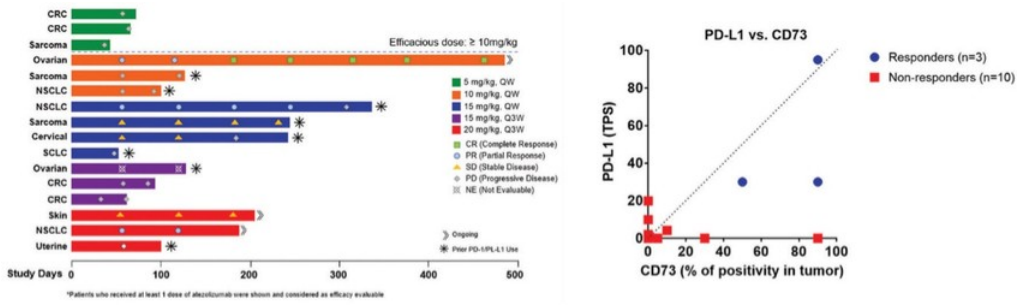


Figure: Treatment duration for the combination therapy of ulilediimab and atezolizumab. Baseline expression of PD-L1 and CD73 in the tumor as measured by immunohistochemistry (IHC) in responders (n=3) and non-responders (n=10).

Phase 2 clinical study of ulilediimab in combination with PD-1 antibody (toripalimab) in advanced NSCLC

In May 2022, we presented the preliminary clinical results of an ongoing phase 2 clinical study of ulilediimab in combination with toripalimab (TUOYI®) in patients with NSCLC at the 2022 ASCO annual meeting. The results are largely consistent with those observed in first-in-human Phase 1 clinical trial in relation to favorable safety, pharmacokinetics (PK), and pharmacodynamic (PD) profile of ulilediimab. Ulilediimab can be safely administered and well-tolerated up to the highest doses tested at 30 mg/kg Q3W, as a monotherapy and as a combination therapy with toripalimab with no dose limiting toxicity (DLT). Ulilediimab exhibited a linear PK profile at doses ≥ 5mg/kg and a dose-dependent receptor occupancy with no “hook effect” where the antibody loses its effectiveness at high concentrations.

As of December 2022, 70 patients had been enrolled in the same Phase 2 study of ulilediimab and PD-1 combination therapy in Stage IV NSCLC patients who were previously ineligible for standard-of-care treatment. In summary, the first data cutoff occurred in March 2022, among 19 efficacy evaluable patients, 5 partial responses (5 PR, overall response rate [ORR]=26%) and 9 stable disease (9 SD, disease control rate [DCR] =74%) were observed. Approximately 80% of patients showed low PD-L1 expression in baseline tumor samples (tumor proportion score [TPS] 1-49% or TPS<1%) who were considered less responsive to a PD-1 monotherapy as demonstrated in KEYNOTE-042 (ORR=16.9% for patients with PD-L1 TPS 1-49%). Notably, the clinical response observed in this patient cohort correlated with tumor CD73 expression. In a subgroup of 7 patients with high CD73 expression (≥35% expression level in tumor cells or immune cells), ORR (4 PRs) was 57% with 100% DCR (3 SDs) (Table 1).

Similar efficacy data were observed in August 2022 among 32 evaluable patients, and December 2022 among 45 evaluable patients, showing a consistent trend of efficacy signals with an overall ORR >30% in all patients and a higher clinical response demonstrated by ORR at approximately 50% in CD73 high expression patients. The efficacy data continue to mature for ORR and more importantly for PFS as the study approaches a closure in 2023. The results have demonstrated that the higher clinical response of ulilediimab and PD-1 combination therapy correlates with high tumor CD73 expression in patients with advanced NSCLC.

Table1. Correlation between CD73 expression and clinical response

	All patients (n=19)#	Patients with **CD73 high expression** (≥35%) (n=7)	Patients with **CD73 low expression** (<35%) (n=11)
ORR	**26% (5 PR)**	**57% (4 PR)**	**9% (1 PR)**
DCR	**74% (9 SD)**	**100% (3 SD)**	**55% (5 SD)**

 # CD73 expression for one patient is unknown.

Clinical Development Plan

Based on the role of CD73 as a predictive biomarker and encouraging clinical efficacy data based on approximately 70 advanced NSCLC patients, we plan to initiate a biomarker-guided pivotal study evaluating clinical efficacy of the combination of ulilediimab and a PD-1 antibody in Stage IV NSCLC patients in the second half of 2023. Another global study of ulilediimab in combination with a PD-1 antibody plus a chemotherapy in patients with advanced NSCLC is also planned in the second half of 2023. In parallel, a standardized companion CD73 diagnostic kit is being developed with WuXi Diagnostics to be employed in the planned studies.

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

Summary

Givastomig 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.

In collaboration with ABL Bio, we developed givastomig, also known as ABL111, which provides two key advantages over current CLDN18.2 antibodies and 4-1BB agonistic antibodies. Firstly, givastomig (also known as TJ033721) can bind to tumor cells even with low levels of CLDN18.2 expression, making it more suitable for a broader patient population with various expression levels of CLND18.2. Secondly, only upon tumor cell engagement by givastomig are T cells stimulated by the 4-1BB antibody moiety, making the 4-1BB antibody arm only active at the tumor site. This localized T cell activation is conditional upon tumor engagement and is expected to exert strong anti-tumor activity while minimizing systemic side effects such as liver toxicity seen with 4-1BB agents in previous clinical studies.

In November 2021, we and ABL Bio jointly announced the pharmacodynamic data and safety of givastomig/ABL111 in animal models and cell cultures at the 2021 SITC annual meeting. The data are summarized as below: (1) Potent anti-tumor activity was observed with the proliferation of immune cells within the tumor microenvironment (TME) as well as an increase in memory T cells in the peripheral blood, suggesting long-term immunity against the tumor; (2) Givastomig was well tolerated in non-human primates and did not induce a systemic immune response or liver toxicity up to levels of 100 mg/kg; and (3) Activation of immune pathways by givastomig was demonstrated by a pro-inflammatory profile and increased gamma interferon-regulated gene expression in primary human CD8+ T cells co-cultured with CLDN18.2 expressing cells. In March 2022, we announced that the U.S. FDA granted givastomig Orphan Drug Designation (ODD) for the treatment of gastric cancer, including gastroesophageal junction carcinoma.

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 a combination of chemotherapy, targeted therapies, and now, immune therapies. However, the clinical benefit remains modest with the current therapies. Therefore, there is a significant unmet medical need for GC treatment. CLDN18.2 has been identified as a new GC tumor marker. Clinical data showed that over 70% of GC patients in Asia and Europe are CLDN18.2 positive. There are multiple new modalities targeting CLDN18.2 being evaluated with some success: (1) Monoclonal antibodies. Zolbetuximab is a CLDN18.2 monoclonal antibody acting through ADCC and CDC. It has demonstrated clinical efficacy (and thus target validation) when combined with standard chemotherapy in early clinical trials. However, the efficacy of zolbetuximab is limited to CLDN18.2 high-expressing tumors (expression cutoff 75%); and (2) Antibody-drug conjugates (ADCs), CAR-Ts, and CD3-based bispecific T cell engagers. Most of these studies are either at pre-clinical stage or early clinical development. Despite their anticipated high efficacy, these treatment modalities suffer from significant safety concerns associated with their drug toxicity or immunotoxicity.

Advantages of Givastomig

Givastomig is a novel bi-specific antibody, with one arm targeting Claudin18.2 (CLDN18.2) and the other targeting 4-1BB through conditional or local activation. The key differentiation of givastomig is two-fold. Firstly, it binds to tumors with a wide range of CLDN18.2 expression levels, including lower expression, as demonstrated in pre-clinical animal models. This feature makes givastomig unique among the CLDN18.2-targeted agents, including ADC and zolbetuximab, whose anti-tumor activity is rather limited by higher CLDN18.2 expression in the tumor. Secondly, the 4-1BB arm of givastomig is designed to function upon local tumor engagement as a mechanism of conditional activation. This feature makes givastomig a unique T cell activator only localized at the tumor site without systemic toxicities, e.g. liver toxicity and systemic cytokine release, that are typically associated with 4-1BB. In addition, givastomig exhibits less gastrointestinal (GI) toxicity than what is commonly observed for other CLDN18.2 targeted therapeutics. As such, givastomig is clinically positioned to target: (1) gastric and pancreatic cancers that have lower CLDN18.2 expression and are considered not eligible for treatment by zolbetuximab or CLDN18.2 ADC; and (2) gastric and pancreatic cancers with high CLDN18.2 expression with more favorable safety profile over other CLDN18.2 therapeutic modalities.

Moreover, unlike previous generations of 4-1BB agonist antibodies with hepatotoxicity issues, givastomig binds to a distinct 4-1BB epitope that only triggers 4-1BB signaling upon CLDN18.2 target engagement 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. If proven in the clinic, these properties enable givastomig to be highly differentiated from other CLDN18.2-based compounds.

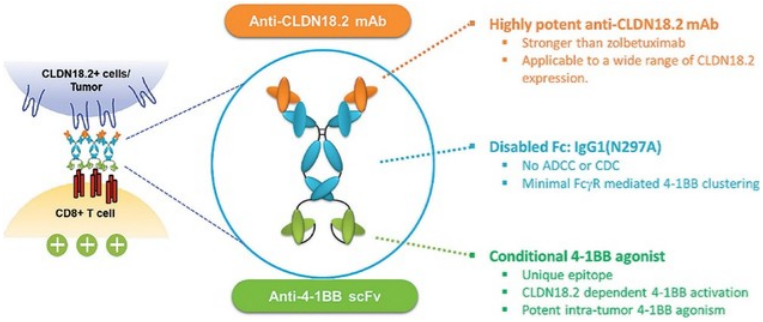


Figure: Schematic diagram of the overall structure of givastomig and its components. The 4-1BB agonistic antibody is a single-chain Fv (scFv) connected to the C-terminus of a disabled Fc in a full anti-CLDNJ8.2 antibody via a flexible linker. The design allows the molecule to fit in the immune synapse (left) and trans-activate T cells only upon tumor cell binding.

Molecular Differentiation of Givastomig

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

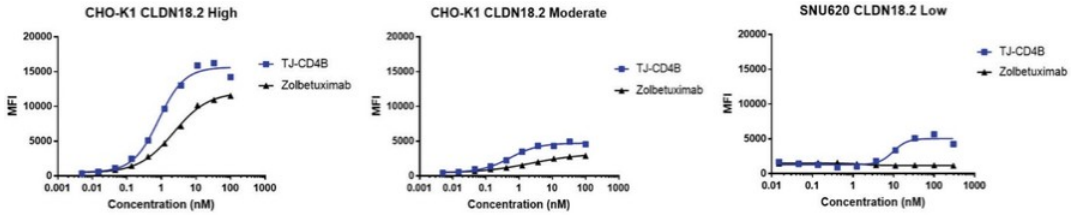


Figure: More potent binding by givastomig than zolbetuximab to cells expressing various levels of CLDN18.2.

CLDN18.2-dependent 4-1BB Activation and T Cell Activity by givastomig. The ability of givastomig 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 givastomig 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. In another experiment where human PBMCs were co-cultured with gastric cancer cells derived from patient biopsies, givastomig was found to increase IL-2 production in a dose-dependent and CLDN18.2 expression-dependent manner.

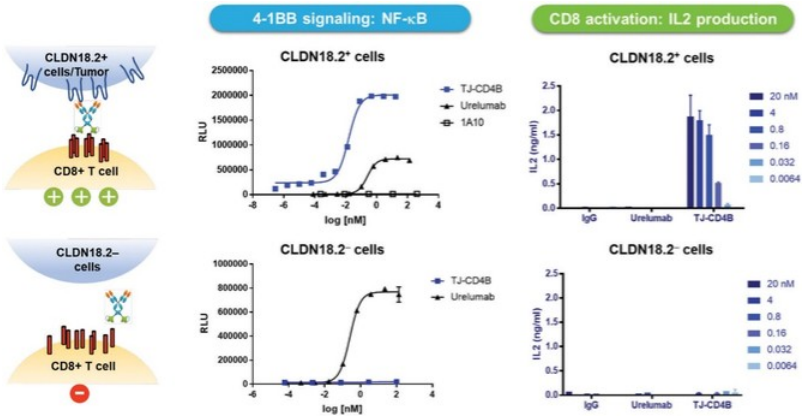


Figure: Dose-dependent CLDN18.2-restricted T cell activity by givastomig but not urelumab in T cell and target cell co-culture system. Left, co-culture scheme; Middle, NF-kB reporter activity; Right, IL-2 production.

Superior in vivo Anti-tumor Efficacy of Givastomig. In mice grafted with tumor cells expressing human CLDN18.2, givastomig treatment twice a week for three 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 givastomig 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 givastomig treatment, but there were no changes in the periphery, suggesting that givastomig could turn a cold tumor into a hot tumor, and the effect was localized. The anti-tumor efficacy of givastomig was dose-dependent, with a minimal efficacious dose of 0.4 mg/kg.

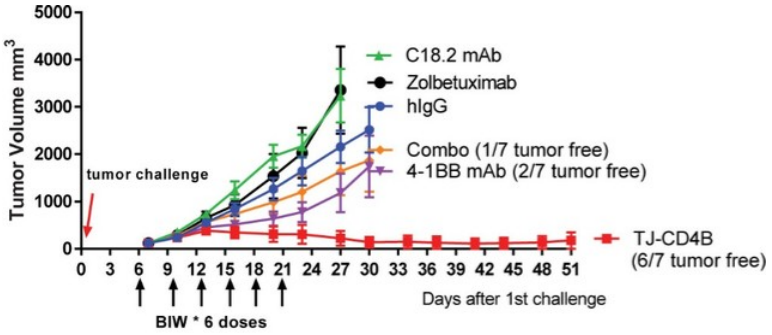


Figure: Potent in vivo anti-tumor activity of givastomig in a mouse tumor model. Mice transgenic for humanized 4-1BB were grafted with MC38 cells expressing human CLDN18.2. Mice were treated with IgG or zolbetuximab as control, or with parental CLDN18.2 mAb, parental 4-1BB mAb, or both, and with givastomig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

Preclinical Pharmacodynamics and Safety. The pharmacodynamic data and safety of givastomig in animal models and cell cultures were jointly announced by I-Mab and ABL Bio, Inc. at the 2021 SITC annual meeting. Analysis of the data found: (1) Potent anti-tumor activity was observed with the proliferation of immune cells in the tumor microenvironment (TME) as well as an increase in memory T cells in the peripheral blood, suggesting long-term immunity against the tumor; (2) Givastomig was well tolerated in non-human primates and did not induce a systemic immune response or liver toxicity up to levels of 100mg/kg; and (3) Activation of immune pathways by givastomig/ABL111 was demonstrated by a pro-inflammatory profile and increased gamma interferon-regulated gene expression in primary human CD8+ T cells co-cultured with CLDN18.2 expressing cells. In the four-week GLP monkey toxicity study, givastomig 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.

Summary of Clinical Results

Phase 1 clinical trial of givastomig in patients with advanced or metastatic solid tumors:

The dose escalation part of the study reached 15 mg/kg without encountering dose limiting toxicity (DLT). By the end of 2022, eight dose cohorts had been completed, with 38 subjects dosed. Givastomig was well tolerated, most of the treatment-related adverse events (TRAEs) were grade 1 or 2 and no DLTs were reported. There is a dose-dependent increase of drug exposure and soluble 4-1BB in serum, suggestive of a favorable PK/PD profile and potentially a longer dosing interval with durable T cell activation. Partial response (PR) and stable disease (SD) signals of givastomig monotherapy were observed across efficacious dose levels in gastric cancer patients who failed multiple lines of prior therapies, including PD-1 therapy. More encouragingly, efficacy signals were also observed in patients with low CLDN18.2 expression, indicating its potential to treat CLDN18.2 low-expressing tumors where other CLDN18.2 targeted agents have a limited treatment effect. The complete Phase 1 data is expected to be presented at a medical conference in the second half of 2023.

Clinical Development Plan

We are accumulating and evaluating the Phase 1 data to determine the RP2D. More data from the ongoing study are anticipated in the second half of 2023. The clinical development plan is being finalized to initiate a Phase 2 study in the second half of 2023. In parallel, we are developing a CLDN18.2 IHC assay for patient selection, which will be used in our future clinical studies. Furthermore, we are in the process of exploring potential global partnership opportunities for givastomig.

Other Clinical Assets

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

Summary

TJ-L14B, also known as ABL503, is a bi-specific antibody targeting both PD-L1 and 4-1BB and was developed in collaboration with ABL Bio. It was designed to overcome the limited efficacy of anti-PD-(L)1 and anti-4-1BB-related toxicity. Similar to givastomig, 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 displayed greater anti-tumor efficacy than anti-PD-L1 or anti-4-1BB alone or in combination and showed evidence of immunological memory response that resisted tumor re-challenge. GMP material at 1000-L scale was successfully produced. In January 2021, we received IND approval from the U.S. FDA for a Phase 1 study of TJ-L14B and dosed the first patient in April 2021. We share the global rights with ABL Bio for TJ-L14B, except for in Greater China and South Korea where ABL Bio has sole rights.

Therapeutic Indications

As previously stated, 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 T cell potentiators, as indicated earlier in this document. Several companies have been developing PD-L1 x 4-1BB bi-specific antibodies, with the most advanced being developed by Genmab and Inhibrx, which are both currently in Phase 2 trials.

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 increase CMC complexity. 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 a 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 families of co-stimulatory molecules. If proven in clinical trials, these potential advantages could differentiate TJ-L14B from other competing compounds.

Summary of Preclinical 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-$_k$B reporter activity elicited by TJ-L14B correlated with the level of PD-L1 expression on the target cells. In contrast, urelumab induced NF-$_k$B 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.

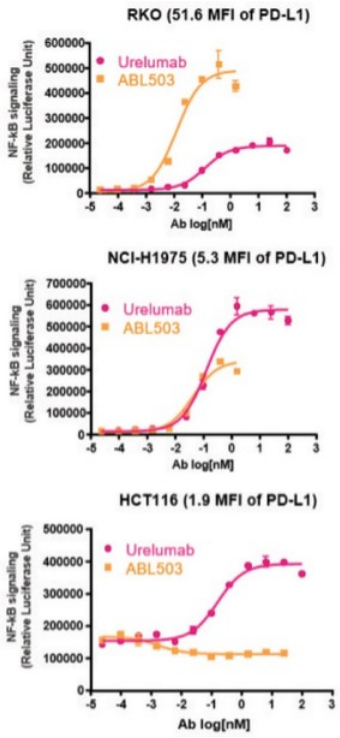
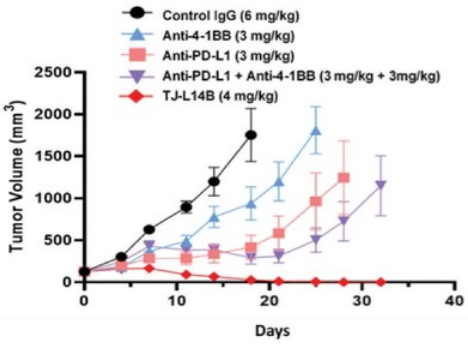


Figure: Dose-dependent PD-L1-restricted T cell activity by TJ-L14B/ABL503 but not urelumab in a co-culture system of T cells and target cells expressing different levels of PD-L1 (as represented by mean fluorescent intensity (MFJ) values).

Superior in vivo Anti-tumor Efficacy of TJ-L14B. In mice grafted with tumor cells expressing human PD-L1, TJ-L14B treatment every three days for four 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 protected, indicating that TJ-L14B produced a durable anti-tumor response.



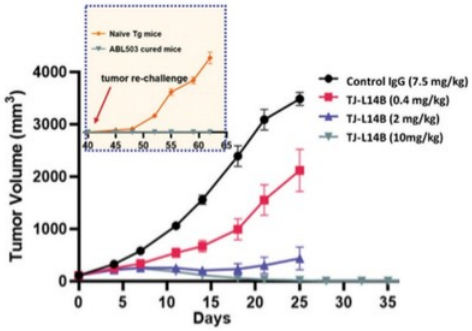


Figure: Potent in vivo anti-tumor activity of TJ-L14B in a mouse tumor model. Mice transgenic for humanized 4-1BB were grafted with MC38 cells expressing human PD-L1. Mice were treated with the indicated antibodies every three days for four times. Tumor-free animals were re-challenged with a second dose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

Preclinical Safety. 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

Phase 1 dose-escalation and dose-expansion study of TJ-L14B is ongoing in patients with progressive locally advanced or metastatic solid tumors who are relapsed or refractory following prior lines of treatment with no available treatment options. The dose escalation has reached an efficacious dose level. TJ-L14B was well tolerated, and MTD was not reached. Clinical PK data indicated a linear dose profile and early clinical efficacy signals were observed. The dose expansion part of TJ-L14B will be initiated in the second half of 2023, both in the U.S. and Korea. The trial is being conducted by our partner ABL Bio. More data will be generated as the trial progresses.

Efineptakin alfa (TJ107): The World's First and Only Long-acting Recombinant Human IL-7 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. This Phase 2 clinical-stage asset is positioned as a monotherapy for the treatment of cancer patients with lymphopenia because of its unique properties of increasing anti-tumor T cell numbers and as combination immunotherapy with a PD-1 or PD-L1 antibody because of its potential synergism with PD-1/PD-L1 therapy. We obtained the rights from Genexine for the development, manufacturing and commercialization of efineptakin alfa in Greater China.

Efineptakin alfa has an advantage over other T lymphocyte cytokines with its therapeutic potential in oncology. Preclinical and clinical results generated so far indicate that efineptakin alfa has a selective and favorable immune function profile over recombinant human interleukin-2 (rhIL-2) in that efineptakin alfa activates and expands tumor-attacking CD4, CD8, and natural killer T cells, but spares tumor-protecting Treg cells.

We are running two Phase 2 clinical trials for the development of efineptakin alfa in China. In January 2022, the first patient was dosed in a Phase 2 study of efineptakin alfa in combination with pembrolizumab (Keytruda®) in patients with advanced solid tumors. The study follows a "basket" trial design to include selected tumor types, including triple-negative breast cancer (TNBC) and squamous cell cancer of the head and neck (SCCHN). The other Phase 2 trial is on track in patients with newly diagnosed glioblastoma multiforme (GBM) with standard concurrent chemoradiotherapy.

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. It 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. Moreover, 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.

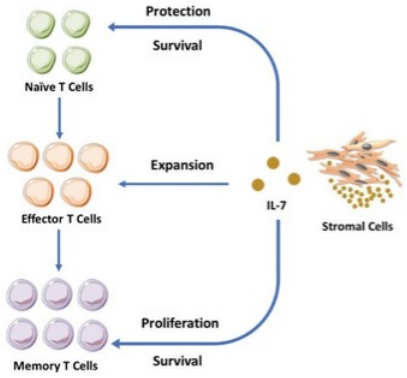


Figure: Role of IL-7 in T cell maintenance and proliferation.

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, further damaging their already compromised immune systems and ability to fight against cancers. Advanced solid tumors are another indication for efineptakin alfa as a combination therapy with PD-1 therapy. As more than 60% of 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 preclinical reports that IL-7 exhibits a synergistic effect with PD-1/PD-L1 therapies in the treatment of cancers and by the clinical data reported by Genexine/NeoImmuneTech (see elsewhere in this section).

Advantages of Efineptakin alfa

Efineptakin alfa has an advantage over other T lymphocyte cytokines with therapeutic potential in oncology. Preclinical 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-attacking CD4, CD8, and natural killer T cells, but spares tumor-protecting Treg cells. Owing to its preferred immune function and molecular profiles demonstrated in preclinical 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, the application of the hyFc technology enhances IL-7's function, increases its half-life (from 48 to 112 hours after a single subcutaneous dose in clinical studies), and allows for a robust purification process. The hyFc in efineptakin alfa is also non-cytolytic, so it will not damage the T cells to which it binds.

Summary of Clinical Results

Clinical Trials in cancer patients in China by I-Mab

We have completed a Phase 1 clinical trial in China in patients with advanced solid tumors and presented the topline safety and PK/PD data at the 2021 Chinese Society of Clinical Oncology (CSCO) annual meeting in September.

As of August 27, 2021, a total of 32 patients (17 colorectal cancer, 5 gastric cancer, 5 lung cancer, 3 head and neck cancer, 1 liver cancer, and 1 breast cancer) were enrolled and received efineptakin alfa treatment at five dose levels, including 240 μg/kg (n = 3), 480 μg/kg (n = 3), 720 μg/kg (n = 4), 960 μg/kg (n = 11) and 1200 μg/kg (n = 11). No DLTs were reported, and MTD was not reached. The most common TEAEs were Grade 1 or 2 injection site reactions (ISRs), occurring in 22 of 32 patients (68.8%), which showed local symptoms including injection-site pain (31.3%), injection-site swelling (28.1%), injection-site pruritus (28.1%) and injection-site erythema (25.0%). The ISRs were able to be controlled after topical or antihistamines treatment. Efineptakin alfa exposure (C_{max} and AUC_{last}) tended to increase the dose proportionally in the 240-1200 μg/kg range. Mean $T_{1/2}$ ranged from 45 to 187 hours, with no accumulation observed. Dose-dependent increases in absolute lymphocyte count (ALC) and CD3+ T cells, including naive and memory subsets, were observed on Day 21 post the first dose in both lymphopenia (ALC<1000/μL) and normal (ALC>1000/μL) patients, while Treg cells were not significantly affected and CD8/Treg ratio was improved at 1200 μg/kg cohorts. More importantly, IFN-γ secreting T cells were amplified, and TCR diversity was significantly increased, suggesting enhanced anti-tumor potential after treatment.

Clinical Trials conducted in the U.S. by Genexine/NeoImmuneTech

Efineptakin alfa and pembrolizumab combination therapy for solid tumors. The data from NeoImmuneTech dose-escalation trial (NCT04332653) presented at ASCO 2021 showed that MTD was not reached and efineptakin alfa was tolerable and safe in combination therapy with pembrolizumab in patients with advanced solid tumors. Of the 11 evaluated patients, 6 patients showed controlled progression (DCR = 55%), and increased median progression-free survival (mPFS) can be estimated. It also significantly increased T cell numbers in both tumor specimens and the peripheral blood in patients treated with efineptakin alfa. Our partner Genexine presented the data from a Phase 1b/2 Keynote-899 study, presented at ASCO 2022, showed that combination treatment of efineptakin alfa with pembrolizumab (Keytruda®) induced ORR of 15.7% (8/51) for phase 1b and 21.2% (7/33) for phase 2 study in patients with metastatic TNBC. Notably, the ORR in patients with PD-L1 CPS ≥ 10 was 60% (6/10) compared to 0% (0/15) in patients with PD-L1 CPS < 10, which warrants a further study of a combination regimen for patients with PD-L1 CPS ≥ 10.

Efineptakin alfa in combination with CAR-T therapy. In December 2022, NeoImmuneTech presented its recent data from an ongoing Phase 1b study evaluating safety, preliminary anti-tumor activity and T cell reconstitution with efineptakin alfa administered following tisagenlecleucel (Kymriah®), a CD19-directed CAR-T therapy in patients with relapsed/refractory large B-cell lymphoma, at the 2022 American Society of Hematology (ASH) annual meeting. The data showed that efineptakin alfa treatment following tisagenlecleucel was safe and well-tolerated with no induction of cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS), nor proinflammatory cytokines. Notably, efineptakin alfa treatment led to a sustained increase in ALC and increased CAR-T cell absolute numbers in the peripheral blood. Preliminary anti-tumor efficacy was also observed, particularly at dose level 3=240 μg/kg.

Clinical Development Plan

By leveraging the clinical results generated by Genexine/NeoImmuneTech so far, we aim to advance the clinical development of efineptakin alfa for approvals in Greater China. Our clinical development plan is focused on evaluating efficacy and safety 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. A Phase 2 study (NCT05145907) has been initiated following a "basket" trial design to include selected tumor types, including triple-negative breast cancer (TNBC) and squamous cell cancer of the head and neck (SCCHN). The first patient was dosed in the Phase 2 study of efineptakin alfa in combination with pembrolizumab (Keytruda®) in patients with advanced solid tumors in January 2022.

TJ210/MOR210: A Novel C5aR1 Antibody for Cancers

Summary

TJ210 is a fully human, high-affinity antibody against human C5aR1 for the treatment of cancers. 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.

Preclinical studies have shown that targeting the C5aR-C5a axis exerts anti-tumor activity with immune checkpoint inhibitors. Furthermore, in *vitro* activity was observed to block the C5a/C5aR pathway 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. The *in vitro* and *in vivo* preclinical studies are ongoing to explore and validate the most effective combination partner(s) of TJ210 in addition to the PD-(L)1 antibody. We obtained the rights from MorphoSys for the development, manufacturing and commercialization of TJ210 in Greater China and South Korea, and are co-developing the asset globally with MorphoSys.

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 mechanisms linking imbalanced complement activation and cancer progression. Upon activation, complement components, including C5a, are released into the TME, inducing the recruitment of immunosuppressive cells, including TAMs, TANs, MDSCs, Tregs, and DCs, thus inhibiting cytotoxic T-cell attack on 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 upregulation of growth factors 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 the promotion of tumor cell adhesion, proliferation, migration, and stemness.

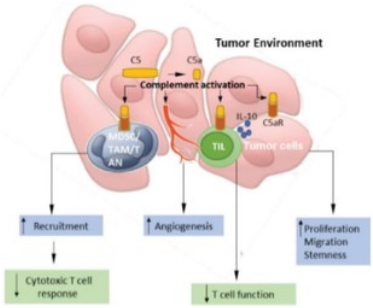


Figure: Role of C5a/C5aR axis in the tumor micro-environment.

Therapeutic Indications

Traditionally regarded as the critical innate immune response, complement components, especially C5a/C5aR axis, have 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 potential 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 the complement cascade in those tumors either plays a critical role in cancer development or correlates with tumor grade and metastatic status.

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 introduced in the Fc region of IgG1 silent the Fc-mediated-effector function. C5aR1 blocking plays an important role in the development and/or progression of various cancers and potentially autoimmune diseases. TJ210 exerts strong antitumor activity by blocking the activation and migration of C5aR1-expressing myeloid cells and has a 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 preclinical 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 four-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.

Summary of Preclinical Results

TJ210 exerts strong anti-tumor activity by blocking the activation and migration of C5aR1-expressing myeloid cells and has the potential to be a differentiated agent 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 TJ210's potential at pathologic concentrations.

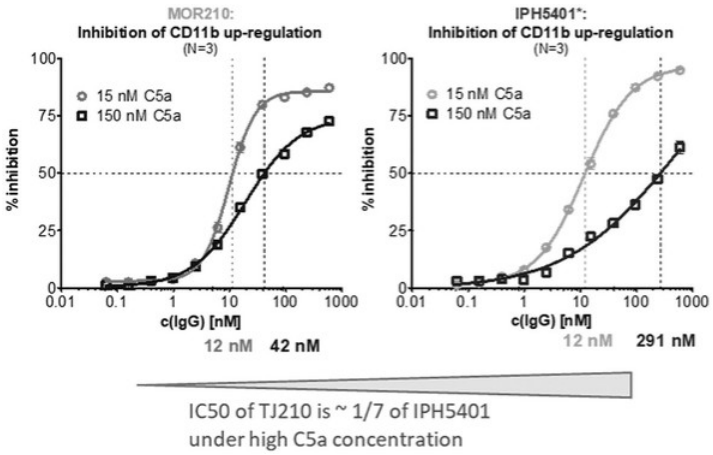


Figure: Inhibition of C5a-induced CD11b upregulation by C5aR mAb in human whole blood assay. Briefly, heparinized blood was incubated with serial dilutions of TJ210 (MOR210) or IPH5401, and then human C5a was added (15 or 150 nM) and further incubated. Fluorescence was measured by FACS Array. The median fluorescence intensity (MEI) 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.

In the four-week GLP toxicity study of TJ210, 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.

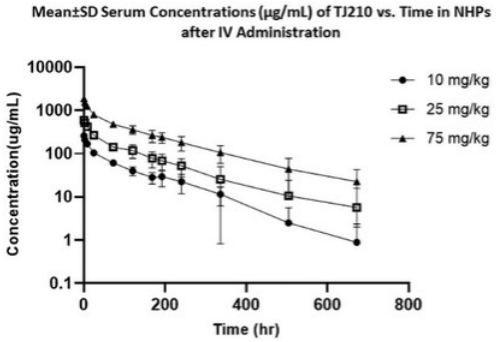


Figure: Cynomolgus monkeys were administered a single IV injection of TJ210 at 10, 25, and 75 mg/kg. Blood samples were collected at multiple time slots for concentration-time analysis using a validated MSD method.

Clinical Development Plan

In September 2020, the U.S. FDA approved our IND to initiate a Phase 1 clinical trial to evaluate the safety, tolerability, MTD or maximum administered dose (MAD), PK and PD of TJ210. In January 2021, we announced the dosing of the first patient in this trial, and patient recruitment for dose escalation was completed in the second quarter of 2022.

In June 2022, our partner MorphoSys entered into an equity participation and license agreements with Human Immunology Biosciences, Inc. ("HIBio"), a biotech company focusing on developing precision medicines for autoimmune and inflammatory diseases, for development and commercialization of felzartamab and MOR210/TJ210 outside of Greater China. Under the terms of C5aR Agreement, we obtained exclusive rights to develop and commercialize MOR210/TJ210 in Greater China and South Korea and share economics upon certain clinical milestones in the U.S.

Selected Preclinical Assets

TJ-C64B: A Novel Bi-Specific Antibody for Ovarian and Other Cancers

TJ-C64B is another bispecific molecule developed by leveraging our conditional 4-1BB platform, which has the advantage of minimizing systemic toxicities, i.e. liver toxicity, with an increased therapeutic window. It is specifically designed to simultaneously target Claudin6 (CLDN6), uniquely expressed in specific cancer types, including ovarian cancer cells, and engage 4-1BB through a unique conditional activation mechanism. CLDN6 is hardly detectable in normal adult tissues to ensure target specificity for ovarian cancers. In addition to the T cell activation through 4-1BB stimulation upon CLDN6 engagement, TJ-C64B has an added function of specifically depleting CLDN6-expressing tumor cells and intra-tumor regulatory T cells highly expressing 4-1BB, which differentiates it from other 4-1BB bispecific antibodies under clinical development. As published in AACR 2022, preclinical data showed that TJ-C64B enhances CLDN6-dependent T cell activation upon the engagement of cancer cell lines with different CLDN6 expression levels. In a syngeneic mouse model, TJ-C64B treatment induces strong anti-tumor activity with complete tumor regression in all tested mice at the dose of 4.5 mg/kg and durable resistance against tumor re-challenge through the immunological memory response. Further, ex vivo analysis confirms localized immune activation by TJ-C64B as evident by the increased CD8+ T cells in tumors.

We have achieved candidate selection and are actively progressing the preclinical development of the candidate molecule.

TJ-L1IF: A Novel PD-L1/IFN-α Antibody-Cytokine Fusion Protein Designed for PD-(L)1 Resistant Cancers

TJ-L1IF is a novel PD-L1/IFN-α antibody-cytokine fusion protein specifically designed for the treatment of PD(L)-1 resistant tumors through the addition of a strong immune adjuvant (interferon-alpha, IFN-α) to convert "cold" tumor to "hot" tumor on top of a PD-L1 antibody to achieve superior anti-tumor activity. Novel drug molecules with such a design are badly needed to address the current clinical challenges where a majority of cancer patients do not or poorly respond to PD-1/PD-L1 therapies. IFN-α was the first cytokine approved for cancer treatment, but its clinical use is limited by its systemic toxicities.

TJ-L1IF is composed of a PD-L1 antibody with an engineered IFN-α2b fused at the C-terminus of IgG. It is a prodrug in that the IFN-α2b moiety is masked by a PEG group through a protease-cleavable linker rendering the drug inactive in the circulation to avoid systemic toxicities. Once the drug accumulates at the tumor site through PD-L1 antibody targeting, the linker is cleaved by proteases that are highly expressed in the tumor environment to achieve specific activation only at the tumor site. This unique property of TJ-L1IF has been validated in a series of in vitro and in vivo studies, in which TJ-L1IF demonstrated good plasma stability, benign safety in cynomolgus monkeys, and superior anti-tumor activity in the PD-1/PD-L1 resistant tumor models as compared to PD-L1 antibody or IFN-α used either alone or in combination. After the first dose of treatment, the active format of the drug was quickly detected and accumulated in the tumor but not in the periphery, confirming the local delivery and conversion to an active form of IFN-α at the tumor site.

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 should 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 should 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, 2022, the costs incurred for the development of this new indication was RMB7.0 million (US$1.1 million) and thus RMB4.7 million (US$0.7 million) was recorded in our audited consolidated financial statements for the year ended December 31, 2022.

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.

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.

In September 2020, we entered into a sublicense agreement with I-Mab Hangzhou, under which we sublicensed to I-Mab Hangzhou an exclusive, sublicensable license to develop, manufacture and commercialize olamkicept in mainland China, Hong Kong, Macau, Taiwan and South Korea. In December 2021, we entered into a supplementary sublicensing agreement with I-Mab Hangzhou, pursuant to which I-Mab Hangzhou, as a sub-licensee of olamkicept (TJ301) in Greater China and Korea, agreed to pay US$3.0 million to us for the completion of olamkicept (TJ301) Phase 2a study report. After receiving the milestone payment of RMB19.1 million (US$3.0 million) from I-Mab Hangzhou, we made the payment of US$3.0 million to Ferring, as of December 31, 2022.

In May 2022, we entered into an amended and restated license and sublicense agreement and a cell line and manufacturing collaboration agreement (the "Cell Line Collaboration Agreement") with Ferring, under which we granted to Ferring an exclusive, perpetual and transferrable sublicense, with the right to grant further sublicenses to sublicensees, under all of the intellectual properties licensed to us by our business partner, to research, develop, make, import, use and sell olamkicept as expressed by or produced by cell lines created by our business partner and its affiliates in any human indications in the territories other than Greater China and Korea. We also granted to Ferring an exclusive, perpetual and royalty-free license, with right of sublicense to sublicensees, under the intellectual property owned or controlled by our company which relates to cell lines created by our business partner and its affiliates, for the research, development, making, using or selling of olamkicept, including prespecified patents and know-how and improvements thereto. As of December 31, 2022, Ferring paid to us the milestone payment as specified in the Cell Line Collaboration Agreement. Ferring also agreed to make milestone payments to us, conditioned on the achievement of certain development milestones in Ferring's licensed territory.

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 retifanlimab (formerly 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 retifanlimab, 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 retifanlimab, and combinations thereof. The license is (i) non-exclusive with respect to the enoblituzumab product, and (ii) exclusive with regard to retifanlimab.

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, we have made a milestone payment of US$4.5 million to MacroGenics. In July 2022, due to an unexpected high incidence of fatal bleeding, MacroGenics terminated a phase 2 study of enoblituzumab as a combination therapy with PD-1 antibody or PD-1/LAG3 bispecific antibody in patients with head and neck cancers. We exercised our right to terminate the license and collaboration agreement with MacroGenics by serving a termination notice on August 29, 2022 and the termination came into effect in February 2023.

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 and allowed us to share certain economics upon certain clinical milestones in the U.S. As of the date of this annual report, we have received the economics sharing of US$0.9 million from Morphosys. 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$2.5 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-PDLl 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 AbbVie Collaboration 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. 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.

In August 2022, we and AbbVie Global Enterprises Ltd., the assignee of AbbVie Ireland Unlimited Company (together with AbbVie Ireland Unlimited Company, "AbbVie"), entered into an amendment to this agreement. The parties are collaborating on the global development of anti-CD47 antibody therapy under the agreement as amended. We will be eligible to receive, and AbbVie will pay, up to US$1.295 billion in the development, regulatory and sales milestone payments, and the tiered royalties at rates from mid-to-high single-digit percentages on global net sales outside of Greater China for certain new anti-CD47 antibodies currently in development, or the original milestone payments and tiered royalties previously disclosed in our annual report in Form 20-F for the fiscal year 2021 for other licensed products. We have the exclusive right to develop and commercialize all licensed products under the agreement (as amended) in Greater China. AbbVie discontinued the global Phase 1b study of lemzoparlimab combination therapy with AZA and venetoclax, in patients with MDS and AML, and a Phase 1b study of lemzoparlimab in patients with relapsed/refractory multiple myeloma. These discontinuations were not related to any specific or unexpected safety concerns. This change led to a lowered probability of achieving a key milestone that was included in the consideration of revenue recognition in prior years. We recorded a reduction in the revenue of approximately US$48.0 million (equivalent to RMB314.2 million) in the second half of 2022. For a more detailed discussion, please see Note 17 "Licensing and Collaboration Arrangements" of our consolidated financial statements included elsewhere in this annual report.

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 all indications 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 in its own territories, 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 (HKEX: 1093) ("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 should be jointly developed by both parties and any changes to the plan should be discussed and approved by the joint development committee) and commercialization.

We also agreed that, during the term of the CSPC Agreement, we should 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 milestone payment of RMB15.0 million. Further, CSPC agreed to make milestone payments in an aggregate amount of RMB118.5 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 will 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 will 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 will 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: ulilediimab, a 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 ulilediimab, 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, further amended in November 2018, May 2019, December 2019, June 2020, September 2021, respectively, whereby both parties agreed to collaborate to develop two 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. 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.

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 will be created using our proprietary monoclonal antibodies and WuXi Biologics' proprietary WuXiBody platform technology for generating bispecific antibodies, will 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. 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. The disputes relating to the TJD5 Agreement and the BsAbs Agreement were presented to a binding arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce before an arbitration tribunal. On April 25, 2023, the arbitration award determined that the TJD5 Agreement has been terminated for a pre-agreed termination fee of $9.0 million plus interest payable pursuant to the original agreement, and, therefore Tracon has no rights to share any future economics with I-Mab. The arbitration award completely denied Tracon's damages claim of over US$200 million for any breach and awarded no damages to Tracon. The tribunal also confirmed the termination of the BsAb Agreement. Based on the arbitration award, I-Mab will bear a portion of Tracon's legal fees and costs, totaling approximately US$13.5 million.

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 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 July 2021, we entered into a collaboration agreement with Immorna, an mRNA biotech company, to discover and develop self-replicating mRNA for *in vivo* synthesized therapeutic biologics. In the same month, we entered into a collaboration agreement with neoX Biotech, an AI-enabled R&D biotech company, to accelerate the R&D process of novel targets and modalities. In March 2023, we terminated the collaboration agreement with Immorna.

In October 2021, we entered into a strategic partnership with Sinopharm to strengthen our commercial capabilities and support our commercialization transformation. We will authorize more than 300 of Sinopharm's subsidiaries as distributors across China to support distribution and retail allocation to terminal markets while we lead the overall commercial activities. The partnership will also include alliance on key projects, to jointly support the commercialization and go-to-market process of our differentiated and novel products.

In November 2021, we entered into a strategic collaboration agreement with Jumpcan, a leading China pharmaceutical company specialized in and committed to pediatric medicines, for the development, manufacturing and commercialization of our highly differentiated long-acting recombinant human growth hormone, eftansomatropin alfa (TJ101) in mainland China. Under the collaboration agreement, we will continue to lead the ongoing registrational Phase 3 clinical trial of eftansomatropin alfa in pediatric growth hormone deficiency (PGHD). The two companies will share costs of manufacturing tech transfer, process optimization and new formulation development. We will be the marketing authorization holder (MAH) of the product and supply the product at agreed cost to Jumpcan. Jumpcan will be responsible for commercializing the product and developing new indications in collaboration with us in mainland China. We will provide clinical, manufacturing and academic support. According to the terms of the collaboration agreement, Jumpcan will make an upfront payment of RMB224 million to I-Mab and, upon achievement of development, registration and sales milestones, certain milestone payments of up to RMB1.792 billion, making the non-royalty payments a total of up to RMB2.016 billion. In addition, we and Jumpcan will share profits generated from commercialization of the product in mainland China on a 50/50 basis, pursuant to which we will be entitled to receive tiered low double-digit royalties on net sales.

In November 2021, we also entered into a strategic collaboration with Roche Diagnostics, a global leader in *in vitro* diagnostics industry, to co-develop companion diagnostics (CDx) solutions for our innovative pipeline, at the Fourth China International Import Expo (CIIE) in Shanghai. Under this collaboration, we and Roche Diagnostics will jointly develop companion diagnostics solutions for the innovative assets under development by us to accelerate the research and development process of innovative biologics with cutting-edge diagnosis and treatment technologies.

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, 2022, our owned patent portfolio consists of (i) 113 issued patents, including 11 issued in the U.S., 16 issued in the PRC, seven issued in Korea and 79 issued in other jurisdictions; and (ii) 185 pending patent applications, including 19 PCT patent applications, 10 U.S. patent applications, 14 PRC patent applications and 142 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, 2022, we in-licensed the Greater China and Korea rights relating to (i) 35 issued patents, including 14 issued in the PRC, three issued in Korea, 12 issued in Hong Kong, two issued in Macau and four issued in Taiwan; and (ii) 26 pending patent applications, including two PCT patent applications, 12 PRC patent applications, four Hong Kong patent applications, six Taiwan patent applications, one Korean patent applications and one Macau patent application. The in-licensed patents and patent applications primarily relate to felzartamab, eftansomatropin alfa, efineptakin alfa and TJ210.

Felzartamab	As of December 31, 2022, we exclusively licensed from MorphoSys 18 issued patents (including eight issued in the PRC, seven issued in Hong Kong, one issued in Taiwan and two issued in Macau) and 13 pending patent applications (including four PCT applications, two in the PRC, two in Hong Kong, and five in Taiwan) relating to felzartamab. The licensed patents include composition of matter patents in China, Hong Kong, Taiwan and Macau. The patents (including patent applications if issued) in this portfolio are expected to expire between 2025 and 2042, 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, 2022, we (i) exclusively licensed from Genexine two pending PRC patent applications and two PCT applications directly relating to eftansomatropin alfa and (ii) non-exclusively licensed from Genexine 3 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.
Efineptakin alfa	As of December 31, 2022, we (i) exclusively licensed from Genexine three issued patents (including three issued in Taiwan) and eight pending patent applications (including seven in the PRC and one in Hong Kong) directly relating to efineptakin alfa and (ii) non-exclusively license from Genexine five issued patents in the PRC and four issued patents in Hong Kong 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 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.
Lemzoparlimab	As of December 31, 2022, we owned eight PCT patent application, three of which has entered national phases including in the PRC, the United States and additional jurisdictions. We expect that any patents that may issue under these applications will expire between 2037 and 2042, 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.
Ulileditimab	As of December 31, 2022, we owned four PCT patent applications and one of which has entered national phases including in the PRC, the United States, and additional jurisdictions. We expect that any patent that may issue under these applications will expire between 2038 and 2042, 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.
TJ210	As of December 31, 2022, we exclusively licensed from MorphoSys four pending patent applications (including one in the PRC, one in Hong Kong, one in Taiwan and one in Korea) relating to TJ210. We co-owned one PCT application with MorphoSys relating to TJ210. We expect that any patent that may issue under these applications will expire between 2040 and 2041, 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.
Givastomig (TJ-CD4B)	As of December 31, 2022, we co-owned one PCT patent application with ABL Bio Inc., which has entered national phases including in the PRC, the United States, and additional jurisdictions. We owned one PCT application relating to TJ-CD4B. We expect that any patent that may issue under this application will expire between 2040 and 2042, 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.
TJ-L14B	As of December 31, 2022, we co-owned one PCT patent application with ABL Bio Inc., which has entered national phases including in the PRC, the Europe, and additional jurisdictions. We expect that any patent that may issue under this application will expire 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.

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, utility models are effective for ten years and designs are effective for fifteen years from the date of application. There are patent term adjustments and patent term extensions available in the PRC for issued patents relating to inventions.

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, 2022, we had (i) 17 registered trademarks in Hong Kong, 98 registered trademarks in the PRC, six registered trademarks in the United States, 17 registered trademarks in Macau, 16 registered trademarks in Taiwan, three registered trademarks in other jurisdictions, and four trademark applications in the PRC; (ii) 10 domain names in the PRC, including www.i-mabbiopharma.com, six domain names in Hong Kong and two domain names in the Cayman Islands; and (iii) 12 software copyrights and three copyrights of works of art in the PRC.

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

Environmental, Health and Safety (EHS) Matters

In August 2021, we established an ESG Committee. The committee consists of Dr. Andrew Zhu, Director, President and Acting Chief Executive Officer, and two independent directors, Mr. Chun Kwok Alan Au and Dr. Rong Shao. Mr. Chun Kwok Alan Au chairs the committee. As the oversight body for our ESG practices, the committee is responsible for supervising our ESG strategies, policies, long-term sustainability objectives and risks. In addition, we also set up an ESG working group to address daily ESG workflows. In May 2022, we published our 2021 ESG report to summarize highlights and progress of our recent ESG practices. In February 2023, we were granted “A” rating by MSCI Environmental, Social and Governance (ESG), following MSCI ESG’s most recent annual review, and such rating outperforms approximately 66% peers among global biotech companies.

With the current state of business operations, we have no significant environmental impact due to no large-scale manufacturing operations. We abide by local laws and regulations on environmental protection and only discharge a small amount of waste gas and wastewater after proper treatment. A small amount of hazardous wastewater produced during the research and development process is carefully collected and handed over to qualified third-party professionals for proper treatment before discharged to the sewage treatment plant. A small amount of harmless waste gas is emitted at a high altitude after filtration by activated carbon. Any hazardous waste generated during the research and development process is carefully collected by laboratory technicians daily and placed in a temporary storage facility, and transported to qualified professionals once a month, in accordance with strict local environmental guidelines. We also provided employee trainings, set up SOPs and contingency plans for of potential EHS accidents.

At present, energy and resources consumed in our daily operations are mainly municipal electricity and domestic water. We assigned a dedicated team to regularly inspect and maintain the equipment, measure total consumption, and train employees on water and energy saving measures.

Safety and health are the foundation of our operational activities. We have created a comprehensive internal safety management system to ensure compliance, strengthen risk assessment and management. In addition, we provide employees with annual physical check-ups to ensure the health of the employees. We offered SOPs to ensure relevant employees are aware of any potential hazards, including providing emergency training, treatment facilities, and Personal Protection Equipment (PPE) to all employees.

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.

In August 2021, we established an Environmental, Social and Governance ("ESG") committee to supervise the ESG strategies, policies, long-term sustainability objectives and risks of the company, and we were granted a "BBB" rating, the highest newly initiated rating among China-based biotech companies, by the MSCI ESG assessment. In February 2023, I-Mab was granted "A" rating by MSCI ESG, following its most recent annual review. Our commitment to ESG can be summarized into three "P"s: patients, philanthropy, people.

Patients. Since our inception, we have been focusing on delivering immuno-oncology biologics with best-in-class and first-in-class potential, with the mission to bring transformative medicines to patients through innovation. We have built an innovative and advanced pipeline of over 10 highly differentiated, novel biologics with potential to address the significant unmet medical needs in cancer.

In 2020, there were 19.29 million new cancer cases worldwide, of which 4.57 million were newly diagnosed in China. This figure accounts for 23.7% of the world's cancer burden and far exceeds the number of new cancer cases of any other country in the world. In fact, one out of every three patients who die from cancer in the world is from China. We are committed to addressing this significant global disease burden and answering unmet needs of patients through our innovation.

In response to the COVID-19 resurgence in 2022, we set up an emergency response plan by coordinating the local warehouses, logistics vendors and CROs, as well as designed direct-to-patient plan, to make sure that our medicines be delivered to patients on time amid lockdowns.

Philanthropy. 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.

In July 2021, we donated RMB1 million to Henan Charity General Federation for the rescue and reconstruction of flood-hit regions in Henan Province in China. We are committed to philanthropic giving which can help build stronger communities.

People. People is the most valuable asset of I-Mab, and we are committed to creating a healthy, engaging, diversified and inclusive environment for all staffs. We are at the forefront of promoting diversity and inclusiveness in the workplace. Women account for over two-thirds of our employees, 59% of them hold a master's degree or above. In 2020, we launched the Women's Leadership Council ("WLC") globally to support our future female leaders to accelerate their career and personal development. In 2021 and 2022, I-Mab was selected into the Asia Pacific Diversity, Equity and Inclusivity Best Practice Guide for two consecutive years.

We value talents and respect knowledge. To support employees' personal and career development, we have built up a systematic talent development system, including an online learning center, advanced leadership program and other tailor-made training courses.

In 2022, in response to the urgent situations caused by COVID-19, we immediately set up an emergency task force to deliver food supplies, including daily necessities and anti-pandemic gift packs, to employees in areas experiencing prolonged home quarantine to support employees and their families affected by the pandemic in Shanghai. We also organized a series of virtual town halls, virtual birthday parties, mental wellbeing lectures, to connect employees and relieve their stress during the lockdown.

International Recognition and Awards

The remarkable achievements made by us are well recognized by the international community of pharma industry. We were among the top companies by the leading global financial publication Institutional Investor in "Honored Companies" "Best CEO," "Best CFO," "Best IR Professional," "Best IR Program," and "Best ESG" categories, based on its 2022 All-Asia Executive Team survey. It was the second consecutive year that I-Mab has been named as the "Honored Company" within the healthcare and pharmaceuticals sector. In September 2022, I-Mab was ranked among the Top 100 Chinese Pharmaceutical Innovation Companies released by Healthcare Executive magazine, a top-tier Chinese pharmaceutical industry media, for the third consecutive year. In November 2022, we were honored by the government of Pudong District of Shanghai for Outstanding Contribution to Economy. In recognition of our efforts and achievements in driving diversity and inclusion, I-Mab was recently selected into the Diversity, Equity and Inclusion Best Practice Guide 2022 for the second year in a row, along with many leading companies across the industries. 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.

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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.

Furthermore, the Company Law of the PRC (Revised Draft) and the Company Law of the PRC (Revised Draft for Second Review) (collectively, the "Draft Company Law") were released for public comments on December 24, 2021 and December 30, 2022, respectively. The major revisions made by the Draft Company Law included improvement of the system for the establishment and exit of companies, optimization of organizational structures of companies, improvement of capital system of companies, strengthening the responsibilities of the controlling shareholder and management personnel, and enhancing the social responsibilities of companies. As of the date of this annual report, the Draft Company Law has not been formally enacted.

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, the Special Management Measures (Negative List) for the Access of Foreign Investment (2019) issued on June 30, 2019 and effective from July 30, 2019, and the Catalogue of Industries for Encouraging Foreign Investment (2019 Version) issued on June 30, 2019 and effective from July 30, 2019, the Special Management Measures (Negative List) for the Access of Foreign Investment (2020) issued on June 23, 2020 and effective from July 23, 2020, and the Catalogue of Industries for Encouraging Foreign Investment (2020 Version) issued on December 27, 2020 and effective from January 27, 2021. 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 should 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), the Special Management Measures (Negative List) for the Access of Foreign Investment (2019), the Catalogue of Industries for Encouraging Foreign Investment (2019 Version), the Special Management Measures (Negative List) for the Access of Foreign Investment (2020) and the Catalogue of Industries for Encouraging Foreign Investment (2020 Version) 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 (2021), and the Catalogue of Industries for Encouraging Foreign Investment (2022 Version), which were promulgated by the National Development and Reform Commission (the "NDRC"), and the MOFCOM, and took effect on January 1, 2022 and on January 1, 2023, respectively. The Catalogue of Industries for Encouraging Foreign Investment (2022 Version) and the Special Management Measures (Negative List) for the Access of Foreign Investment (2021) 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 should 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 is subject to the Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors. Particularly, application should 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 should 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 should 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 6, 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—

On January 22, 2020, the SAMR promulgated the new Administrative Measures for Drug Registration (the "Measures for Drug Registration"), which became effective from July 1, 2020 and provided the standards and requirements for clinical trials and drug registration applications. According to the Measures for Drug 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 should 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 should 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 Measures for Drug 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 Measures for Drug 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

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, clinical trial registration should be completed and trial information should be published through the Drug Clinical Trial Information Platform. The applicant should complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and should 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 should submit an explanation, and if the procedure is not completed within three years, the clinical trial approval will automatically expire.

Pursuant to the Measures for Drug 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 are 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 May 28, 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, which was lately revised in 2020. 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 should 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 should 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 Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Pharmaceutical and Medical Devices, 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 Measures for Drug 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.

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), which provide for fast track clinical trial approval, drug registration pathway or conditional approval to innovative drugs or drugs with revolutionary therapeutic effects.

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 should 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 Measures for Drug 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.

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.

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 Measures for Drug Registration, upon completion of relevant research and other preparation work, the applicant may apply to the NMPA for approval of a new drug application. The NMPA will then determine whether to approve the application according to the comprehensive evaluation opinion issued by the CDE of the NMPA.

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 Measures for Drug 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 should 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 should 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 should consider the representativeness of the research subjects, i.e., the participating patients;

- The applicant should 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 should be subject to on-site inspections by competent PRC governmental agencies.

International multi-center clinical trials should follow international prevailing GCP principles and ethics requirements. Applications should ensure the truthfulness, reliability and trustworthiness of clinical trials results; the researchers should have the qualification and capability to perform relevant clinical trials; and an ethics committee should continuously review the trials and protect the subjects' interests, benefits and safety. Before the performance of the international multi-center clinical trial, applicants should 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. According to the International Multi-Center Clinical Trial Guidelines (Trial), when using international multi-center clinical trial data to support new drug applications in China, applicants should 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 should 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 should 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 should 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 will 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 should be responsible for proper packaging and labeling of drugs for clinical trials, and in double-blinded clinical trials, the test drug should 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 October 25, 2018. According to these regulations, basic healthcare institutions funded by the government should store up and use drugs listed in the National List of Essential Drugs. The drugs listed in the National List of Essential Drugs should be purchased by centralized tender process and should 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 should 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 should 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, December 27, 2008 and October 17, 2020, respectively, and the latest revision thereto became effective from June 1, 2021, 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, patents relating to utility models are effective for ten years, and patents relating to designs are effective for fifteen 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 CNIPA. Normally, the CNIPA 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 CNIPA for a substantive examination within three years from the date of application.

Article 19 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 CNIPA 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 CNIPA 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.

Meanwhile, 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 should, 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 should provide the Term Compensation to the patentee, for the duration of patent rights at the request of the patentee. The Term Compensation should not exceed five (5) years, and the total effective patent right period after the new drug is approved for marketing should 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 should 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 should 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 CNIPA 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 should 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 will 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 will be timely referred to a judicial authority and decided according to the law.

Domain Names

Domain names are historically 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. On June 18, 2019, China Internet Network Information Center issued the Implementing Rules of China Country Code Top-level Domain Names Registration, repealing the Implementing Rules on Registration of Domain Names. 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 should be liable for the quality of products produced by them, and sellers should take measures to ensure the quality of the products sold by them. A manufacturer should 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 should 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 should 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.

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. 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 10, 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 should 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 should 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. Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA

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 should 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 should 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 should check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities should hold income to account for previous years' losses before remitting the profits. Moreover, domestic entities should 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 should 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% should 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 "PDLTFA"), 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.

Preclinical 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 to leverage the GMP manufacturing process managed by I-Mab Biopharma (Hangzhou) Limited ("I-Mab Hangzhou"), in order to ensure quality, secure production slots and maximize cost-effectiveness for clinical trial materials and commercial supplies. We have taken concrete steps to execute our strategic plan. These steps include detailed operational planning for the facility, actions taken to secure an appropriate site, and negotiations with external financing providers. The construction of the Hangzhou Facility commenced in April 2021. The Hangzhou Facility completed the establishment of a pilot capacity of two production lines (one line configured with 2 x 2,000L and the other line with 1 x 2,000L) in the middle of 2022. The project has been 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, we, through our wholly-owned subsidiary, and parties acting in concert, remain the majority shareholder of I-Mab Hangzhou, the entity holding the Hangzhou Facility. On July 16, 2022, I-Mab Hangzhou entered into a definitive financing agreement with a group of domestic investors in China to raise approximately US$46 million in RMB equivalent. Upon closing of the financing, we, through our wholly-owned subsidiary, will remain the largest shareholder. Upon the occurrence of certain triggering events as specified in the shareholders agreement among I-Mab Hangzhou, we, through our wholly-owned subsidiary, and other domestic investors, including but not limited to I-Mab Hangzhou's failure to accomplish certain public offering condition, we may be obligated to repurchase the equity held by other domestic investors in cash or in our stocks in the period beyond 12 months. I-Mab Hangzhou is an affiliate of our company and 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 preclinical 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. Zhengyi Wang, Dr. Jane Meng, Isaac Meng, Dr. Weimin Tang, Dr. Zheng Huang and Dr. Xi Chen, chaired by Dr. Zhengyi Wang. 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.

R&D Council

Our R&D Council is composed of Dr. Andrew Zhu, Dr. John Hayslip, Dr. Zhengyi Wang, Isaac Meng and Dr. Zheng Huang, with Dr. Andrew Zhu serving as the chair. The R&D Council is responsible for reviewing potential options elevated by our program team and making scientific decisions on proposals for our clinical assets. On clinical program level, our R&D Council reviews and endorses decisions regarding dose selection, dose changes or other substantial changes to a study that would have impact on the clinical development plan, such as disease of focus, line of therapy and significant changes to patient population.

Portfolio Governance Committee

Our Portfolio Governance Committee is composed of Dr. Andrew Zhu, Dr. John Hayslip, Dr. Junhua Qiao, Richard Yeh, Dr. Weimin Tang and Dr. Zheng Huang, with Dr. Andrew Zhu serving as the chair. Our Portfolio Governance Committee is a decision-making body that focuses on reviewing and approving our portfolio strategy, determining portfolio and project prioritization, approving project development strategy, resource and execution plan to ensure the R&D investments and decisions are in line with our company's overall business strategy. The Portfolio Governance Committee responsibilities include:

- reviewing our portfolio strategy, including but not limited to in-licensing and out-licensing plan and strategy, internal and external policy changes that could impact our portfolio strategically;
- determining portfolio and project prioritization;
- approving development stage gates;
- reviewing project development strategy, including but not limited to FIH studies, early development, proof-of-concept trials, pivotal trials, regulatory submission for BLA, commercial strategy, and any significant changes to the development plan; and
- reviewing execution plans, including but not limited to timeline and budgets, major health authority interactions and changes to such timeline and milestones.

Medical Safety Council ("MSC")

Our MSC is composed of selected research and development functional heads and Subject Matter Experts, including Isaac Meng, Dr. Andrew Zhu, Yang Zhou, Dr. Zhengyi Wang, Dr. Jane Meng, Dr. Claire Xu and Richard Cheng Li, chaired by Isaac 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 first-in-human ("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 Isaac 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 Isaac 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 Management Committee.

I-Mab Biopharma Quality Management Review ("I-Mab QMR") is composed of Dr. Andrew Zhu, Isaac Meng, Dr. Junhua Qiao and Thomas Song, co-chaired by Isaac Meng and Dr. Junhua Qiao. I-Mab QMR is responsible for supervising our overall quality management system ("QMS"), including R&D, production and manufacturing, and our other functional departments, to set up a comprehensively risk control system and ensure that our operations are in accordance with the requirements of laws and regulations, industry Good X Practices (GXP) and our internal regulations and systems. The QMS covers all business activities such as the selection of outsourcing service vendors, daily management and audit, research, development, and production, and we also have signed quality agreements with CDMO, CMO, CRO, and other vendors.

Under QMR, we have established an R&D Quality Management Committee composed of representatives of various R&D functional departments, including Dr. Andrew Zhu, Isaac Meng, Yang Zhou, Dr. Claire Xu, Dr. Jane Meng and heads of therapeutic areas (in China and the United States), chaired by Dr. Andrew Zhu. Our R&D Quality Management Committee is responsible for supervising the operation of the R&D QMS and making final decisions on important quality issues such as patient safety, data integrity and regulatory compliance in the R&D process.

An audit team consisting of experts who are responsible for R&D, CMC, and quality assurance within I-Mab will conduct an annual audit of all sites of our key vendors. Other vendors will be audited as required at least once every three years.

Code of Conduct

We have formulated a Code of Conduct that covers business ethics, responsible research and development activities, public relations, intellectual property and data protection, workplace, assets, corporate governance, concerns reporting and other behaviors, and serves as a guide for all employees and third parties to take compliance actions in business activities. We have arranged compliance training courses for newly hired employee to help them understand the business code of conduct that falls in line with industry and our standards. 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. Andrew Zhu, 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:

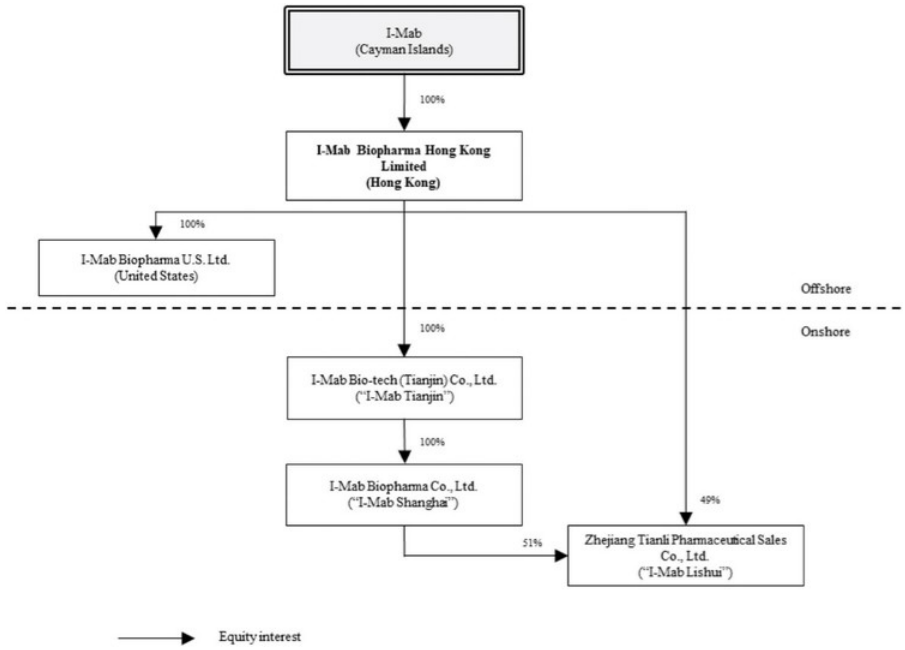
- predefined policies and procedures to manage pre-clinical and clinical studies;
- dedicated resources and personnel with well delineated roles and responsibilities;
- quality risk management across the product lifecycle;
- continuous quality management system improvement;
- non-conformance management 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 4,420 square meters as office space and 1,270 square meters as laboratories. We currently lease approximately 839 square meters of office space in Beijing, approximately 54 square meters of office space in Tianjin, approximately 2,468 square meters of warehouse space and office space in Lishui, approximately 743 square meters of office space in Gaithersburg and approximately 1,081 square meters of office space and laboratories in San Diego. The terms of these leases range from one year to seven 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 biotech 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 diseases. To date, we have developed an innovative pipeline of more than 10 clinical and preclinical stage assets through our internal research and development efforts and in-licensing arrangements with global pharmaceutical and biotech companies.

Our research and development capabilities encompass discovery, translational medicine, biologics CMC development, pre-clinical development and clinical development with footprints in Shanghai, Beijing and the United States.

Since the commencement of our operation in 2014, we have devoted most of our efforts and financial resources to organize and staff our operations, formulate 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 the sales of our commercial products, and as a result, we had incurred net losses since the commencement to the end of 2019 of our operations. In 2020, we achieved corporate profitability with net income of RMB470.9 million, which was primarily attributable to the revenues recognized in connection with the strategic collaboration with AbbVie of RMB1,542.7 million. In 2021 and 2022, our net losses were RMB2,331.5 million and RMB2,507.3 million (US$363.5 million), respectively. We do not expect to generate product revenue unless and until we obtain marketing approval for and commercialize a drug candidate, and we cannot assure you that we will ever generate significant revenue or profits.

Key Factors Affecting Our Results of Operations

Our results of operations, financial condition, and the year-to-year comparability of our financial results have been, and are expected to continue to be, principally affected by the below factors:

Cost and Expenses Structure

Our results of operations are significantly affected by our cost structure, which primarily consists of research and development expenses and administrative expenses.

Research and development activities are central to our business model. We believe our ability to successfully develop drug candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high-quality drug candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Since our inception, we have focused our resources on our research and development activities, including conducting pre-clinical studies and clinical trials, and activities related to regulatory filings for our drug candidates. Our research and development expenses primarily include the following:

- costs related to development of our pipeline assets under all stages including discovery, pre-clinical testing or clinical trials;
- patent license fees and other fees under the licensing, collaboration and development agreements with respect to our in-licensed drug candidates; and
- employee salaries and related benefit costs, including share-based compensation expenses, for research and development personnel and key management.

At this time, we are unable to predict when, if ever, we will be able to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. This is due to the numerous risks and uncertainties associated with developing such drug candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety profile;

- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing the drug candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our drug candidates;
- continued acceptable safety profiles of the products following approval; and
- retention of key research and development personnel.

Any change in the outcome of any of these variables with respect to the development of any of our drug candidates would significantly change the costs, timing and viability associated with the development of that drug candidate. We expect research and development costs to continue to increase for the foreseeable future as we expand our operations and our development programs progress, including as we continue to support and advance the clinical trials of our drug candidates.

Our administrative expenses consist primarily of employee salaries and related benefit costs. Other administrative expenses include professional fees for consulting and auditing as well as other direct and allocated expenses for rental expenses for our facilities, travel costs and other supplies used in administrative activities. We expect our administrative expenses to increase in the future to support our pipeline assets and research and development efforts, and the commercialization of our drug candidates once approval is obtained. We also anticipate that our administrative expenses will increase as we operate as a public company.

Revenue from Out-Licensing Agreements

We continue to seek out-licensing opportunities for our drug assets through our strengthened and expanded network of global partnerships and alliances. As we have not obtained marketing approval for or commercialized a drug candidate, our revenues at the current stage are primarily subject to the availability of the payments from granting licenses to use and otherwise exploit certain of our intellectual properties linked to our drug assets, which primarily contributed to our revenues in 2020 and 2021. See "Item 4. Information on the Company—B. Business Overview—Licensing and Collaboration Arrangements" for more information on the existing out-licensing arrangements." However, substantial uncertainties remain as to the availability and the recognition of revenue from out-licensing agreement. For example, we recognized an aggregate revenue of US$48.0 million in 2020 and 2021 in relation to our collaboration with AbbVie based on the probability of achieving a key milestone. However, we witnessed an amendment to the overall collaboration arrangement with AbbVie, which resulted in a lowered probability of achieving such key milestone and a reversal of revenue of US$-48.0 million (equivalent to RMB-314.2 million) in 2022. In addition, after validating clinical safety and preliminary efficacy of a drug candidate in our Global Portfolio in clinical trials in the United States, we may elect to out-license the global rights (excluding Greater China) of such drug candidate, while retaining the Greater China rights for further development and commercialization. But we may also choose to retain these rights for the United States or other countries or regions as we may deem fit. Before the commercialization of one or more of our drug candidates, we expect that the majority of our revenue will continue to be generated from out-licensing our intellectual properties.

Funding for Our Operations

During the periods presented, we funded our operations primarily from financing through the issuance and sale of preferred shares and convertible promissory notes in private placement transactions. Going forward, in the event of successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with revenue generated from sales of our commercialized drug products. However, with the continuing expansion of our business and our product pipeline, we may require further funding through public or private offerings, debt financing, collaboration, and licensing arrangements or other sources. Any fluctuation in our ability to fund our operations will impact our cash flow plan and our results of operations.

Our Ability to Commercialize Our Drug Candidates

Our business and results of operations depend on our ability to commercialize our drug candidates, once and if those candidates are approved for marketing by the respective health authority. Currently, our pipeline consists of more than ten drug candidates ranging in development status from pre-clinical to late-stage clinical programs. Although we currently do not have any product approved for commercial sale and have not generated any revenue from product sales, we expect to generate revenue from sales of drug candidates after we complete the clinical development, obtain regulatory approval, and successfully commercialize such drug candidates. Our late-stage investigational drugs at or potentially near registrational trials are felzartamab, eftansomatropin alfa, and lemzoparlimab. 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, 2022. In connection with our acquisition of I-Mab Tianjin, we identified intangible assets of RMB148.8 million and goodwill of RMB162.6 million of I-Mab Tianjin. Goodwill is not amortized, but impairment of goodwill assessment is performed on at least an annual basis on December 31 or whenever events or changes in circumstances indicate that the carrying value of the reporting unit exceeds its fair value. No impairment was identified as of December 31, 2020, 2021 and 2022. 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, lemzoparlimab and eftansomatropin alfa. See "Item 4. Information on the Company—B. Business Overview—Our Drug Pipeline" for the clinical development plans of our drug candidates. As of the date of this annual report, the COVID-19 pandemic has not caused any early termination of our clinical trials or necessitated removal of any enrolled patients. We 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.

Most of the travel restrictions and quarantine requirements in China were lifted in December 2022. There were surges of cases in many cities during this time which caused disruptions to the operations of our company, our suppliers, CROs, CMOs and other contractors, and there remains uncertainty as to the future impact of the COVID-19. 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 frequency, duration and extent of outbreaks of COVID-19, the appearance of new variants with different characteristics, the effectiveness of efforts to contain or treat cases, and future actions that may be taken in response to these developments.

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, as well as 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.

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 may continue to be materially and adversely affected by the effects of the COVID-19 pandemic in China." 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

For the years ended December 31, 2021 and 2022, we generated revenue from (i) licensing and collaboration, primarily through granting licenses to use and otherwise exploiting certain of our intellectual properties in connection with our drug assets, and (ii) supply of investigational products to AbbVie. The decrease in 2022 net revenue was primarily due to a non-cash adjustment of US$-48.0 million (equivalent to RMB-314.2 million) recorded in the second half of 2022 following the amendment to the original license and collaboration agreement with AbbVie in August 2022. For the year ended December 31, 2020, we generated substantially all of our revenues 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:

- Eftansomatropin alfa, a differentiated long-acting growth hormone for pediatric growth hormone deficiency, if approved;
- Felzartamab, a differentiated CD38 antibody for multiple myeloma and potentially autoimmune diseases, if approved;
- Lemzoparlimab, a novel CD47 antibody for immuno-oncology, if approved;
- Uliledlimab, a highly differentiated CD73 antibody for solid tumors, if approved;
- Givastomig, a novel, tumor-dependent T-cell engager for gastric and other cancers, if approved;
- TJ-L14B, a PD-L1-based tumor-dependent T-cell engager for solid tumors, if approved;
- Efineptakin alfa, the world's first and only long-acting recombinant human IL-7 for cancer treatment-related lymphopenia and cancer immunotherapy, if approved; and
- TJ210, a novel C5aR1 antibody for cancers, if approved.

We incurred research and development expenses of RMB984.7 million, RMB1,213.0 million and RMB904.9 million (US$131.2 million) for the years ended December 31, 2020, 2021 and 2022, respectively, representing 71.0%, 57.4% and 55.7% 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, 2020, 2021 and 2022, our administrative expenses amounted to RMB402.4 million, RMB899.9 million and RMB815.8 million (US$118.3 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 (expenses), net consists primarily of income from the equity transfer of I-Mab Hangzhou, fair value change of short-term and other investments, fair value change of put right liabilities, net foreign exchang gains (losses) and subsidy income.

Equity In Loss Of Affiliates

Equity in loss of affiliates consists primarily of the loss recognized based on our proportionat share in I-Mab Hangzhou.

Taxation

Cayman Islands

I-Mab, our holding entity, is incorporated in the Cayman Islands. According to Harney Westwood & Riegels, our Cayman Islands counsel, 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, companies registered in Hong Kong are 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, 2020, 2021 and 2022, the income tax expenses recorded in the consolidated statements of comprehensive income (loss) for I-Mab were nil, nil and RMB0.7 million, respectively. For the years ended December 31, 2020, 2021 and 2022, 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 and 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 the Corporate Income Tax Law (the "CIT Law") (as amended in 2017 and 2018, respectively), under which Foreign Investment Enterprises ("FIEs") and domestic companies would be subject to corporate income tax at a uniform rate of 25%. The CIT Law became effective on January 1, 2008. Under the CIT Law, preferential tax treatments will 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 2021 to 2023. 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, 2022. Therefore, we have provided full valuation allowances for the deferred tax assets as of December 31, 2020, 2021 and 2022.

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, 2020, 2021 and 2022, 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,			
	2020	2021	2022	
	RMB	RMB	RMB	US$
	(in thousands, except for per share data)			
Summary Consolidated Statements of Comprehensive Income (Loss) Data:				
Revenues				
Licensing and collaboration revenue	1,542,668	40,115	(249,665)	(36,198)
Supply of investigational products	—	47,911	28,102	4,074
Total revenues	1,542,668	88,026	(221,563)	(32,124)
Cost of revenues	—	(46,432)	(27,237)	(3,949)
Expenses				
Research and development expenses [(1)]	(984,689)	(1,212,958)	(904,901)	(131,198)
Administrative expenses [(1)]	(402,409)	(899,943)	(815,766)	(118,275)
Income (loss) from operations	155,570	(2,071,307)	(1,969,467)	(285,546)
Interest income	24,228	21,333	26,908	3,901
Interest expense	(957)	—	(9)	(1)
Other income (expenses), net	412,892	83,162	(126,587)	(18,353)
Equity in loss of affiliates [(1)]	(108,587)	(367,883)	(437,465)	(63,426)
Income (loss) before income tax expense	483,146	(2,334,695)	(2,506,620)	(363,425)
Income tax benefit (expense)	(12,231)	3,154	(697)	(101)
Net income (loss) attributable to I-Mab	470,915	(2,331,541)	(2,507,317)	(363,526)
Net income (loss) attributable to ordinary shareholders	470,915	(2,331,541)	(2,507,317)	(363,526)
Other comprehensive income (loss)				
Foreign currency translation adjustments, net of nil tax	(120,920)	(135,717)	400,304	58,039
Total comprehensive income (loss) attributable to I-Mab	**349,995**	**(2,467,258)**	**(2,107,013)**	**(305,487)**
Net income (loss) attributable to ordinary shareholders	**470,915**	**(2,331,541)**	**(2,507,317)**	**(363,526)**
Weighted-average number of ordinary shares used in calculating net income (loss) per share				
Basic	134,158,824	174,707,055	189,787,292	189,787,292
Diluted	157,231,652	174,707,055	189,787,292	189,787,292
Net loss per share attributable to ordinary shareholders				
Basic	3.51	(13.35)	(13.21)	(1.92)
Diluted	3.00	(13.35)	(13.21)	(1.92)
Net income (loss) per ADS attributable to ordinary shareholders				
—Basic	8.07	(30.71)	(30.38)	(4.41)
—Diluted	69.0	(30.71)	(30.38)	(4.41)

Note:

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

	For the Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$
	(in thousands)			
Research and development expenses	284,431	201,926	117,876	17,090
Administrative expenses	209,033	406,683	239,272	34,691
Equity in loss of affiliates	32,707	13,267	13,852	2,008
Total	526,171	621,876	371,000	53,789

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

Revenues

Total net revenues for the year ended December 31, 2022 were RMB-221.6 million (US$-32.1 million), compared with RMB88.0 million for the year ended December 31, 2021. The decrease in 2022 net revenue was primarily due to a non-cash adjustment of US$-48.0 million (equivalent to RMB-314.2 million) recorded in the second half of 2022 following the amendment to the original license and collaboration agreement with AbbVie in August 2022. This amendment led to a lowered probability of achieving a key milestone that was included in the total consideration of revenue recognition in prior years. The decrease was partially offset by revenue of RMB92.6 million from license and collaboration arrangements and the supply of investigational products.

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,				
	2021		2022		
	RMB	%	RMB	US$	%
	(in thousands, except percentages)				
CRO service fees	727,573	60.0	523,559	75,909	57.9
In-licensed patent right fees	66,344	5.5	3,316	481	0.4
Employee benefit expenses	347,571	28.7	324,363	47,028	35.8
Material costs for drug candidates	23,141	1.9	20,857	3,024	2.3
Other expenses	48,329	3.9	32,806	4,756	3.6
Total	**1,212,958**	**100.0**	**904,901**	**131,198**	**100.0**

Our research and development expenses decreased by 25.4% from RMB1,213.0 million for the year ended December 31, 2021 to RMB904.9 million (US$131.2 million) for the year ended December 31, 2022, primarily attributable to (i) a decrease in CRO and CMO service fees from RMB727.6 million for the year ended December 31, 2021 to RMB523.6 million (US$75.9 million) for the year ended December 31, 2022, primarily due to the reduced demand for investigational products as we procured sufficient stock in 2021; (ii) a decrease in in-licensed patent right fees from RMB66.3 million for the year ended December 31, 2021 to RMB3.3 million (US$0.5 million) for the year ended December 31, 2022; and (iii) a slight decrease in employee benefit expenses of employees involved in research and development from RMB347.6 million for the year ended December 31, 2021 to RMB324.4 million (US$47.0 million) for the year ended December 31, 2022.

In 2022, 88.2% and 11.8% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively, as compared to 94.3% and 5.7% in 2021. In 2022, felzartamab and eftansomatropin alfa accounted for approximately 23.6% and 20.6% of our external research and development expenses, which primarily included payments to CROs and CMOs. In 2021, felzartamab and lemzoparlimab accounted for approximately 26.4% and 34.8% of our external research and development expenses, which primarily included licensing fees and payments to CROs and CMOs. No other programs accounted for a significant portion of our research and development expenses in 2022 and 2021. 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 RMB899.9 million for the year ended December 31, 2021 to RMB815.8 million (US$118.3 million) for the year ended December 31, 2022, primarily attributable to the decrease in share-based compensation expenses by RMB167.4 million (US$24.3 million) in relation to the management personnel and optimized control of operating and administrative expenses, and partially offset by the increase of the accrued expenses in relation to the disputes with Tracon of RMB95.5 million (US$13.8 million).

Interest Income

We recorded interest income of RMB21.3 million and RMB26.9 million (US$3.9 million) for the years ended December 31, 2021 and 2022, respectively. The change was primarily attributable to the interest income derived from bank deposits and a decrease in bank balance.

Other Income (Expenses), Net

We recorded other income of RMB83.2 million and other expenses of RMB126.6 million (US$18.4 million) for the years ended December 31, 2021 and 2022, respectively. The change was primarily attributable to unrealized exchange losses due to the significant fluctuation in the exchange rate of RMB against USD in 2022, and the fair value change of short-term and other investments.

Equity in Loss of Affiliates

We recorded equity in loss of affiliates of RMB367.9 million and RMB437.5 million (US$63.4 million) for the years ended December 31, 2021 and 2022, respectively. The change was primarily due to the increased expenditure of our investee, I-Mab Hangzhou.

Year Ended December 31, 2021 Compared to Year Ended December 31, 2020

Revenues

Our revenues generated for the year ended December 31, 2021 consisted of (i) revenue generated from licensing and collaboration, which primarily includes revenue recognized in connection with the strategic collaboration with AbbVie, and milestone payments from CSPC Pharmaceutical Group Limited pursuant to our licensing agreement, and (ii) revenue generated from supply of investigational products to AbbVie under the strategic collaboration agreement. In comparison, the revenues generated for the year ended December 31, 2020 solely consisted of the revenues recognized in connection with the strategic collaboration with AbbVie.

Our revenues decreased from RMB1,542.7 million for the year ended December 31, 2020 to RMB88.0 million for the year ended December 31, 2021, primarily attributable to the decrease in our revenue generated from licensing and collaboration from RMB1,542.7 million for the year ended December 31, 2020 to RMB40.1 million for the year ended December 31, 2021, offset by the revenue we generated from supply of investigational products of RMB47.9 million for the year ended December 31, 2021.

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,			
	2020		2021	
	RMB	%	RMB	%
	(in thousands, except percentages)			
CRO service fees	439,537	44.6	727,573	60.0
In-licensed patent right fees	28,266	2.9	66,344	5.5
Employee benefit expenses	460,149	46.7	347,571	28.7
Material costs for drug candidates	15,610	1.6	23,141	1.9
Other expenses	41,127	4.2	48,329	3.9
Total	**984,689**	**100.0**	**1,212,958**	**100.0**

Our research and development expenses increased by 23.2% from RMB984.7 million for the year ended December 31, 2020 to RMB1,213.0 million for the year ended December 31, 2021, primarily attributable to (i) an increase in CRO service fees from RMB439.5 million for the year ended December 31, 2020 to RMB727.6 million for the year ended December 31, 2021, to advance our clinical and preclinical pipelines, especially for lemzoparlimab (TJC4), uliledlimab (TJD5), and eftansomatropin alfa (TJ101); (ii) an increase in in-licensed patent right fees from RMB28.3 million for the year ended December 31, 2020 to RMB66.3 million for the year ended December 31, 2021, (iii) partially offset by a decrease in employee benefit expenses of employees involved in research and development from RMB460.1 million for the year ended December 31, 2020 to RMB347.6 million for the year ended December 31, 2021, mainly due to the decrease of share-based compensation expense by RMB82.5 million.

In 2021, 94.3% and 5.7% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. In 2020, 77.6% and 22.4% of our total research and development expenses were attributable to clinical programs and preclinical programs, respectively. In 2021, felzartamab and lemzoparlimab accounted for approximately 26.4% and 34.8% of our external research and development expenses, which primarily included licensing fees and payments to CROs and CMOs. In 2020, felzartamab and lemzoparlimab accounted for approximately 36.9% and 13.4% of our external research and development expenses, which primarily included payments to CROs and CMOs. No other programs accounted for a significant portion of our research and development expenses in 2021 and 2020. 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 RMB402.4 million for the year ended December 31, 2020 to RMB899.9 million, primarily attributable to (i) an increase in employee benefit expenses by RMB291.7 million due to an increase of share-based compensation expenses by RMB197.7 million; (ii) an increase in accrued termination fee to Tracon of US$9.0 million; (iii) an increase in professional service expenses by RMB145.2 million due to the increase in attorneys' fees occurred during our arbitration with Tracon.

Interest Income

We recorded interest income of RMB24.2 million and RMB21.3 million for the years ended December 31, 2020 and 2021, respectively. The change was primarily attributable to interest income derived from bank deposits and the fluctuation of bank balance.

Interest Expense

We recorded interest expenses of nil for the year ended December 31, 2021, as compared to an interest expense of RMB1.0 million for the year ended December 31, 2020. The change was primarily attributable to the interest expense related to our short-term borrowings, which were repaid in June 2020.

Other Income (Expenses), Net

We recorded other income of RMB412.9 million and RMB83.2 million for the years ended December 31, 2020 and 2021, respectively. The change was primarily attributable to the decrease in gains on deconsolidation of a subsidiary from RMB407.6 million in 2020 to nil in 2021, as the equity transfer of I-Mab Hangzhou to a group of domestic investors was completed on September 15, 2020.

Equity in Loss of Affiliates

We recorded equity in loss of affiliates of RMB108.6 million and RMB367.9 million for the years ended December 31, 2020 and 2021, respectively. The change was primarily due to that I-Mab Hangzhou became an unconsolidated affiliate of our company since September 15, 2020.

Critical Accounting Policies and Significant Judgments and Estimates

Our reported results are impacted by the application of certain accounting policies that require us to make subjective or complex judgments. These judgments involve estimations of the effect of matters that are inherently uncertain and may significantly impact our quarterly or annual results of operations or financial condition. Changes in the estimates and judgments could significantly affect our results of operations, financial condition and cash flows in future years. A description of what we consider to be our most significant critical accounting policies and estimates follows.

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. We allocate 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 reporting unit exceeds its fair value.

We first assess qualitative factors to determine whether it is more likely than not that the fair value of our reporting unit is less than its carrying amount, including goodwill. The qualitative assessment includes our evaluation of relevant events and circumstances affecting our single reporting unit, including macroeconomic, industry, market conditions and our overall financial performance. If qualitative factors indicate that it is more likely than not that our reporting unit's fair value is less than its carrying amount, then we 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.

We applied significant judgement in developing the fair value of our single reporting unit. Fair value of the reporting unit is estimated by us using a discounted cash flow model which requires us to make judgements and assumptions related to future revenues, discount rate and terminal growth rate. The probabilities of the success of the clinical trials based on the status of these trials and reference to the industry benchmark were also incorporated into the assumption of future revenues. No impairment was recognized for the year ended December 31, 2022.

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.

Currently, the majority of our revenues come from the collaboration revenue arrangements. Once a contract is determined to be within the scope of ASC 606 at contract inception, we evaluate 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.

Variable consideration in collaboration revenue arrangements

If the consideration promised in a contract includes a variable amount, we will estimate the amount of consideration to which we will be entitled in exchange for transferring the promised goods or services to a customer. An amount of consideration can vary because of discounts, rebates, refunds, credits, price concessions, incentives, performance bonuses, penalties, or other similar items. The promised consideration also can vary if an entity's entitlement to the consideration is contingent on the occurrence or nonoccurrence of a future event. We estimate an amount of variable consideration by using either of the following methods, depending on which method we expect to better predict the amount of consideration to which it will be entitled:

a. The expected value—The expected value is the sum of probability-weighted amounts in a range of possible consideration amounts. An expected value may be an appropriate estimate of the amount of variable consideration if an entity has a large number of contracts with similar characteristics.

b. The most likely amount—The most likely amount is the single most likely amount in a range of possible consideration amounts (that is, the single most likely outcome of the contract). The most likely amount may be an appropriate estimate of the amount of variable consideration if the contract has only two possible outcomes (for example, an entity either achieves a performance bonus or does not).

We include in the transaction price some or all of an amount of variable consideration estimated in accordance with above only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Determination of the standalone selling price of each performance obligation

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 standalone 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.

Cost-to-cost measure of progress for over time performance obligations

Under our certain licensing and collaboration arrangement entered into with a business partner, we recognized revenue using the cost-to-cost measure of progress for its over time performance obligations as we believe this recognition best depicts the transfer of benefits to its business partner as costs are incurred under the licensing and collaboration arrangement. Under the cost-to-cost measure of progress method, the extent of progress towards completion is measured based on the ratio of costs incurred to-date to the total estimated costs for completion of the performance obligations. We applied significant judgment in estimating the total estimated costs for completion of performance obligations under such licensing and collaboration arrangement.

See Note 17 "Licensing and Collaboration Arrangements" of our consolidated financial statements included elsewhere in this annual report for a further discussion of our licensing and collaboration revenues.

Fair value measurement of put right liabilities

Put right written by us to third party investors in our affiliate was recorded as a freestanding equity-linked instrument and classified as a put right liability. We determined the fair value of the put right with the assistance of an independent third-party valuation firm. We used the option pricing model (finnerty model) to estimate the fair value of the put right. The model requires the input of key assumptions including the expected terms, estimated volatility, spot price and probability of triggering event for redemption option. The significant unobservable inputs used in the option pricing model included spot price, estimated volatility 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 companies for a period with length commensurate to the expected terms of redemption event. The spot price was determined using the income approach with assistance from an independent third-party valuation firm. The significant unobservable inputs used in the income approach include revenue growth rates and discount rates.

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 preclinical testing of our technologies under development and clinical trials such as payments to 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 our research and development activities and have no alternative future uses.

We applied significant judgment in estimating the progress of our research and development activities and completion of or likelihood of achieving milestone events per underlying agreements when estimating the research and development costs to be accrued at each reporting period end. The process of estimating our research and development expenses involves reviewing open contracts and purchase orders, communicating with personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs.

Recent Accounting Pronouncements

A list of recently issued accounting pronouncements that are relevant to us is included in Note 2 “Principal Accounting Policies—2.29 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 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. We have incurred net losses and negative cash flows from our operations for the years ended December 31, 2021 and 2022. Substantially all of our losses have resulted from funding our research and development programs and administrative costs associated with our operations. We generated net income of RMB470.9 million for the year ended December 31, 2020, and incurred net losses of RMB2,331.5 million and RMB2,507.3 million (US$363.5 million) for the year ended December 31, 2021 and 2022, respectively. Our primary use of cash is to fund our research and development activities. We generated RMB433.6 million in cash from our operating activities for the year ended December 31, 2020, and used RMB973.1 million and RMB1,102.8 million (US$159.9 million) in cash for our operating activities for the year ended December 31, 2021 and 2022, respectively. As of December 31, 2022, we had cash, cash equivalents and restricted cash of RMB3,310.8 million (US$480.0 million). Our cash, cash equivalents and restricted cash consist primarily of cash in bank and on hand. 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. 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; 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, which were fully exercised in 2021 and increased the proceeds by approximately US$104.5 million.

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

	For the Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$
		(in thousands)		
Summary Consolidated Statements of Cash Flow Data:				
Net cash (used in)/generated from operating activities	433,558	(973,093)	(1,102,805)	(159,892)
Net cash (used in)/generated from investing activities	(201,901)	(727,206)	458,382	66,459
Net cash generated from financing activities	3,440,481	593,924	42,357	6,141
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(106,643)	(128,771)	389,203	56,429
Net increase/(decrease) in cash, cash equivalents and restricted cash	3,565,495	(1,235,146)	(212,863)	(30,863)
Cash, cash equivalents and restricted cash, beginning of the year	1,193,283	4,758,778	3,523,632	510,879
Cash, cash equivalents and restricted cash, end of the year	4,758,778	3,523,632	3,310,769	480,016

We do not expect to generate any revenue from the sales of our commercial products 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, 2022, 26.3% 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, some other events that are beyond our control 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 used in operating activities for the year ended December 31, 2022 was RMB1,102.8 million (US$159.9 million). Our net loss was RMB2,507.3 million (US$363.5 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 equity in loss of affiliates of RMB437.5 million (US$63.4 million) and share-based compensation of RMB357.1 million (US$51.8 million), and changes in certain working capital items, including a decrease of a contract assets of RMB253.8 million (US$36.8 million), an increase in accruals and other payables of RMB109.9 million (US$15.9 million), a decrease in prepayments and other receivables of RMB109.2 million (US$15.8 million) and an increase in contract liabilities of RMB52.6 million (US$7.6 million), partially offset by a decrease of lease liabilities of RMB35.7 million (US$5.2 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, 2020 Plan, 2021 Plan and 2022 Plan.

Net cash used in operating activities for the year ended December 31, 2021 was RMB973.1 million. Our net loss was RMB2,331.5 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 RMB608.6 million and equity in loss of affiliates of RMB367.9 million, and changes in certain working capital items, including an increase in the contract liabilities of RMB224.0 million and an increase in accruals and other payables of RMB152.1 million, partially offset by an increase of inventories of RMB27.2 million and an increase of contract assets of RMB26.4 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, 2020 Plan and 2021 Plan.

Net cash generated from operating activities for the year ended December 31, 2020 was RMB433.6 million. Our net income was RMB470.9 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, equity in loss of an affiliate of RMB108.6 million, non-cash gains on deconsolidation of a subsidiary of RMB407.6 million and changes in certain working capital items, including an increase in the accounts receivable of RMB130.5 million, an increase in the contract assets of RMB227.4 million, an increase in the prepayments and other receivables of RMB58.7 million, partially offset by an increase in the accruals and other payables of RMB173.7 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.

Investing Activities

Net cash generated from investing activities for the year ended December 31, 2022 was RMB458.4 million (US$66.5 million). The net cash increase was primarily attributable to RMB7,911.5 million (US$1,147.1 million) of the proceeds from disposal of short-term and other investments, partially offset by RMB7,407.3 million (US$1,074.0 million) of the cash used in the purchase of short-term and other investments.

Net cash used in investing activities for the year ended December 31, 2021 was RMB727.2 million. The net cash decrease was primarily attributable to RMB10,173.3 million of purchase of short-term investments, partially offset by RMB9,482.0 million of proceeds from disposal of short-term investments.

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

Financing Activities

Net cash generated from financing activities for the year ended December 31, 2022 was RMB42.4 million (US$6.1 million), primarily attributable to the proceeds from exercise of stock options of RMB44.7 million (US$6.5 million) and the proceeds from bank borrowings of RMB19.0 million (US$2.7 million), partially offset by RMB21.2 million (US$3.1 million) of the cash used in the payment of stock repurchase.

Net cash generated from financing activities for the year ended December 31, 2021 was RMB593.9 million, primarily attributable to the proceeds from exercise of warrants of RMB672.7 million, partially offset by payments of the issuance cost in relation to private placement of RMB128.8 million.

Net cash generated from financing activities for the year ended December 31, 2020 was RMB3,440.5 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, the proceeds from private placement, net of payment of issuance cost of RMB2,782.5 million, partially offset by the repayment of bank borrowings of RMB50.0 million.

Material Cash Requirements

Contractual Obligation

Our material cash requirements as of December 31, 2022 and any subsequent interim period primarily include our capital expenditures and operating lease obligations.

Our capital expenditures were incurred for purposes of purchasing property, equipment and software. Our capital expenditures were RMB8.0 million, RMB29.9 million and RMB45.8 million (US$6.6 million) in the years ended December 31, 2020, 2021 and 2022, respectively.

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, 2022.

The following table sets forth our contractual obligations as of December 31, 2022:

	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	81,009	11,745	37,867	5,490	31,916	4,627	10,017	1,453	1,209	175
Capital commitments	4,392	637	4,268	619	124	18	—	—	—	—

We entered into certain unconditional purchase obligations and other commitments in the normal course of business. There have been no changes to these commitments that would have a material impact on our ability to meet either short-term or long-term future cash requirements.

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. Other than as discussed above, we did not have any significant capital and other commitments, long-term obligations or guarantees as of December 31, 2022. We have a contingent obligation to repurchase the equity held by certain investors in the period beyond 12 months. See Note 10 of the Consolidated Financial Statements for a further discussion of this contingent obligation.

Collaborations, Licensing and Other Arrangements

We entered into collaborative, licensing, and other arrangements with third parties that may require future milestone payments to third parties contingent upon the achievement of certain development, regulatory, or commercial milestones. Individually, these arrangements are insignificant in any one annual reporting period. However, if milestones for multiple products covered by these arrangements would happen to be reached in the same reporting period, the aggregate charge to expense could be material to the results of operations in that period. From a business perspective, the payments are viewed as positive because they signify that the product is successfully moving through development and is now generating or is more likely to generate future cash flows from product sales. It is not possible to predict with reasonable certainty whether these milestones will be achieved or the timing for achievement. See Note 17 "Licensing and Collaboration Arrangements" of our consolidated financial statements included elsewhere in this annual report for additional information on these collaboration arrangements.

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.

Sec "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, 2022 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. Critical Accounting Estimates

For our critical accounting estimates, see "Item 5. Operating and Financial Review and Prospects—A. Operating Results—Critical Accounting Policies and Significant Judgments and Estimates."

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.	67	Founder and Chairman of the Board of Directors
Andrew Zhu, M.D., Ph.D.	62	Director, President and Acting Chief Executive Officer
Richard Yeh	54	Director, Chief Operating Officer and Interim Chief Financial Officer
Wei Fu	41	Director
Lan Kang	54	Director
Shuai Chen	49	Director
Chun Kwok Alan Au	50	Independent Director
Conor Chia-hung Yang	60	Independent Director
Pamela M. Klein, M.D.	61	Independent Director
Ruyi He, M.D.	62	Independent Director
Rong Shao, Ph.D.	60	Independent Director
Weimin Tang, Ph.D.	57	Chief Business Officer
John Hayslip, Ph.D.	46	Chief Medical Officer
Gigi Qi Feng	41	Chief Communications Officer
Richard Cheng Li	38	Chief Legal Officer

Jingwu Zhang Zang, M.D., Ph.D., is our founder and has served as our chairman of the board of directors since March 2021. Between December 2021 and September 2022, Dr. Zang served as our acting chief executive officer. Prior to serving as our chairman of the board of directors, 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.

Andrew Zhu, M.D., Ph.D., has served on our scientific advisory board since August 2021 and as our director and president since December 2021 and acting chief executive officer since September 2022. Dr. Zhu is an internationally renowned oncologist. He was Professor of Medicine at Harvard Medical School and served as Director of Liver Cancer Research at Massachusetts General Hospital (MGH) Cancer Center. In collaboration with his colleagues, Dr. Zhu established and led the multidisciplinary liver cancer clinic at the MGH and created one of the most productive clinical and translational research programs in hepatobiliary cancers in the U.S. Prior to joining us, Dr. Zhu was Director of Jiahui International Cancer Center of the Jiahui International Hospital in Shanghai, China and subsequently served as Chief Scientific Officer of Jiahui Health. Dr. Zhu has an excellent track record in clinical development of innovative oncology drugs. He has led early-stage development of numerous targeted therapy and immuno-oncology drugs for liver cancer and several pivotal studies that led to regulatory approval by the FDA, including the development of pembrolizumab (KEYNOTE-224) and ramucirumab (REACH-2) for advanced liver cancer, and the successful development of the first IDH-1 inhibitor (Ivosidenib) for cholangiocarcinoma. Dr. Zhu also served on the Steering Committee of several phase III trials in the development of combination immunotherapies for liver cancer, including atezolizumab combined with bevacizumab. He has also served on the committee for the establishment of many global HCC Clinical Trial Design and Practice Guidelines, including the NCCN Guidelines for Hepatobiliary Cancers, AASLD Guidelines for the Treatment of Hepatocellular Carcinoma, and ASCO Guidelines on Systemic Therapy for Advanced Hepatocellular Carcinoma. Dr. Zhu received his M.D. degree from Peking University Health Science Center in 1982, and Ph.D. in Microbiology from Columbia University in 1990. Following his postdoctoral research training at Harvard Medical School, Dr. Zhu completed his clinical training in internal medicine at Yale New Heaven Hospital, Yale School of Medicine, and a fellowship in Hematology-Oncology at Memorial Sloan-Kettering Cancer Center. Dr. Zhu has published more than 300 scientific papers and reviews in top international journals such as New England Journal of Medicine, Lancet, JAMA, Nature Medicine, Lancet Oncology, Journal of Clinical Oncology and Cancer Discovery.

Richard Yeh has served as our director, chief operating officer since April 2022 and interim chief financial officer since September 2022. Mr. Yeh has over 20 years of experience working for investment banks and multinational biopharmaceutical companies. Prior to joining us, Mr. Yeh served as director, chief financial officer and head of strategic of operations in Abbisko Cayman Limited, a company listed on the Hong Kong Stock Exchange from November, 2020 to April 2022. From July 2018 to April 2020, Mr. Yeh served as the chief financial officer of CStone Pharmaceuticals, a Hong Kong Stock Exchange listed company. Prior to joining CStone Pharmaceuticals, Mr. Yeh was a managing director and the business unit leader of Asia Pacific healthcare equity research at Goldman Sachs (Asia) L.L.C. in Hong Kong. Before that, Mr. Yeh served as the head of China healthcare research team at Citigroup Capital Markets Asia Limited. In October 1995, Mr. Yeh joined Amgen Inc., a leading global biotechnology company traded on the Nasdaq, as a research associate conducting drug research. Mr. Yeh obtained an MBA from Cornell University in the United States in May 2002 and a Master of Science from the University of Toronto in Canada in November 1995. He graduated from the University of Manitoba in Canada with a bachelor of science in May 1993.

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 CBC Group since April 2014. Mr. Fu currently also serves on the board of Everest Medicines Limited (HKEX: 1952) and 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.

Lan Kang has served as our director since August 2021. Ms. Kang is currently a managing director at CBC Group, where she is responsible for managing all the portfolio companies of the CBC Group. Prior to CBC Group, she was an Executive Board Director and SVP of Fosun International and led Fosun's insurance business globally. She was also on the board of Fosun Pharma and Fosun United Health Insurance. Prior to joining Fosun, Ms. Kang was a Senior Client Partner at Korn/Ferry (KF) International. She successfully developed the Life Sciences practice for KF in mainland China, providing executive search and leadership assessment and human resources consulting to both multinational and local Chinese clients. Prior to that, Ms. Kang was a management consultant at McKinsey & Company, also focusing on the healthcare practice in China. Ms. Kang also serves as a director of Everest Medicines Limited (HKEX: 1952), Avantor, Inc. (NYSE: AVTR) and several private companies.

Shuai Chen, has served as our director since April 2023. Mr. Chen joined Hony Capital in 2003 and is currently a partner and managing director of Hony Capital and managing director of Hony private equity investment fund. Mr. Chen is also a member of the investment committee of Hony real estate investment fund. Mr. Chen has extensive experience in investment management, supplier management and retail business. Currently, Mr. Chen also serves as a non-executive director of Century Ginwa Retail Holdings Limited (HKEX: 0162) and an executive director, chairman of the board and acting chief executive officer of Hospital Corporation of China Limited (HKEX: 3869). Mr. Chen received a Master of Business Administration degree from China Europe International Business School in 2010 and a bachelor's degree in economics from Beijing Forestry University in 1997.

Chun Kwok Alan Au has served as our director since January 2020. Mr. Au is the founder of GT Healthcare, a private equity fund focusing on cross border healthcare investments, and has served as the managing partner of GT Healthcare since September 2015. Mr. Au has served as a member of the board, and the chairman of the audit committee of CSPC Pharmaceutical Group (HKEX: 1093), a leading pharmaceutical group in China, since January 2021. 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. He was also a member of the board of Cellular BioMedicine Group (Nasdaq: CBMG, privatized in February 2021), a clinical-stage biopharmaceutical firm engaged in the development of immunotherapies for cancer and stem cell therapies from November 2014 to February 2021. Prior to these, 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 also worked at KPMG and KPMG Corporate Finance from 1995 to 1999. 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 a member of the Hong Kong Institute of Financial Analysts and member of the American Institute of Certified Public Accountants.

Conor Chia-hung Yang has served as our director since January 2020. Mr. Yang has also served as the chief financial officer of Sunrate Holdings Limited since February 2023. Mr. Yang was a co-founder of Black Fish Group Limited and has served as the president of Black Fish Group Limited since November 2017 to February 2021. 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 also serves as an independent director of iQIYI, Inc. (Nasdaq: IQ), Tongcheng Travel Holdings Limited (HKEX: 0780) and UP Fintech Holdings Limited (Nasdaq: TIGR). Mr. Yang received a master's degree of business administration from University of California, Los Angeles in 1992.

Pamela M. Klein, M.D., has served as our director since January 2020. Dr. Klein currently a director of argenx SE (Nasdaq: ARGX) since April 2016, a director of Patrys Limited (ASX: PAB) since October 2019 and a director of Frontier Medicines (private) since January 2023. She previously served as a director of Spring Bank Pharmaceuticals (Nasdaq: SBPH); F-Star (Nasdaq: FSTR) and Jiya Acquisition Corp (Nasdaq: JYAC). 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.

Ruyi He, M.D., has served as our director since June 2021. Dr. He is the Chief Medical Officer (CMO) of RemeGen Inc and Venture Partner of SDIC Fund Management Co., the former Chief Scientist at the Center for Drug Evaluation at the National Medical Products Administration (NMPA). He joined the NMPA in 2016, after having worked at the U.S. Food and Drug Administration (FDA) for almost two decades. As the first overseas expert hired by NMPA as the Chief Scientist, Dr. He organized and led many NMPA reforms on the drug evaluation system. In addition to establishing guidance for drug evaluation and approvals in China, Dr. He has also introduced multiple international policies into the NMPA, including conditional approval and acceptance of clinical data from abroad. Dr. He received his medical degree from China Medical University. Dr. He received his bachelor's degree and master's degree in medical from China Medical University in 1983 and 1986, respectively, and his M.D. in Internal Medicine from Howard University in 1999. He completed his residency training in Internal Medicine at Howard University Hospital in Washington DC and received his clinical and research training at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) in Bethesda, Maryland. Dr. He is a licensed, board-certified physician in Internal Medicine in the United States.

Rong Shao, Ph.D., has served as our director since June 2021. Dr. Shao is a professor of drug administration policies and regulations, the Executive Deputy Director of the Research Center of National Drug Policy & Ecosystem (NDPE) and the Director of the NMPA Key Laboratory of Drug Regulatory Innovation and Evaluation, at China Pharmaceutical University. Dr. Shao has been engaged in the research and education of drug policies and regulations for more than three decades and has contributed to the development of China's drug regulatory innovation and reform, including serving as an expert committee member for NMPA in the revision of Drug Administration Law (2019). Dr. Shao is currently a board member and the committee chair in academic associations, such as the China Pharmaceutical Association and the China Society for Drug Regulation. She is also an editorial board member of China Pharmacy, Chinese Journal of New Drugs, and Chinese Journal of Health Policy. Dr. Shao holds a Ph.D. in Pharmacy Administration from Shenyang Pharmaceutical University, bachelor's degree in Medicinal Chemistry from China Pharmaceutical University, and bachelor's degree in Law from Nanjing University. Dr. Shao is also a Chinese practicing lawyer.

Weimin Tang, Ph.D., has served as our executive vice president of global business development since April 2018 and as our chief business officer since July 2021. Prior to joining our company, Dr. Tang served as an executive director and a business director at Hengrui Therapeutics, Inc. from July 2015 to March 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.

John Hayslip, M.D., has served as our Chief Medical Officer since April 2022 and has spent over 10 years leading global development teams across biopharma companies. Before joining I-Mab, Dr. Hayslip was the vice president of clinical development at Nektar Therapeutics (Nasdaq: NKTR) and prior to that, he led development activities for multiple therapies while at AbbVie Oncology. While previously at AbbVie, Dr. Hayslip assembled and led the AbbVie cross-functional lemzoparlimab team to setup for patient enrollment for the global partnership between I-Mab and AbbVie on lemzoparlimab. Prior to joining AbbVie Oncology, Dr. Hayslip was an accomplished academic researcher and physician at the University of Kentucky's Markey Cancer Center, where he led numerous cancer research studies with a primary focus in lymphoma and leukemia and served in leadership positions for the SWOG cancer research network, the oldest and largest publicly funded cancer research network in the United States. He also served as the chief for hematology and bone marrow transplant and as director of clinical research and data management at the Markey Cancer Center and was instrumental in securing National Cancer Institute cancer center designation for the university. Dr. Hayslip received his medical degree from Northeast Ohio Medical University and a master's degree in Clinical Research from the Medical University of South Carolina. Following his residency in internal medicine, Dr. Hayslip completed his fellowship in Hematology-Oncology at the Medical University of South Carolina leading to dual board certifications in both Hematology and Medical Oncology. Dr. Hayslip holds multiple U.S. and international patents and has published dozens of scientific papers and reviews in renowned journals including Lancet Haematology, Clinical Cancer Research, Leukemia Research, Blood, and Journal of Clinical Oncology.

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.

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. LoRusso 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, M.D., Ph.D., 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.

For the fiscal year ended December 31, 2022, we paid an aggregate of approximately US$9.8 million for salaries and benefits in cash to our executive officers, including the ones who resigned in 2022, and an aggregate of approximately US$448 thousand for compensation in cash to our independent directors. We did not pay any compensation to our directors who are not our independent directors or 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 March 31, 2023, options to purchase an aggregate of 1,748,628 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 is 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 becomes 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 March 31, 2023, 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
Weimin Tang	*	1.00	April 2, 2018	October 1, 2027
Other grantees	*	1.00	October 1, 2017 to December 28, 2018	October 1, 2027
Total	**1,748,628**			

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 March 31, 2023, awards to purchase an aggregate of 1,354,384 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 is 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 will vest in full with immediate effect upon the listing. Except as otherwise approved by the board of directors, vested portion of option becomes 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 will 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 March 31, 2023, 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
Weimin Tang	*	1.00	July 25, 2019	February 22, 2029
Other grantees	*	1.00	July 25, 2019	February 22, 2029
Total	**1,354,384**			

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 March 31, 2023, 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 March 31, 2023, 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 is 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 should not exceed 7,686,081 ordinary shares. As of March 31, 2023, options to purchase an aggregate of 2,586,302 ordinary shares and restricted share units to receive an aggregate of 808,792 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 will vest according to the schedules specified in the plan, unless otherwise determined by the plan administrator. The vesting schedule of other share-based awards should 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 March 31, 2023, 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 March 4, 2022	—
	*	9.20	March 4, 2022	March 4, 2032
Weimin Tang	* (1)	N/A	September 4, 2020 to March 4, 2022	—
	*	9.20	March 4, 2022	March 4, 2032
Gigi Qi Feng	* (1)	N/A	September 4, 2020 to March 4, 2022	—
	*	9.20	March 4, 2022	March 4, 2032
Richard Cheng Li	* (1)	N/A	March 4, 2022	—
Other grantees	*	5.91	August 14, 2020 to January 11, 2021	January 11, 2031
	*	19.67	April 1, 2021	April 1, 2031
	*	9.20	March 4, 2022	March 4, 2032
	* (1)	N/A	August 14, 2020 to March 4, 2022	—
Total	**3,395,094**			

Notes:

* Less than 1% of our total outstanding shares.

(1) Represents restricted share units.

2021 Share Incentive Plan

In May 2021, we adopted 2021 Share Incentive Plan, which we refer to as the 2021 Plan, to promote the success and enhance the value of our company. Under the 2021 Plan, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards is 12,023,618 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 2021 Plan should not exceed 6,011,809 ordinary shares. As of March 31, 2023, options to purchase an aggregate of 4,142,040 ordinary shares and restricted share units to receive an aggregate of 1,752,194 ordinary shares under the 2021 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 2021 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 will vest according to the schedules specified in the plan, unless otherwise determined by the plan administrator. The vesting schedule of other share-based awards should 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 March 31, 2023, the number of ordinary shares underlying outstanding options and restricted share units that we granted under the 2021 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	July 27, 2021	—
	*	26.39	July 27, 2021	July 27, 2031
Weimin Tang	* (1)	N/A	July 27, 2021 to February 1, 2023	—
	*	26.39	July 27, 2021	July 27, 2031
Gigi Qi Feng	*	N/A	July 27, 2021	—
	*	26.39	July 27, 2021	July 27, 2031
Richard Cheng Li	* (1)	N/A	July 27, 2021	—
	*	26.39	July 27, 2021	July 27, 2031
	*	9.20	March 4, 2022	March 4, 2032
Andrew Zhu	* (1)	N/A	March 4, 2022	—
	*	9.20	March 4, 2022	March 4, 2032
Richard Yeh	* (1)	N/A	January 4, 2023	—
	*	6.20	January 4, 2023	January 4, 2033
Ruyi He	* (1)	N/A	June 11, 2021	—
	*	31.23	June 11, 2021	June 11, 2031
Rong Shao	* (1)	N/A	June 11, 2021	—
	*	31.23	June 11, 2021	June 11, 2031
Other Grantees	* (1)	N/A	July 27, 2021 to February 1, 2023	—
	*	26.39	July 27, 2021	July 27, 2031
	*	9.20	March 4, 2022	March 4, 2032
	*	2.43	September 6, 2022	September 6, 2032
Total	**5,894,234**			

Notes:

* Less than 1% of our total outstanding shares.

(1) Represents restricted share units.

2022 Share Incentive Plan

In June 2022, we adopted 2022 Share Incentive Plan, which we refer to as the 2022 Plan, to promote the success and enhance the value of our company. Under the 2022 Plan, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards is 13,148,594 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 2022 Plan should not exceed 5,478,577 ordinary shares. Notwithstanding the foregoing, if we successfully complete extraordinary goals as approved by our board of directors, or such extraordinary goals are waived by our board of directors, the maximum aggregate number of ordinary shares which may be issued pursuant to all awards is 15,340,034 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 2022 Plan should not exceed 7,670,017 ordinary shares. The maximum aggregate number of ordinary shares which may be issued pursuant to all awards under the 2022 Plan shall be proportionately adjusted in the event of any share dividend, subdivision, reclassification, recapitalization, split, reverse split, combination, consolidation or similar transactions. As of March 31, 2023, options to purchase an aggregate of 6,672,944 ordinary shares and restricted share units to receive an aggregate of 4,883,452 ordinary shares under the 2022 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 2022 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 any authorized officer to the extent that the Board's powers or authority under the Plan have been delegated to such officer will administer the plan. The board of directors or any authorized officer, 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, consultants and other service providers of our company that our board of directors or any authorized officer deems appropriate. 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 plan administrator determines conditions and the time or times at which options and restricted share units may be exercised in whole or part. The vesting schedule of other share-based awards should be determined by the plan administrator, which is specified in the relevant award agreement.

Exercise of Options. The plan administrator determines the price, conditions and time(s) for exercising 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 March 31, 2023, the number of ordinary shares underlying outstanding options and restricted share units that we granted under the 2022 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	January 4, 2023	—
	*	2.41	January 4, 2023	January 4, 2033
Andrew Zhu	* (1)	N/A	January 4, 2023	—
	*	2.41	January 4, 2023	January 4, 2033
Richard Yeh	* (1)	N/A	January 4, 2023	—
	*	6.20	January 4, 2023	January 4, 2033
Weimin Tang	* (1)	N/A	January 4, 2023	—
	*	2.41	January 4, 2023	January 4, 2033
John Hayslip	* (1)	N/A	January 4, 2023	—
	*	2.41	January 4, 2023	January 4, 2033
Gigi Qi Feng	* (1)	N/A	January 4, 2023	—
	*	2.41	January 4, 2023	January 4, 2033
Richard Cheng Li	* (1)	N/A	January 4, 2023	—
	*	2.41	January 4, 2023	January 4, 2033
Other Grantees	3,087,267 (1)	N/A	January 4, 2023	—
	4,116,701	2.41	January 4, 2023	January 4, 2033
Total	**11,556,396**		—	—

Notes:

* Less than 1% of our total outstanding shares.

(1) Represents restricted share units.

C. Board Practices.

As of the date of this annual report, 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 should 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 four committees under the board of directors: an audit committee, a compensation committee, a nominating and corporate governance committee, and an environmental, social and governance (ESG) committee. We have adopted a charter for each of the four 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. Shuai Chen. Mr. Conor Chia-hung Yang is the chairperson of our audit committee. We have determined that each of Mr. Conor Chia-hung Yang, Mr. Chun Kwok Alan Au and Mr. Shuai Chen 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, Dr. Pamela M. Klein, and Dr. Ruyi He. Dr. Jingwu Zhang Zang is the chairperson of our compensation committee. We have determined that each of Mr. Chun Kwok Alan Au, Dr. Pamela M. Klein and Dr. Ruyi He 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, Mr. Conor Chia-hung Yang and Dr. Rong Shao. Mr. Wei Fu is the chairperson of our nominating and corporate governance committee. We have determined that each of Mr. Chun Kwok Alan Au, Mr. Conor Chia-hung Yang and Dr. Rong Shao 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.

Environmental, Social and Governance Committee. Our environmental, social and governance committee consists of Dr. Andrew Zhu, Mr. Chun Kwok Alan Au and Dr. Rong Shao. Mr. Chun Kwok Alan Au is the chairman of our environmental, social and governance committee. We have determined that each of Mr. Chun Kwok Alan Au and Dr. Rong Shao satisfies the "independence" requirements of Rule 5605(a)(2) of the Nasdaq Stock Market Rules. In addition, we will also establish an ESG working group to address daily ESG workflows. The environmental, social and governance committee is responsible for, among other things:

- supervising the ESG strategies, policies, long-term sustainability objectives and risks.

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 should 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 should 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.

Board Diversity

Board Diversity Matrix (As of March 31, 2023)

Country of Principal Executive Offices:	People's Republic of China
Foreign Private Issuer	Yes
Disclosure Prohibited Under Home Country Law	No
Total Number of Directors	11

	Female	Male	Non-Binary	Did Not Disclose Gender
Part I: Gender Identity				
Directors	3	8	—	—
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction			—	
LGBTQ+			—	
Did Not Disclose Demographic Background			—	

D. Employees.

We had 228, 378 and 318 employees as of December 31, 2020, 2021 and 2022, respectively. As of December 31, 2022, 272 employees were located in China and 46 were located outside China. The table below sets forth our employees by function as of December 31, 2022:

	Number
Management	11
Research and development	190
Chemistry, manufacturing and controls	31
General and administrative	62
Business and corporate development	9
Commercial	15
Total	318

We recruit our employees primarily through recruitment websites, recruiters, internal referrals and job fairs. Approximately 28% of total employees were hired through internal referrals. 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 mainland China. We prohibit any form of discrimination (including, but not limited to, employment, career development, salary, and benefits) on the basis of an employees' gender, race, age, physical condition, sexual orientation, marital status, or disability, so as to ensure a diverse and fair corporate culture. We aim to be a role model in promoting female business leadership in the biotech industry. We have undertaken multiple initiatives to encourage female leadership, including launching the I-Mab Women's Leadership Council (WLC) in July 2020. Approximately 71% of our employees are female, of which 59% hold a master's degree or above, while over 25% of our board of directors are female. We are carrying out a series of female leadership development programs committed to women's career and personal development.

We offer competitive salaries, benefits, and additional incentive to its employees. Employee compensation and benefits include position-specific salary, bonus and allowance, statutory insurance, and housing employee benefit funds (for those in China), statutory holidays, benefits and vacations, etc. In addition, we purchase additional commercial insurance for employees' underaged children, as well as a series of internal morale boosting incentive programs. We work to reward employees for exceptional performance. Our employee awards include Project Awards, Quarterly Stars, Management Awards, etc., with the goal of creating a culture of recognition.

We provide new hire training to our employees and periodic on-the-job training to enhance the skills and knowledge of our employees. We invest in employees' career development and provide them opportunities to keep updating their skills and knowledge. Our training system includes induction training for new employees, training on general knowledge, professional skills training, and leadership training, among which, leadership training focuses on improving employees' knowledge and ability in compliance management, drug quality control, business audit, financial standard procedures, as well as female leadership development. We encourage our employees to develop various training courses, and grade the content setting, applicability, practicability, and lecturer quality of the courses, to continuously improve them through collecting and addressing feedbacks. 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, 2023 by:

- each of our directors and executive officers; and

- each person known to us to own beneficially 5% or more of our total outstanding shares.

Percentage of beneficial ownership is based on 191,911,402 total outstanding ordinary shares as of March 31, 2023 (excluding 2,096,836 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)	10,689,505	5.5 %
Andrew Zhu	*	*
Richard Yeh	*	*
Wei Fu (2)	29,448,395	15.3 %
Lan Kang	—	—
Shuai Chen	*	*
Conor Chia-hung Yang	*	*
Pamela M. Klein	*	*
Ruyi He	*	*
Rong Shao	*	*
Weimin Tang	*	*
John Hayslip	—	—
Gigi Qi Feng	*	*
Richard Cheng Li	*	*
All Directors and Executive Officers as a Group	41,323,739	21.4 %
Other Principal Shareholders:		
C-Bridge entities (2)	29,448,395	15.3
Hillhouse entities (3)	16,520,560	8.6
GIC Private Limited (4)	12,131,203	6.3
Infini Capital (5)	11,509,674	6.0

Notes:

* Less than 1% of our total ordinary shares on an as-converted basis outstanding as of March 31, 2023.

** Except as otherwise indicated below, the business address of our directors and executive officers is 55th Floor, New Bund Center, 555 West Haiyang Road, Pudong District, Shanghai, China. The business address of Wei Fu is Suite 3306-3307, Two Exchange Square, 8 Connaught Place, Central, Hong Kong. The business address of Lan Kang is Floor 62, Plaza 66, Tower 1, 1266 West Nanjing Road, Shanghai, China. The business address of Mr. Shuai Chen is 25/F, Hexa International Plaza, No.9 Chaoyangmen North Street, Dongcheng District, Beijing, China. The business address of Ruyi He is Unit 1506, Central Tower, China Overseas Plaza, No.8 Guanghua Dongli, Chaoyang District, Beijing, China. The business address of Rong Shao is No. 24 Tongjiaxiang, Gulou District, Nanjing, Jiangsu Province, China. The business address of Chun Kwok Alan Au is 22 Pottinger Street, Central, Hong Kong. The business address of Conor Chia-hung Yang is 2/F, East Tower, Qihao Beijing, No. 8 Xinyuan South Road, Chaoyang District, Beijing, China. The business address of Pamela M. Klein is 231 Fort Mason, San Francisco, California 94123, the United States.

(1) Represents (i) 3,235,161 ordinary shares directly held by Mabcore Limited, a British Virgin Islands company, (ii) 207,765 ordinary shares held by Dr. Zang through The 2019 Hasselt Revocable Trust, (iii) 5,962,625 ordinary shares, including 114,890 ordinary shares in the form of ADSs, held by Dr. Zang through The Doctor Zang 2020 Dynasty Trust, and (iv) 684,416 ordinary shares in the form of ADSs and 599,538 ordinary shares issuable upon the exercise of options exercisable and the vesting of restricted share units within 60 days after March 31, 2023 held by Dr. Zang. Dr. Zang, through himself and The Jingwu Zhang Zang 2018 Irrevocable Family Trust, owns a 55.6% equity interest in Mabcore Limited. Three 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 co-managed by Ms. Zang, as the trustee, and by Dr. Zang, as the settlor. 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 3,235,161 ordinary shares held by Mabcore Limited, while three other 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. The 2019 Hasselt Revocable Trust was established under the laws of the State California and is co-managed by Dr. Zang and Ms. Zang (Dr. Zang's spouse), each as a settlor and a trustee. The Doctor Zang 2020 Dynasty Trust was established under the laws of the State of California and is co-managed by Dr. Zang, as the settlor and the investment trustee, and by Ms. Zang, as the trustee.

(2) Represents (i) 1,583,280 ADSs and 10 ordinary shares directly held by IBC Investment Seven Limited, a Hong Kong limited liability company, (ii) 2,423,720 ADSs and 4 ordinary shares directly held by CBC SPVII LIMITED, a Hong Kong limited liability company, (iii) 5,123,540 ADSs and 22 ordinary shares directly held by CBC Investment I-Mab Limited, a British Virgin Islands limited liability company, (iv) 1,030,230 ADSs and 17 ordinary shares directly held by C-Bridge II Investment Ten Limited, a British Virgin Islands limited liability company, and (v) 6,078,571 ordinary shares directly held by Everest. IBC Investment Seven Limited, CBC SPVII LIMITED, CBC Investment I-Mab Limited, C-Bridge II Investment Ten Limited, Everest 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. Information regarding beneficial ownership is reported as of December 31, 2022, based on the information contained in the Schedule 13G/A filed by the C-Bridge entities on February 15, 2023. Please see the Schedule 13G/A filed by the C-Bridge entities with SEC on February 15, 2023 for information relating to the C-Bridge entities. 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) 7,182,850 ADSs (representing 16,520,555 ordinary shares) held by funds managed by HHLR Advisors, Ltd., or HHLR, an exempted Cayman Islands company, and (ii) 5 ordinary shares held by a fund managed by Hillhouse Investment Management, Ltd., or HIM, an exempted Cayman Islands company. HHLR acts as the sole investment manager of YHG Investment, L.P., or YHG, and the sole management company of HHLR Fund, L.P., or HHLR Fund. HHLR is hereby deemed to be the beneficial owner of, and to control the voting and investment power of, the voting ordinary shares held by YHG and HHLR Fund. HIM acts as the sole management company of Hillhouse Fund IV, L.P., or Fund IV. Fund IV owns HH IMB Holdings Limited, or HH IMB. HIM is hereby deemed to be the beneficial owner of, and to control the voting and investment power of, the voting ordinary shares held by HH IMB. HH IMB, YHG and HHLR Fund are collectively referred to as the Hillhouse entities. The directors of each of HHLR and HIM are Colm O'Connell and Bridget Kidner. Mr. O'Connell and Ms. Kidner are employees of each of HHLR and HIM and Mr. Lei Zhang is the Founder and President of each of HHLR and HIM. Information regarding beneficial ownership is reported as of September 23, 2021, based on the information contained in the Schedule 13D/A jointly filed by HHLR and HIM on September 27, 2021. Please see the Schedule 13D/A jointly filed by HHLR and HIM with SEC on September 27, 2021 for information relating to the Hillhouse entities, HHLR and HIM. The business address of each of HHLR and HIM is Office #122, Windward 3 Building, Regatta Office Park, West Bay Road, Grand Cayman, Cayman Islands, KY1-9006.

(4) Represents 5,274,436 ADSs (representing 12,131,203 ordinary shares) held by GIC Private Limited ("GIC"), a Singapore fund manager. Cliff Investment Pte. Ltd. shares the power to vote and the power to dispose of 5,538,471 ordinary shares (represented by 2,408,031 ADSs) held directly by it with GIC Special Investments Private Limited ("GIC SI") and GIC. GIC SI is wholly owned by GIC and is the private equity investment arm of GIC. Gamsino Pte. Ltd. shares the power to vote and the power to dispose of 6,592,732 ordinary shares (represented by 2,866,405 ADSs) held directly by it with GIC Asset Management Private Limited ("GAM") and GIC. GAM is wholly owned by GIC and is the public equity investment arm of GIC. GIC is a fund manager and only has two clients – the Government of Singapore ("GoS") and Monetary Authority of Singapore ("MAS"). Under the investment management agreement with GoS, GIC has been given the sole discretion to exercise the voting rights attached to, and the disposition of, any shares managed on behalf of GoS. GIC is wholly owned by the GoS and was set up with the sole purpose of managing Singapore's foreign reserves. The GoS disclaims beneficial ownership of such shares. Information regarding beneficial ownership is reported as of December 31, 2022, based on the information contained in the Schedule 13G/A filed by GIC Private Limited on February 7, 2023. Please see the Schedule 13G/A filed by GIC Private Limited with SEC on February 7, 2023 for information relating to GIC Private Limited. The business address of GIC Private Limited is 168 Robinson Road, #37-01 Capital Tower, Singapore 068912.

(5) Represents 5,004,206 ADSs held by Infini Master Fund, an exempted company incorporated in the Cayman Islands with limited liability. Infini Capital Management Limited, a private company limited by shares incorporated in Hong Kong, serves as investment manager to Infini Master Fund and has discretionary and voting power over the shares held by Infini Master Fund. Accordingly, Infini Capital Management Limited may be deemed to be the beneficial owner of 5,004,206 ADSs which are held by Infini Master Fund. Infini Capital Management Limited disclaims beneficial ownership of the ADSs held by Infini Master Fund, except to the extent of any pecuniary interest therefrom. Information regarding beneficial ownership is reported as of June 7, 2022, based on the information contained in the Schedule 13G jointly filed by Infini Master Fund and Infini Capital Management Limited on June 13, 2022. Please see the Schedule 13G jointly filed by Infini Master Fund and Infini Capital Management with SEC on June 13, 2022 for information relating to Infini Master Fund and Infini Capital Management Limited. The address of the principal business office of the Infini Master Fund is c/o Walkers Corporate Limited, Cayman Corporate Centre, 27 Hospital Road, George Town, Grand Cayman, KY1-9008, Cayman Islands.

To our knowledge, as of March 31, 2023, three of our ordinary shares were held by three record holders in the United States (including 2,096,836 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 85.8% of our total outstanding shares. One of the U.S. holders 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.

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

Not applicable.

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 should, 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 should 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 should 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 will 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 will 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 will 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 should 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 should be reduced pro rata among all such selling shareholders. We should 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 should 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 should 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 should 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 (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 does 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 should 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 should cause an individual jointly designated by the Hillhouse Entities to be appointed as the investor director with immediate effect no later than the fifteenth (15th) 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 should 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 should 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—Share Incentive Plans."

Other Transactions with Related Parties

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 mainland China, Hong Kong, Macau and Taiwan. On November 4, 2019, we and Everest Medicines Limited terminated the collaboration agreement (including all the supplements and amendments thereto) with respect to the co-development and commercialization of felzartamab in Greater China.

In August 2021, we entered into a project development service agreement with I-Mab Hangzhou, for the product development services we rendered for selected pipeline sub-licensed or assigned to I-Mab Hangzhou, including TJ301, TJM2 (excluding cytokine release syndrome indications) and a few pre-clinical programs that are unessential to our immune-oncology focus. In 2021 and 2022, I-Mab Hangzhou paid us RMB52.4 million and nil for the product development services we offered. In July 2021, we entered into a biologics master services agreement with I-Mab Hangzhou. Under the framework of this biologics master services agreement, we entered into series of work orders with respect to process development and manufacturing service for our drug assets in 2021 and 2022, respectively. Pursuant to the work orders signed with I-Mab Hangzhou in 2022, I-Mab Hangzhou will provide us with CMC development and manufacturing services for a total of RMB126.5 million (US$18.3 million). We paid I-Mab Hangzhou RMB10.7 million and RMB46.2 million (US$6.7 million) for the years ended December 31, 2021 and 2022, respectively.

In December 2021, we entered into a supplementary sublicensing agreement with I-Mab Hangzhou, pursuant to which I-Mab Hangzhou, as a sub-licensee of olamkicept (TJ301) in Greater China and Korea, agreed to pay US$3.0 million to us for the completion of olamkicept (TJ301) Phase 2a study report. After receiving the milestone payment of RMB19.1 million (US$3.0 million) from I-Mab Hangzhou, we settled the payment of US$3.0 million with Ferring, as of December 31, 2022.

On July 16, 2022, I-Mab Hangzhou entered into a definitive financing agreement with a group of domestic investors in China to raise approximately US$46 million (in RMB equivalent). On the same date, we, through our wholly-owned subsidiary, entered into a shareholders agreement with I-Mab Hangzhou and other domestic investors in I-Mab Hangzhou named therein (the "I-Mab Hangzhou Shareholders Agreement"). Upon the occurrence of certain triggering events as specified in the I-Mab Hangzhou Shareholders Agreement, including but not limited to I-Mab Hangzhou's failure to accomplish certain public offering condition, we may be obligated to repurchase the equity held by other domestic investors in cash or in our stocks in the period beyond 12 months.

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. 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. Accordingly, we have already accrued and recorded this termination fee of US$9.0 million as administrative expenses in our consolidated financial statements for the year ended December 31, 2021. The disputes relating to the TJD5 Agreement and the BsAbs Agreement were presented to a binding arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce before an arbitration tribunal. On April 25, 2023, we announced positive outcomes in the arbitration. The arbitration award determined that the TJD5 Agreement has been terminated for a pre-agreed termination fee of $9.0 million plus interest payable pursuant to the original agreement, and, therefore Tracon has no rights to share any future economics with I-Mab. The arbitration award completely denied Tracon's damages claim of over US$200 million for any breach and awarded no damages to Tracon. The tribunal also confirmed the termination of the BsAb Agreement. Based on the arbitration award, I-Mab will bear a portion of Tracon's legal fees and costs, totaling approximately US$13.5 million, which was recorded as administrative expenses in our consolidated financial statements for the year ended December 31, 2022. Due to Tracon's wrong-doing during the confidential arbitration process, we are pursuing a trade secret misappropriation lawsuit case against a competitor of us and seeking remedies, including potentially substantial monetary damages. Regardless of the outcome, litigations or arbitrations can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. 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.

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 amended and restated 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 should 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.

Alteration 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 prescribes;
- 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 should 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 should specify the meeting as such in the notices calling it, and the annual general meeting will 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 should, 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 should 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 are more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus should 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 should 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 should 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 determines.

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. Shareholders have no general right under Cayman Islands law to inspect or obtain copies of our list of shareholders or our corporate records (save for our memorandum and articles of association and our register of mortgages and charges). 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 should 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 should be reduced pro rata among all such selling shareholders. We should 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 should 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 does 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 should 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 and the Dividend Distribution."

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

According to Harney Westwood & Riegels, our Cayman Islands counsel, 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 to, or produced before a court 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 and save that stamp duties may be applicable on instruments executed in, or brought to, or produced before a court of 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, as I-Mab does not meet all of the above conditions and given that neither I-Mab nor any of its PRC Subsidiaries has received any notice from the PRC tax authorities confirming, directly or indirectly, that I-Mab is a PRC resident enterprise for PRC tax income purposes as of the date of this annual report, I-Mab should not be considered as a PRC resident enterprise for PRC income tax purposes.

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." 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 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.

Based upon the nature and composition of our assets (in particular, the retention of substantial amounts of cash and investments), and the market price of our ADSs, we believe that we were a PFIC for the taxable year ended December 31, 2022 and we will likely be a PFIC for our current taxable year unless the market price of our ADSs increases and/or we invest a substantial amount of the cash and other passive assets we hold in assets that produce or are held for the production of active income.

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. However, if we cease to be a PFIC, provided that you have not made a mark-to-market election, as described below, you may avoid some of the adverse effects of the PFIC regime by making a "deemed sale" election with respect to the ADSs or ordinary shares, as applicable. If such election is made, you will be deemed to have sold our ADSs or ordinary shares you hold at their fair market value and any gain from such deemed sale would be subject to the rules described below under "Passive Foreign Investment Company Rules." After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, your ADSs or ordinary shares with respect to which such election was made will not be treated as shares in a PFIC and you will not be subject to the rules described below with respect to any "excess distribution" you receive from us or any gain from an actual sale or other disposition of the ADSs or ordinary shares. The rules dealing with deemed sale elections are very complex. Each U.S. Holder should consult its tax advisors regarding the possibility and considerations of making a deemed sale election.

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. Our ADSs (but not our ordinary shares) are listed on the Nasdaq Global Market and is considered readily tradable on an established securities market in the United States. 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.

As discussed above, we believe that we were a PFIC for the taxable year ended December 31, 2022, and we will likely be classified as a PFIC for our current taxable year. U.S. Holders are urged to consult their tax advisors regarding the availability of the reduced rate of taxation on dividends with respect to our ADSs or ordinary shares 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. Pursuant to recently issued Regulations, however, if a U.S. Holder is not eligible for the benefits of the Treaty or does not elect to apply the Treaty, then such holder may not be able to claim a foreign tax credit arising from any PRC tax imposed on the disposition of ADSs or ordinary shares. The rules regarding foreign tax credits and deduction of foreign taxes are complex. U.S. Holders should consult their tax advisors regarding the availability of a foreign tax credit or deduction in light of their particular circumstances, including their eligibility for benefits under the Treaty and the potential impact of the recently issued Regulations.

As discussed above, we believe that we were a PFIC for the taxable year ended December 31, 2022, and we will likely be classified as a PFIC for our current taxable year. U.S. Holders are urged to consult their tax advisors regarding the tax considerations of the sale or other disposition of our ADSs or ordinary shares under their particular circumstances.

Passive Foreign Investment Company Rules

As discussed above, we believe that we were a PFIC for the taxable year ended December 31, 2022, and we will likely be classified as a PFIC for our current taxable year. 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, provided that such stock is regularly traded on a qualified exchange or other market, as defined in the applicable United States Treasury regulations. For those purposes, our ADSs, but not our ordinary shares, are listed on the Nasdaq Global Market, which is a qualified exchange. We anticipate that our ADSs should qualify as being regularly traded, but no assurances may be given in this regard. 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.

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.

J. Annual Report to Security Holders

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 2020, 2021 and 2022 were increases of 0.2%, 1.5% and 1.8%, 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 RMB4,758.8 million, RMB3,523.6 million and RMB3,310.8 million (US$480.0 million) as of December 31, 2020, 2021 and 2022, 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, 2022, we had RMB-denominated cash and cash equivalents, restricted cash and short-term investments of RMB1,744.0 million (US$252.9 million). A 10% depreciation of RMB against U.S. dollar based on the foreign exchange rate on December 30, 2022 would result in a decrease of US$25.3 million in cash and cash equivalents. A 10% appreciation of RMB against U.S. dollar based on the foreign exchange rate on December 30, 2022 would result in an increase of US$25.3 million in cash and cash equivalents.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Charges Our ADS Holders May Have to Pay

The depositary of our ADS facility, Citibank, N.A., charges 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 US$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 US$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 US$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 US$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 US$5.00 per 100 ADSs (or fraction thereof) held.	Person to whom the distribution is made.
(6) ADS Services.	Up to US$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 US$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 US$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 arid 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 should 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 received approximately US$3.7 million 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

See "Item 10. Additional Information—B. Memorandum and Articles of Association" for a description of the rights of securities holders, which remain unchanged.

ITEM 15. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our acting chief executive officer and interim 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 Exchange Act) as of the end of the period covered by this report, as required by Rule 13a-15(b) under the Exchange Act.

Based upon that evaluation, our management has concluded that, as of December 31, 2022, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file and furnish under the Exchange Act was 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 acting chief executive officer and interim chief financial officer, to allow timely decisions regarding required disclosure.

Management's Annual 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 internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with Generally Accepted Accounting Principles (GAAP) in the United States of America and includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with GAAP, and that receipts and expenditures of our company are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of the unauthorized acquisition, use or disposition of our company's assets that could have a material effect on the consolidated financial statements.

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.

As required by Section 404 of the Sarbanes-Oxley Act of 2002 and related rules as promulgated by the Securities and Exchange Commission, our management including our acting chief executive officer and interim chief financial officer assessed the effectiveness of internal control over financial reporting as of December 31, 2022 using the criteria set forth in the report "Internal Control—Integrated Framework (2013)" published by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Attestation Report of the Registered Public Accounting Firm

The effectiveness of internal control over financial reporting as of December 31, 2022 has been audited by PricewaterhouseCoopers Zhong Tian LLP, an independent registered public accounting firm, who has also audited our consolidated financial statements for the year ended December 31, 2022.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during the period covered by this annual report on Form 20-F 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,	
	2021	2022
	(in thousands of RMB)	
Audit fees [(1)]	7,730	5,450
Tax fees [(2)]	75	86
All other fees	—	—

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 planned dual listing.

(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 29, 2021, we announced that our board of directors has authorized a stock repurchase program, under which we may repurchase up to US$40 million of our ordinary shares in the form of ADS for a 12-month period. The stock repurchase program became effective on September 12, 2022, the date on which a formal stock repurchase plan engagement agreement was signed with a qualified broker-dealer(s), and terminates over a twelve-month period depending upon market and economic conditions, and other factors including price, legal and regulatory requirements and capital availability. The program does not obligate I-Mab to acquire any particular number of its ADSs, and the program may be modified or suspended at any time at the management's discretion.

In 2022, we purchased an aggregate of 718,496 ADSs under our stock repurchase program. The table below is a summary of the shares repurchased by us in 2022. All shares were repurchased in the open market pursuant to the authorized stock repurchase program.

Period	Total Number of ADSs Purchased	Average Price Paid Per ADS	Total Number of ADSs Purchased as Part of the Publicly Announced Plan	Approximate Dollar Value of ADSs that May Yet bePurchased Under the Plan
September 2022	242,411	US$4.83	242,411	US$38.8 million
October 2022	411,792	US$3.77	654,203	US$37.7 million
November 2022	64,293	US$4.37	718,496	US$37.0 million
Total	**718,496**	**US$4.18**	**718,496**	**US$37.0 million**

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.

In lieu of (i) the requirements of Rule 5605(b) of the Nasdaq Rules that a majority of a Nasdaq-listed company's board of directors be independent directors as defined in Rule 5605(a)(2), (ii) the requirements of Rule 5605(d) that a compensation committee be comprised solely of independent directors, (iii) the requirements of Rule 5605(e) that a nominating committee be comprised solely of independent directors, (iv) the requirements of Rule 5620(a) that each Nasdaq-listed company should hold an annual general meeting of shareholders no later than one year after the end of its fiscal year-end, and (v) the requirements of Rule 5635(c) of the Nasdaq Rules that shareholder approval be required prior to the issuance of securities when a stock option or purchase plan is to be established or materially amended or other equity compensation arrangement made or materially amended, pursuant to which stock may be acquired by officers, directors, employees, or consultants, we have followed and intend to continue to follow our home country practices with respect to the composition of our board of directors and board committees, annual shareholders meeting as well as the approval for adoption and material amendment to our equity-based compensation plans. 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—General 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.

ITEM 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

On December 16, 2021, the PCAOB issued a report to notify the SEC of its determination that the PCAOB was unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong, and our auditor was subject to that determination.

In May 2022, I-Mab was conclusively listed by the SEC as a Commission-Identified Issuer under the HFCAA following the filing of our annual report on Form 20-F for the fiscal year ended December 31, 2021.

On December 15, 2022, the PCAOB removed mainland China and Hong Kong from the list of jurisdictions where it is unable to inspect or investigate completely registered public accounting firms. For this reason, we do not expect to be identified as a Commission-Identified Issuer under the HFCAA after we file this annual report.

To the best of our knowledge, no Cayman Islands governmental entities own any shares of I-Mab as of the date of this annual report.

To the best of our knowledge, no PRC governmental entities own any shares of I-Mab or its subsidiaries as of the date of this annual report. Therefore, PRC governmental entities do not have a controlling financial interest in I-Mab or its subsidiaries as of the date of this annual report.

No member of the board of directors of I-Mab or our operating entities is an official of the Chinese Communist Party as of the date of this annual report.

The currently effective memorandum and articles of association of I-Mab and the equivalent organizing documents of our operating entities do not contain any charter of the Chinese Communist Party.

ITEM 16J. INSIDER TRADING POLICIES

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	2021 Share Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the registration statement on Form S-8 (File No. 333-256603), as amended, initially filed with the SEC on May 28, 2021)
4.6	2022 Share Incentive Plan (incorporated herein by reference to Exhibit 10.1 to the registration statement on Form S-8 (File No. 333-265684), as amended, initially filed with the SEC on June 17, 2022)
4.7	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)

Exhibit Number	Description of Document
4.8	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)
4.9	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)
4.10†	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)
4.11	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)
4.12	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)
4.13	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)
4.14†	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)
4.15	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)
4.16	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)
4.17	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)
4.18	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†	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)
4.20†	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)
4.21†	English translation of Exclusive Development Manufacture, and Sales Collaboration Agreement, dated as of November 10, 2021, among I-Mab Biopharma Hong Kong Limited, I-Mab Biopharma Co., Ltd., Jumpcan Pharmaceutical Group Co., Ltd. and Jiangsu Jiyuan Medicine Co., Ltd. (incorporated herein by reference to Exhibit 4.24 to the annual report on Form 20-F (File No. 001-39173), as amended, initially filed with the SEC on April 29, 2022)

Exhibit Number	Description of Document
4.22†*	Amendment No.1 to the License and Collaboration Agreement dated as of August 15, 2022 among I-Mab Shanghai, I-Mab US and AbbVie Global Enterprise Ltd.
4.23*	English translation of Investment Agreement, dated as of July 16, 2022, among I-Mab Biopharma (Hangzhou) Co., Ltd. and other parties thereto
4.24*	English translation of Shareholders Agreement, dated as of July 16, 2022, among I-Mab Biopharma (Hangzhou) Co., Ltd. and other parties thereto
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
15.3*	Consent of Harney Westwood & Riegels
101.INS*	Inline XBRL Instance Document—this instance document does not appear in the Interactive Data File because its XBRL tags are 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/ Richard Yeh
Name: Richard Yeh
Title: Director, Chief Operating Officer and
Interim Chief Financial Officer

Date: May 1, 2023

I-Mab

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of I-Mab

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of I-Mab and its subsidiaries (the "Company") as of December 31, 2022 and 2021, 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, 2022, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 15. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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 risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Accrued Research and Development Expenses

As described in Notes 2.18 and 12 to the consolidated financial statements, the Company has entered into various research and development contracts with research organizations and other companies. Total research and development costs incurred during the year ended December 31, 2022 were RMB905 million, and research and development costs accrued were RMB265 million as of December 31, 2022. Management applied significant judgment in estimating the progress of its research and development activities and completion of or likelihood of achieving milestone events per underlying agreements when estimating the research and development costs to be accrued at each reporting period end.

The principal considerations for our determination that performing procedures relating to accrued research and development expenses is a critical audit matter are the significant judgment made by management in estimating the accrued research and development expenses, including the estimation of the progress of its research and development activities and completion of or likelihood of achieving milestone events per underlying agreements. This in turn led to a relatively high degree of auditor judgement, subjectivity, and effort in performing procedures relating to management's estimation of accrued research and development costs and evaluating the related audit evidence.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the estimation of accrued research and development costs. These procedures also included, among others, (i) testing management's process for estimating accrued research and development costs; (ii) evaluating the appropriateness of the method used by management to develop the estimates; (iii) evaluating the reasonableness of the estimates related to the progress of research and development activities and completion of or likelihood of achieving milestone events per underlying agreements; and (iv) testing the completeness and accuracy of underlying data used to estimate accrued research and development expenses.

Valuation of put right liabilities

As described in Notes 2.4, 10 and 18 to the consolidated financial statements, the put right written by the Company to domestic investors in its affiliate was recorded as a freestanding equity-linked instrument and classified as put right liabilities. The fair value of the put right liabilities was determined by management using an option pricing model. The significant unobservable inputs used in the option pricing model included spot price, estimated volatility and probability of triggering event for redemption option, among which the spot price was determined by management using the market approach and the expected volatility was estimated based on daily stock prices of the comparable companies for a period with length commensurate to the expected terms of redemption event. The significant unobservable inputs used in the market approach include estimated volatility and probability of triggering event for redemption option. The Company recognized the put right liabilities of RMB89 million as of December 31, 2022 and the decrease in fair value of the put right liabilities of RMB34 million during the year ended December 31, 2022.

The principal considerations for our determination that performing procedures relating to the valuation of put right liabilities is a critical audit matter are the significant judgment made by management in determining the fair value of the put right liabilities related to estimated volatility and probability of triggering event for redemption option, which in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures relating to the fair value measurement of the put right liabilities and evaluating the related audit evidence, and the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's valuation of the put right liabilities. These procedures also included, among others, testing management's process for estimating the fair value of the put right liabilities, which included (i) evaluating the appropriateness of the valuation methods, (ii) testing the completeness, mathematical accuracy and relevance of the underlying data used in the option pricing model and market approach, and (iii) evaluating the reasonableness of significant assumptions related to estimated volatility and probability of triggering event for redemption option. The estimated volatility was evaluated by considering the relevance and appropriateness of the comparable company selection for the volatility calculation. The probability of triggering event for redemption option was evaluated by considering the business development status and plan of the affiliate. Professionals with specialized skill and knowledge were used to assist in evaluating the appropriateness of the Company's valuation methods and the reasonableness of the significant assumptions related to the estimated volatility applied.

Goodwill impairment assessments

As described in Notes 2.14 and 9 to the consolidated financial statements, the Company's goodwill balance was RMB163 million as of December 31, 2022. Management performs impairment tests to assess the carrying value of goodwill on an annual basis or more frequently if events or changes in circumstances indicate that goodwill might be impaired. Where the qualitative assessment indicated that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, including goodwill, a quantitative goodwill impairment test is performed. Goodwill impairment charge is recognized for the amount by which the carrying amount exceeds the reporting unit's fair value. Fair value of the reporting unit is estimated by management using a discounted cash flow model. The use of discounted cash flow model requires management to make judgments and assumptions related to future revenues, discount rate and terminal growth rate. Based on the goodwill impairment test of the Company's reporting unit as of December 31, 2022, management determined that the estimated fair value of the reporting unit exceeded its carrying value and therefore, no impairment was recorded.

The principal considerations for our determination that performing procedures relating to the goodwill impairment assessments is a critical audit matter are the significant judgment made by management in developing the fair value of the reporting unit. This in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and in evaluating management's significant assumptions related to future revenues, discount rate and terminal growth rate, and the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's goodwill impairment assessment process, including controls over the valuation of the Company's reporting unit. These procedures also included, among others, testing management's identification of the reporting unit and the process for developing the fair value estimates, which included (i) evaluating the appropriateness of the discounted cash flow model, (ii) testing the completeness, accuracy and relevance of the underlying data used in the discounted cash flow model, and (iii) evaluating the reasonableness of the significant assumptions related to future revenues, discount rate and terminal growth rate. Evaluating management's assumptions related to future revenues, discount rate and terminal growth rate involved evaluating whether the assumptions used by management were reasonable considering the current and historical performance of the reporting unit; the consistency with relevant industry and market data; and whether these assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in the evaluation of the Company's discounted cash flow model, and the discount rate and terminal growth rate assumptions.

/s/PricewaterhouseCoopers Zhong Tian LLP
Shanghai, the People's Republic of China
May 1, 2023

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

I-MAB
Consolidated Balance Sheets
As of December 31, 2021 and 2022
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Notes	As of December 31, 2021 RMB	2022 RMB	2022 US$ (Note 2.5)
Assets				
Current assets				
Cash and cash equivalents		3,523,632	3,214,005	465,987
Restricted cash	2.7	—	96,764	14,029
Accounts receivable	3, 17	33,081	—	—
Contract assets	3, 17	253,780	—	—
Short-term investments	2.4, 2.9	753,164	235,429	34,134
Inventories	4	27,237	—	—
Prepayments and other receivables	5	190,824	80,278	11,639
Total current assets		4,781,718	3,626,476	525,789
Property, equipment and software	6	45,716	60,841	8,821
Operating lease right-of-use assets	7	112,781	63,125	9,152
Intangible assets	8	119,666	118,888	17,237
Goodwill	9	162,574	162,574	23,571
Investments accounted for using the equity method	10	352,106	30,850	4,473
Other non-current assets		26,634	10,911	1,582
Total assets		**5,601,195**	**4,073,665**	**590,625**
Liabilities and shareholders' equity				
Current liabilities				
Short-term bank borrowings	11	—	18,956	2,748
Accruals and other payables	12	593,335	706,572	102,443
Contract liabilities, current		—	8,677	1,258
Operating lease liabilities, current	7	30,669	23,961	3,474
Total current liabilities		624,004	758,166	109,923
Put right liabilities	2.4, 10	96,911	88,687	12,858
Contract liabilities, non-current	17	224,000	267,878	38,839
Operating lease liabilities, non-current	7	81,786	32,069	4,650
Other non-current liabilities	12	14,934	16,963	2,459
Total liabilities		**1,041,635**	**1,163,763**	**168,729**
Commitments and contingencies	21			
Shareholders' equity				
Ordinary shares (US$0.0001 par value, 800,000,000 shares authorized as of December 31, 2021 and 2022; 183,826,753 and 190,879,919 shares issued and outstanding as of December 31, 2021 and 2022, respectively)	14	126	132	19
Treasury stock	14	—	(21,249)	(3,081)
Additional paid-in capital		9,100,777	9,579,375	1,388,879
Accumulated other comprehensive income (loss)		(186,510)	213,794	30,997
Accumulated deficit		(4,354,833)	(6,862,150)	(994,918)
Total shareholders' equity		**4,559,560**	**2,909,902**	**421,896**
Total liabilities and shareholders' equity		**5,601,195**	**4,073,665**	**590,625**

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, 2020, 2021 and 2022
(All amounts in thousands, except for share and per share data, unless otherwise noted)

		Year Ended December 31,			
		2020	2021	2022	
	Notes	RMB	RMB	RMB	US$ (Note 2.5)
Revenues					
Licensing and collaboration revenue	17	1,542,668	40,115	(249,665)	(36,198)
Supply of investigational products	4	—	47,911	28,102	4,074
Total revenues		**1,542,668**	**88,026**	**(221,563)**	**(32,124)**
Cost of revenues		—	(46,432)	(27,237)	(3,949)
Expenses					
Research and development expenses	2.18	(984,689)	(1,212,958)	(904,901)	(131,198)
Administrative expenses		(402,409)	(899,943)	(815,766)	(118,275)
Income (loss) from operations		**155,570**	**(2,071,307)**	**(1,969,467)**	**(285,546)**
Interest income		24,228	21,333	26,908	3,901
Interest expense		(957)	—	(9)	(1)
Other income (expenses), net	18	412,892	83,162	(126,587)	(18,353)
Equity in loss of affiliates	10	(108,587)	(367,883)	(437,465)	(63,426)
Income (loss) before income tax expense		**483,146**	**(2,334,695)**	**(2,506,620)**	**(363,425)**
Income tax benefit (expense)	13	(12,231)	3,154	(697)	(101)
Net income (loss) attributable to I-MAB		**470,915**	**(2,331,541)**	**(2,507,317)**	**(363,526)**
Net income (loss) attributable to ordinary shareholders		**470,915**	**(2,331,541)**	**(2,507,317)**	**(363,526)**
Net income (loss) attributable to I-MAB		**470,915**	**(2,331,541)**	**(2,507,317)**	**(363,526)**
Other comprehensive income (loss):					
Foreign currency translation adjustments, net of nil tax		(120,920)	(135,717)	400,304	58,039
Total comprehensive income (loss) attributable to I-MAB		**349,995**	**(2,467,258)**	**(2,107,013)**	**(305,487)**
Net income (loss) attributable to ordinary shareholders		**470,915**	**(2,331,541)**	**(2,507,317)**	**(363,526)**
Weighted-average number of ordinary shares used in calculating net income (loss) per share - basic	19	134,158,824	174,707,055	189,787,292	189,787,292
Weighted-average number of ordinary shares used in calculating net income (loss) per share - diluted	19	157,231,652	174,707,055	189,787,292	189,787,292
Net income (loss) per share attributable to ordinary shareholders					
—Basic	19	3.51	(13.35)	(13.21)	(1.92)
—Diluted	19	3.00	(13.35)	(13.21)	(1.92)
Net income (loss) per ADS attributable to ordinary shareholders					
—Basic		8.07	(30.71)	(30.38)	(4.41)
—Diluted		6.90	(30.71)	(30.38)	(4.41)

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, 2020, 2021 and 2022
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Ordinary share (Note 14) (US$0.0001 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 16)	7,000	—	—	46	—	—	46
Conversion from convertible promissory notes	900,000	1	—	58,825	—	—	58,826
Capital contribution from stock option surrender (Note 16)	—	—	—	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 10 (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**

I-MAB
Consolidated Statements of Changes in Shareholders' Equity (Deficit) (Continued)
For the Years Ended December 31, 2020, 2021 and 2022
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Ordinary share (Note 14) (US$0.0001 par value)						
	Number of shares	Amount	Treasury stock	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity
		RMB	RMB	RMB	RMB	RMB	RMB
Balance as of December 31, 2020	**164,888,519**	**114**	**—**	**7,701,116**	**(50,793)**	**(2,023,292)**	**5,627,145**
Foreign currency translation adjustments	—	—	—	—	(135,717)	—	(135,717)
Net loss	—	—	—	—	—	(2,331,541)	(2,331,541)
Share-based compensation of I-Mab	—	—	—	608,609	—	—	608,609
Exercise of stock options	8,227,843	5	—	51,310	—	—	51,315
Issuance of ordinary shares for restricted share units (Note 16 (f))	5,369,140	4	—	8,547	—	—	8,551
Exercise of warrants (Note 15)	5,341,267	3	—	672,661	—	—	672,664
Ordinary shares surrendered by a shareholder	(16)	—	—	—	—	—	—
Proportionate share of share-based compensation expenses recorded in an equity method affiliate (Note 10 (a))	—	—	—	58,534	—	—	58,534
Balance as of December 31, 2021	**183,826,753**	**126**	**—**	**9,100,777**	**(186,510)**	**(4,354,833)**	**4,559,560**

I-MAB
Consolidated Statements of Changes in Shareholders' Equity (Deficit) (Continued)
For the Years Ended December 31, 2020, 2021 and 2022
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Ordinary share (Note 14) (US$0.0001 par value)		Treasury stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity
	Number of shares	Amount	Number of shares	Amount				
		RMB		RMB	RMB	RMB	RMB	RMB
Balance as of December 31, 2021	**183,826,753**	**126**	**—**	**—**	**9,100,777**	**(186,510)**	**(4,354,833)**	**4,559,560**
Foreign currency translation adjustments	—	—	—	—	—	400,304	—	400,304
Net loss	—	—	—	—	—	—	(2,507,317)	(2,507,317)
Share-based compensation of I-Mab	—	—	—	—	357,148	—	—	357,148
Exercise of stock options	6,845,888	5	—	—	44,645	—	—	44,650
Issuance of ordinary shares for restricted share units (Note 16)	1,859,819	1	—	—	(1)	—	—	—
Repurchase of shares (Note 14)	—	—	(1,652,541)	(21,249)	—	—	—	(21,249)
Proportionate share of share-based compensation expenses recorded in an equity method affiliate (Note 10 (a))	—	—	—	—	76,806	—	—	76,806
Balance as of December 31, 2022	**192,532,460**	**132**	**(1,652,541)**	**(21,249)**	**9,579,375**	**213,794**	**(6,862,150)**	**2,909,902**

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, 2020, 2021 and 2022
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Cash flows from operating activities				
Net income (loss)	470,915	(2,331,541)	(2,507,317)	(363,526)
Adjustments to reconcile net income (loss) to net cash used in operating activities				
Depreciation of property, equipment and software	12,743	13,776	25,340	3,674
Amortization of intangible assets	1,556	778	778	113
Loss on disposal of property, equipment and operating lease right-of-use asset	8	288	117	17
Fair value change of put right liabilities	(3,024)	(16,628)	(34,260)	(4,967)
Equity in loss of affiliates	108,587	367,883	437,465	63,426
Share-based compensation	493,464	608,609	357,148	51,782
Amortization of right-of use assets and interest of lease liabilities	8,837	19,582	37,698	5,466
Recognition of deferred cost for planned dual listing	—	—	14,613	2,119
Gains on deconsolidation of a subsidiary	(407,598)	—	—	—
Fair value change of short-term and other investments	(11,288)	(30,360)	13,549	1,964
Changes in operating assets and liabilities				
Accounts receivable	(130,498)	97,417	33,081	4,796
Contract assets	(227,391)	(26,389)	253,780	36,795
Prepayments and other receivables	(58,692)	(5,155)	109,226	15,835
Inventories	—	(27,237)	27,237	3,949
Accruals and other payables	173,713	152,101	109,863	15,928
Contract liabilities	—	224,000	52,555	7,620
Other non-current liabilities	7,474	5,959	2,029	294
Deferred subsidy income	3,589	(7,509)	—	—
Lease liabilities	(8,837)	(18,667)	(35,707)	(5,177)
Net cash generated from (used in) operating activities	**433,558**	**(973,093)**	**(1,102,805)**	**(159,892)**
Cash flows from investing activities				
Purchase of property, equipment and software	(8,008)	(29,932)	(45,830)	(6,645)
Proceeds from disposal of property and equipment	—	—	26	4
Capital injection in an affiliate	—	(6,000)	—	—
Proceeds from disposal of short-term and other investments	2,503,749	9,482,040	7,911,518	1,147,062
Purchase of short-term and other investments	(2,491,991)	(10,173,314)	(7,407,332)	(1,073,962)
Cash disposed of resulting from deconsolidation of a subsidiary	(257,651)	—	—	—
Cash received from repayment of loans due from an affiliate	52,000	—	—	—
Net cash generated from (used in) investing activities	**(201,901)**	**(727,206)**	**458,382**	**66,459**

I-MAB
Consolidated Statements of Cash Flows (Continued)
For the Years ended December 31, 2020, 2021 and 2022
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Cash flows from financing activities				
Proceeds from initial public offering and over-allotment, net of underwriting discounts and commissions	726,300	—	—	—
Payment of issuance cost for initial public offering and over-allotment	(27,595)	—	—	—
Proceeds from private placement	2,789,699	—	—	—
Payments of the issuance cost in relation to private placement	(7,244)	(128,786)	—	—
Payments of cost in relation to planned dual listing	—	(9,820)	—	—
Proceeds from exercise of warrants	—	672,664	—	—
Proceeds from exercise of stock options	9,275	51,315	44,650	6,474
Proceeds from issuance of ordinary shares for restricted share units	46	8,551	—	—
Proceeds from bank borrowings	—	—	18,956	2,748
Repayment of bank borrowings	(50,000)	—	—	—
Payment for stock repurchase	—	—	(21,249)	(3,081)
Prepayment for stock repurchase	(34,859)	—	—	—
Cash received from collection of prepayment for stock repurchase program	34,859	—	—	—
Net cash generated from financing activities	**3,440,481**	**593,924**	**42,357**	**6,141**
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(106,643)	(128,771)	389,203	56,429
Net increase (decrease) in cash, cash equivalents and restricted cash	3,565,495	(1,235,146)	(212,863)	(30,863)
Cash, cash equivalents and restricted cash, beginning of year	1,193,283	4,758,778	3,523,632	510,879
Cash, cash equivalents and restricted cash, end of the year	**4,758,778**	**3,523,632**	**3,310,769**	**480,016**

I-MAB
Consolidated Statements of Cash Flows (Continued)
For the Years ended December 31, 2020, 2021 and 2022
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	Year Ended December 31,			
	2020	2021	2022	
	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	8,837	18,667	35,707	5,177
Right-of-use assets obtained in exchange for operating lease obligations	7,459	118,436	9,888	1,434
Other supplemental cash flow disclosures				
Interest paid	957	—	—	—
Income tax paid	—	9,077	—	—
Non-cash activities				
Payables for purchase of property, equipment and software	—	6,679	7,124	1,033
Accrued planned dual listing costs payable	—	4,793	—	—
Recognition of put right liabilities	—	—	17,729	2,570
Accrued private placement offering costs payable	128,786	—	—	—
Ordinary shares issued to Everest	254,848	—	—	—
Conversion of preferred shares to ordinary shares	3,104,177	—	—	—
Conversion of convertible promissory notes to ordinary shares	58,826	—	—	—

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.

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, 2022, 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 Biopharma Co., Ltd. ("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
Zhejiang Tianli Pharmaceutical Sales Co., Ltd.	PRC	September 29,2021	100 %	Sales and distribution of medicine products

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.

I-MAB

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

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.2 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 10).

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, 2022, 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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NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
(All amounts in thousands, except for share and per share data, unless otherwise noted)

2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.3 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 short-term investments, 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, accrued research and development expenses, cost-to-cost measure of progress for over time performance obligations, 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, deferred tax assets valuation allowances and provision for ongoing litigation. 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, accounts receivable, contract assets, other receivables, short-term borrowings, accruals and other payables, contract liabilities, put right liabilities, and other non-current liabilities. As of December 31, 2021 and 2022, except for short-term investments 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 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).

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 and put right liabilities at fair value on a recurring basis. As the Group's short-term investments 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 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.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.4 Fair value measurements (continued)

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, 2021 and 2022:

	As of December 31, 2021			
	Active market (Level 1) RMB	Observable input (Level 2) RMB	Non-observable input (Level 3) RMB	Total RMB
Assets:				
Short-term investments	—	—	753,164	753,164
Liabilities				
Put right liabilities	—	—	96,911	96,911

	As of December 31, 2022			
	Active market (Level 1) RMB	Observable input (Level 2) RMB	Non-observable input (Level 3) RMB	Total RMB
Assets:				
Short-term investments	—	—	235,429	235,429
Liabilities				
Put right liabilities	—	—	88,687	88,687

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

	Short-term investments	Put right liabilities
Fair value of Level 3 financial assets and liabilities as of December 31, 2020	**31,530**	**116,006**
Purchase of short-term and other investments	10,173,314	—
Disposal of short-term and other investments	(9,482,040)	—
Fair value changes	30,360	(16,628)
Currency translation differences	—	(2,467)
Fair value of Level 3 financial assets and liabilities as of December 31, 2021	**753,164**	**96,911**
Purchase of short-term and other investments	7,407,332	—
Disposal of short-term and other investments	(7,911,518)	—
Recognition of put right liabilities	—	17,729
Fair value changes	(13,549)	(34,260)
Currency translation differences	—	8,307
Fair value of Level 3 financial assets and liabilities as of December 31, 2022	**235,429**	**88,687**

See Note 10 for additional information about Level 3 put right liabilities measured at fair value on a recurring basis for the year ended December 31, 2021 and 2022.

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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, 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, 2021 and 2022 were US$1.00 = RMB6.3757 and RMB6.9646 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, 2022 are solely for the convenience of the readers and were calculated at the rate of US$1.00=RMB6.8972, representing the noon buying rate in The City of New York for cable transfers of RMB as certified for customs purposes by the Federal Reserve Bank of New York on December 30, 2022. No representation is made that the RMB amounts could have been, or could be, converted, realized or settled into US$ at that rate on December 31, 2022, 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 and bank notes agreements. Such restricted cash will be released when the Group repays the related bank borrowings or bank notes. The Group has presented restricted cash separately from cash and cash equivalents in the consolidated balance sheets.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.7 Restricted cash (continued)

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,	
	2021	2022
	RMB	RMB
Cash and cash equivalents	3,523,632	3,214,005
Restricted cash	—	96,764
Total	3,523,632	3,310,769

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).

2.10 Inventories

Prior to the regulatory approval of product candidates, the Company may incur expenses for the manufacture of drug product to support the commercial launch of those products. Until the date at which regulatory approval has been received or is otherwise considered probable, all such costs are recorded as research and development expenses as incurred.

Investigational products for external supply are capitalized as inventories with probable future economic benefit. Inventories are stated at the lower of cost and net realizable value, with cost determined in a manner that approximates the first-in, first-out method. The Company periodically analyzes its inventory levels, and writes down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory in excess of expected sales requirements as cost of product sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded in the consolidated statements of comprehensive income (loss).

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.11 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
Delivery equipment	4 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).

2.12 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 contract related intangible assets with finite useful lives over 10 to 20 years on a straight-line basis in accordance with the economic life of the out-licensed patent. 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 intangible assets with finite useful life, the impairment loss is recognized in cost of revenues in the consolidated statements of comprehensive income (loss).

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.13 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, 2020, 2021 and 2022, there was no impairment of the value of the Group's long-lived assets.

2.14 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 reporting unit exceeds its fair value.

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. No impairment charge was recognized for the years ended December 31, 2020, 2021 and 2022.

2.15 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.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.15 Long-term investments (continued)

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 years ended December 31, 2020, 2021 and 2022.

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)

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.

*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).

Supply of investigational products

Revenue from supply of investigational products is recognized when there is a transfer of control from the Group to the customer. The Group determines transfer of control based on when the product is delivered, and title passed to the customer. Sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.16 Revenue recognition (continued)

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, 2020, 2021 and 2022.

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.

Cost-to-cost measure of progress for over time performance obligations

Under the Group's certain licensing and collaboration arrangement entered into with a business partner, the Group recognized revenue using the cost-to-cost measure of progress for its over time performance obligations as this recognition best depicts the transfer of benefits to its business partner as costs are incurred under the licensing and collaboration arrangement. Under the cost-to-cost measure of progress method, the extent of progress towards completion is measured based on the ratio of costs incurred to-date to the total estimated costs for completion of the performance obligations. The Group applied significant judgment in estimating the total estimated costs for completion of performance obligations under such licensing and collaboration arrangement.

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.

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.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.18 Research and development expenses (continued)

The Group applied significant judgment in estimating the progress of its research and development activities and completion of or likelihood of achieving milestone events per underlying agreements when estimating the research and development costs to be accrued at each reporting period end. The process of estimating its research and development expenses involves reviewing open contracts and purchase orders, communicating with personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated costs incurred for the services when the Group has not yet been invoiced or otherwise notified of the actual costs.

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.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.20 Government subsidies

Government subsidies primarily consist of financial subsidies received from provincial and local governments for operating a business in their jurisdictions and compliance with specific policies promoted by the governments. The Group's PRC based subsidiaries received government subsidies from certain local governments. The Group's government subsidies consist of specific subsidies and other subsidies. Specific subsidies are subsidies that the local government has set certain conditions for the subsidies. Other subsidies are the subsidies that the local government has not set any conditions and are not tied to future trends or performance of the Group, receipt of such subsidy income is not contingent upon any further actions or performance of the Group and the amounts do not have to be refunded under any circumstances. For the years ended December 31, 2020, 2021 and 2022, no specific subsidies were received by the Group. Other subsidies of RMB11,633, RMB9,216 and RMB25,470 for the years ended December 31, 2020, 2021 and 2022 respectively, are recognized as other income upon receipt as further performance by the Group is not required.

2.21 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).

2.22 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)

2.23 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.

2.24 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.

2.25 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)

2.26 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.

2.27 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. 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.

2.28 Adopted accounting pronouncements

In March 2020, the FASB issued ASU 2020-04, "Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting", which provides optional expedients and exceptions for applying U.S. GAAP on contract modifications and hedge accounting to contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform, if certain criteria are met. These optional expedients and exceptions provided in ASU 2020-04 are effective for the Company as of March 12, 2020 through December 31, 2022. The Company adopted this from January 1, 2022, which did not have a material impact on the Group's consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40) to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. The Company adopted this from January 1, 2022, which did not have a material impact on the Group's consolidated financial statements.

In July 2021, the FASB issued ASU 2021-05, Lessors—Certain Leases with Variable Lease ("ASU 2021-05"). It requires lessors to classify leases as operating leases if they have variable lease payments that do not depend on an index or rate and would have selling losses if they were classified as sales-type or direct financing leases. The Company adopted this from January 1, 2022, which did not have a material impact on the Group's consolidated financial statements.

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2. PRINCIPAL ACCOUNTING POLICIES (CONTINUED)

2.28 Adopted accounting pronouncements (Continued)

In June 2022, the FASB issued ASU 2022-03, "Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions", which clarifies that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. The amendments also clarify that an entity cannot, as a separate unit of account, recognize and measure a contractual sale restriction. This guidance also requires certain disclosures for equity securities subject to contractual sale restrictions. The new guidance is required to be applied prospectively with any adjustments from the adoption of the amendments recognized in earnings and disclosed on the date of adoption. This guidance is effective for the Company for the year ending March 31, 2025 and interim reporting periods during the year ending March 31, 2025. Early adoption is permitted. The Company does not expect that the adoption of this guidance will have a material impact on the financial position, results of operations and cash flows.

2.29 Recent accounting pronouncements

In October 2021, the FASB issued ASU 2021-08, Business Combinations (Topic 805) — Accounting for Contract Assets and Contract Liabilities from Contracts with Customers ("ASU 2021-08"). It requires issuers to apply ASC 606 Revenue from Contracts with Customers to recognize and measure contract assets and contract liabilities from contracts with customers acquired in a business combination. ASU 2021-08 is effective for the Company from January 1, 2023, with early adoption permitted. The ASU is currently not expected to have a material impact on the Group's consolidated financial statements.

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,		
	2021	2022	
	RMB	RMB	US$ (Note 2.5)
Accounts receivable, gross	33,081	—	—
Allowance for credit losses	—	—	—
Accounts receivable, net	33,081	—	—

	As of December 31,		
	2021	2022	
	RMB	RMB	US$ (Note 2.5)
Contract assets, gross (Note 17)	253,780	—	—
Allowance for credit losses	—	—	—
Contract assets, net	253,780	—	—

No allowance for credit losses was recorded as of December 31, 2021 and 2022.

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4. Inventories

Inventories consist of the following:

	As of December 31,		
	2021	2022	
	RMB	RMB	US$ (Note 2.5)
Investigational products	27,237	—	—

In April 2021, the Group entered into a master clinical supply agreement with AbbVie. Inc for the supply of investigational products for use in the clinical trials. For the year ended December 31, 2021, the Group recognized revenue of RMB47,911 for the products delivered to AbbVie. Inc. The inventories balance as of December 31, 2021 represented the investigational products that have been produced by the contract manufacturer and transferred control to the Group. For the year ended December 31, 2022, the Group recognized revenue of RMB28,102 for the products delivered to AbbVie. Inc.

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5. PREPAYMENTS AND OTHER RECEIVABLES

	As of December 31,		
	2021	2022	
	RMB	RMB	US$ (Note 2.5)
Prepayments:			
– Prepayments to CRO vendors	79,568	32,960	4,779
– Prepayments for other services	906	1,321	192
– Prepayments to an affiliate (Note 22)	8,079	8,231	1,193
Value-added tax recoverable	89,578	8,197	1,188
Deposits	616	4,570	663
Other receivables	12,077	24,999	3,624
	190,824	80,278	11,639

6. PROPERTY, EQUIPMENT AND SOFTWARE

Property, equipment and software consist of the following:

	As of December 31,	As of December 31,	
	2021	2022	
	RMB	RMB	US$ (Note 2.5)
Cost			
Laboratory equipment	36,295	52,989	7,683
Leasehold improvement	18,945	37,375	5,419
Software	11,071	14,506	2,103
Office furniture and equipment	2,468	11,171	1,620
Delivery equipment	—	165	24
Total property, equipment and software	68,779	116,206	16,849
Less: accumulated depreciation and amortization	(44,162)	(61,583)	(8,929)
Net book value	24,617	54,623	7,920
Construction in progress	21,099	6,218	901
Total net book value of property, equipment and software	45,716	60,841	8,821

The total amounts charged to the consolidated statements of comprehensive income/(loss) for depreciation and amortization expenses amounted to approximately RMB12.7 million and RMB13.8 million and RMB25.3 million (US$3.7 million), for the years ended December 31, 2020, 2021 and 2022, respectively.

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7. LEASES

As of December 31, 2022, the Company has operating leases recorded on its balance sheet for certain office spaces and facilities that expire on various dates through 2028. 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 the Group's leases qualify as operating leases.

Information related to operating leases as of December 31, 2021 and 2022 is as follows (in thousands, except for percentages and years).

	As of December 31,		
	2021	2022	
	RMB	RMB	US$ (Note 2.5)
Assets			
Operating lease right-of-use assets	112,781	63,125	9,152
Liabilities			
Operating lease liabilities, current	30,669	23,961	3,474
Operating lease liabilities, non-current	81,786	32,069	4,650
Weighted average remaining lease term (years)	3.6	2.9	2.9
Weighted average discount rate	5 %	5 %	5 %

Information related to operating lease activities during the years ended December 31, 2020, 2021 and 2022 are as follows:

	For the Year Ended			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Operating lease rental expense				
Amortization of right-of-use assets	8,158	16,997	34,520	5,005
Expense for short-term leases within 12 months	—	16	12	2
Interest of lease liabilities	679	2,585	3,178	461
	8,837	19,598	37,710	5,468

Maturities of lease liabilities were as follows:

	As of December 31, 2022	
	RMB	US$ (Note 2.5)
2023	37,867	5,490
2024	26,723	3,874
2025	5,193	753
2026	5,288	767
2027	4,729	686
Thereafter	1,209	175
Total undiscounted lease payments	81,009	11,745
Less: imputed interest	(24,979)	(3,621)
Total lease liabilities	**56,030**	**8,124**

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8. INTANGIBLE ASSETS

Intangible assets as of December 31, 2021 and 2022 are summarized as follows:

	As of December 31, 2021		
	Gross carrying amount	Accumulated amortization	Net carrying amount
	RMB	RMB	RMB
Intangible assets			
TJ103	11,670	(2,334)	9,336
IPR&D TJ101	110,330	—	110,330
Total intangible assets	122,000	(2,334)	119,666

	As of December 31, 2022		
	Gross carrying amount	Accumulated amortization	Net carrying amount
	RMB	RMB	RMB
Intangible assets			
TJ103	11,670	(3,112)	8,558
IPR&D TJ101	110,330	—	110,330
Total intangible assets	122,000	(3,112)	118,888

The two IPR&D assets (TJ103 and TJ101) 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 two 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.

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, 2020, 2021 and 2022 was RMB1,556, RMB778 and RMB778, respectively. The estimated amortization expense for each of the five succeeding fiscal years is RMB778.

As of December 31, 2021 and 2022, there was no impairment of the value of the Group's intangible assets.

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9. 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 8). As of December 31, 2021 and 2022, the goodwill of RMB162,574 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, 2021, 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.

As of December 31, 2022, the Group performed the quantitative impairment test by comparing the Group's single reporting unit's carrying amount, including goodwill, to its fair value. The Group's single reporting unit fair value was determined using discounted cash flows based on ten-year financial projections with future revenues assumption for direct product sales of each pipeline plus a terminal value related to cash flows beyond the projection period extrapolated at an estimated terminal growth rate. A pre-tax discount rate was applied, which reflected an assessment of time value and specific risks relating to the industries that the Group operates in. The probabilities of the success of the clinical trials based on the status of these trials and reference to the industry benchmark was also incorporated into the assumption of future revenues.

Management leveraged their experiences in the industries and provided forecast based on past performance and their anticipation of future business and market developments. Management has not identified reasonably possible change in key assumptions that could cause carrying amounts of the Group's single reporting unit to exceed the fair value as material headroom resulted from the impairment reviews over their respective carrying amounts. No impairment was recognized for the year ended December 31, 2022.

10. INVESTMENTS ACCOUNTED FOR USING THE EQUITY METHOD AND PUT RIGHT LIABILITIES

(a) Investments accounted for using the equity method

Investment in I-Mab Hangzhou

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 "Series A Closing Date"), I-Mab Hong Kong entered into an equity transfer and investment agreement (the "Series A 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 ("Series A Domestic Investors").

In accordance with the terms of the Series A 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 Series A 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 Series A Closing Date;

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10. INVESTMENTS ACCOUNTED FOR USING THE EQUITY METHOD AND PUT RIGHT LIABILITIES (CONTINUED)

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

Investment in I-Mab Hangzhou (continued)

(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 Series A 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) Series A 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.

Upon closing of the Series A 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 Series A 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, Series A Domestic Investors, Management Holdco and ESOP Holdco would be 45%, 40%, 10% and 5% respectively. For the years ended December 31, 2021 and 2022, 750,000 and 750,000 shares were issued to Management Holdco, respectively.

On the same day, I-Mab Hong Kong also entered into a shareholders agreement with the aforementioned investors (the "Series A 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 Series A 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 Series A Closing Date in accordance with ASC 810 since I-Mab Hangzhou meets the definition of a business under ASC 805. Pipeline candidate related matters are considered to be the activities that most significantly impact the economic performance of I-Mab Hangzhou at the current stage, and these matters cannot be acted without the consent from Series A Investors Directors. 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.

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10. INVESTMENTS ACCOUNTED FOR USING THE EQUITY METHOD AND PUT RIGHT LIABILITIES (CONTINUED)

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

Investment in I-Mab Hangzhou (continued)

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 Series A 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 Series A Closing Date.

A gain of RMB407,598 was recognized as a result of the deconsolidation in September 2020. The gain represented the difference between:

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

ii) The aggregate of all of the following:

a) the carrying amount of transferred intellectual property related to TJ102 at the Series A Closing Date;

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

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

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. The Group recognized RMB67,425, RMB309,208 and RMB360,436 in equity in loss of an affiliate in the consolidated statements of comprehensive loss for the years ended December 31, 2020, 2021 and 2022, and in investment accounted for using the equity method in the consolidated balance sheets as of December 31, 2020, 2021 and 2022, respectively.

The purchase price of US$3 million committed by Management Holdco under Series A 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 Series A Closing Date. Consequently, the Group recognizes its proportionate share of the compensation expense recorded by I-Mab Hangzhou. For the years ended December 31, 2020, 2021 and 2022, the Group recognized RMB8,456, RMB28,236 and RMB29,375 in equity in loss of affiliates in the consolidated financial statements of comprehensive loss, respectively.

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 16(d)). And there were some employees transferred from the Group to I-Mab Hangzhou in 2021 and 2022.These individuals continued to qualify the definition of the eligible participants under the 2020 Plan and 2021 Share Incentive Plan ("2021 Plan", see Note 16(e)) after their resignation date from the Group. 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 and 2021 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 years ended December 31, 2020, 2021 and 2022, such expenses of RMB32,707, RMB13,267 and RMB13,852 were recorded in the equity in loss of affiliates in the consolidated statements of comprehensive income (loss), respectively.

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10. INVESTMENTS ACCOUNTED FOR USING THE EQUITY METHOD AND PUT RIGHT LIABILITIES (CONTINUED)

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

Investment in I-Mab Hangzhou (continued)

In 2021 and 2022, I-Mab Hangzhou granted stock options to its employees. 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. Accordingly, the Group recorded RMB17,031 and RMB33,579 in the equity in loss of affiliates in the consolidated financial statements of comprehensive loss for the years ended December 31, 2021 and 2022, and in additional paid-in capital in the consolidated balance sheets as of December 31, 2021 and 2022, respectively.

In July 2022, I-Mab Hangzhou entered into an equity transfer and investment agreement (the "Series B SPA") and a shareholders agreement (the "Series B SHA") with a group of domestic investors ("Series B Domestic Investors") in China to raise approximately US$46 million in RMB equivalent. As of the date of this report, this round of financing has not completed yet. Once all the shares of I-Mab Hangzhou are purchased by or issued to its investors, including Management Holdco and ESOP Holdco, the Group would hold 37.13% equity interest in I-Mab Hangzhou. Pursuant to the Series B SHA, Management Holdco and ESOP Holdco no longer had irrevocably consented to act in concert with I-Mab Hong Kong. I-Mab Hangzhou remains the affiliate of the Group. The Group increased the carrying amount of the long-term investment based on the fair value of the put right liabilities written by I-Mab Hong Kong to Series B Domestic Investors with the amount of RMB17,729 (Note 10 (b)).

As of December 31, 2021 and 2022, the carrying value of the Group's long-term investment in I-Mab Hangzhou RMB346,247 and RMB25,214, respectively.

Other long-term investment measured under equity method

In July 2021, the Group, as a limited partner, entered into a partnership agreement with other investors and subscribed RMB20,000 for a 4% equity interest in a partnership located in Hangzhou. In August 2021, the Group paid the initial investment of RMB6,000 to the partnership. Pursuant to the partnership agreement, the Group, as a limited partner, shall not participate in any activities in relation to management of the investment business. In addition, members of the investment committee shall only be appointed by the general partner. For the years ended December 31, 2021 and 2022, the Group recorded RMB141 and RMB223 in the equity in loss of affiliates in the consolidated financial statements of comprehensive loss. As of December 31, 2021 and 2022, the carrying value of the Group's long-term investment in this affiliate was RMB5,859 and RMB5,636, respectively.

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	For the year ended December 31, 2021		For the year ended December 31, 2022	
	I-Mab Hangzhou	I-Mab Hangzhou	Other equity investments	I-Mab Hangzhou	Other equity investments
Operating data:					
Revenue	271	5,660	—	103,826	—
Loss from operations	(85,945)	(295,186)	(3,513)	(356,734)	(5,565)
Net Loss	(85,945)	(290,586)	(3,513)	(346,322)	(5,565)

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10. INVESTMENTS ACCOUNTED FOR USING THE EQUITY METHOD AND PUT RIGHT LIABILITIES (CONTINUED)

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

Other long-term investment measured under equity method (continued)

	As of December 31,			
	2021		2022	
	I-Mab Hangzhou	Other equity investments	I-Mab Hangzhou	Other equity investments
Balance sheet data:				
Current assets	602,047	20,037	499,665	81,683
Non-current assets	1,207,132	40,000	1,432,328	135,347
Current liabilities	168,763	50	281,587	107
Non-current liabilities	176,436	—	232,083	—
Non-controlling interests	—	—	—	—

(b) Put right liabilities

Pursuant to the Series A SHA and Series B 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 Series A SHA and Series B SHA within 4 years after September 15, 2020, I-Mab Hong Kong is obligated to repurchase the equity held by Series A 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 Series A 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 (expenses) 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:

Put right liabilities - Series A	As of December 31, 2021	As of December 31, 2022
Expected terms (Year)	2.7	1.7
Estimated volatility	34.5 %	33.9 %
Spot price	US$ 171,134	US$ 148,276
Probability of triggering event for redemption option	70 %	70 %

Put right liabilities - Series B	As of August 19, 2022	As of December 31, 2022
Expected terms (Year)	2.1	1.7
Estimated volatility	31.3 %	31.1 %
Spot price	US$ 36,570	US$ 36,516
Probability of triggering event for redemption option	70 %	70 %

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10. INVESTMENTS ACCOUNTED FOR USING THE EQUITY METHOD AND PUT RIGHT LIABILITIES (CONTINUED)

(b) Put right liabilities (continued)

The model requires the input of key assumptions including the expected terms, estimated volatility, spot price and probability of triggering event for redemption option. The significant unobservable inputs used in the option pricing model included spot price, estimated volatility 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 companies for a period with length commensurate to the expected terms of redemption event. The spot price was determined using the market approach with assistance from an independent third-party valuation firm. The significant unobservable inputs used in the market approach include estimated volatility and probability of triggering event for redemption option. 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.

11. SHORT-TERM BORROWINGS

In December 2022, I-Mab Shanghai borrowed a loan of RMB18,956 from Shanghai Pudong Development Bank Co., Ltd. for a term of six months and at the interest rate of 3.40% per annum. To facilitate this borrowing, I-Mab Hong Kong placed cash deposits of USD5,000 (equivalent to approximately RMB34,823) 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.

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12. ACCRUALS AND OTHER PAYABLES

	As of December 31, 2021	As of December 31, 2022	
	RMB	RMB	US$ (Note 2.5)
Current:			
Staff salaries and welfare payables	52,526	43,483	6,304
Accrued external research and development activities related expenses	367,976	264,972	38,417
Accrued cost in relation to planned dual listing	4,793	—	—
Payable due to an affiliate (Note 22)	—	64,782	9,393
Accrued Termination fee and other expenses in relation to the disputes with Tracon (Note 17)	57,381	161,106	23,358
Non-refundable incentive payment from depositary bank [(1)]	2,369	6,428	932
Accrued traveling expenses, office expenses and others	108,290	165,801	24,039
	593,335	706,572	102,443
Non-current:			
Non-refundable incentive payment from depositary bank [(1)]	4,934	6,963	1,009
Non-refundable payment received in relation to the exclusive promotion right granted to a third party [(2)]	10,000	10,000	1,450
	14,934	16,963	2,459
Total	608,269	723,535	104,902

(1) The Group received a non-refundable incentive payment of US$1,857 (equivalent to approximately RMB12,982) and US$1,195 (equivalent to approximately RMB8,075) from depositary bank in April 2020 and December 2022, respectively. The amount was recorded ratably as other gains over a five-year arrangement period. For the years ended December 31, 2020, 2021 and 2022, the Group has recorded RMB2,348, RMB2,395 and RMB2,821 as other income in the consolidated statements of comprehensive income (loss), respectively.

(2) In November 2021, the Group entered into a collaboration agreement with a third party located in China to grant the third party an exclusive right to conduct promotion activities for the TJ202 drug products in designated hospitals after the commercialization of TJ202 in future years. In November 2021, the Group received a non-refundable payment of RMB10,000 from the third party and recorded it as the non-current liabilities in the consolidated balance sheet as of December 31, 2021. This amount will be recorded as the deduction of the selling expenses after the commercialization of TJ202 products.

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13. INCOME TAXES

Cayman Islands

I-Mab is incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, I-Mab is not subject to tax on income or capital gain. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

Hong Kong

I-Mab did business registration in Hong Kong and has 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. The applicable tax rate in Hong Kong is 16.5%. For the years ended December 31, 2020, 2021 and 2022, the income tax expenses recorded in the consolidated statements of comprehensive income (loss) for I-Mab were nil, nil and RMB697, respectively. For the years ended December 31, 2020, 2021 and 2022, 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 and 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 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".

I-Mab Shanghai has been qualified as "High and New Technology Enterprise" and enjoys a preferential income tax rate of 15% from 2021 to 2023.

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 accrued 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. As the actual withholding taxes paid to local tax bureau was RMB9,077, the Group reversed the tax expenses of RMB3,154 in the year ended December 31, 2021.

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13. INCOME TAXES (CONTINUED)

China (continued)

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, 2020, 2021 and 2022 are as follows:

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Income (loss) before income tax	483,146	(2,334,695)	(2,506,620)	(363,425)
Income tax computed at respective applicable tax rate	66,044	(410,899)	(442,343)	(64,134)
Non-deductible expenses	72,256	68,400	38,570	5,592
Research and development expenses plus deduction	(60,776)	(50,530)	(74,415)	(10,789)
True up of withholding tax expenses	—	(3,154)	—	—
Changes in valuation allowance	(65,293)	393,029	478,885	69,432
	12,231	(3,154)	697	101
Effect of tax holidays entitled by the PRC subsidiaries on basic income (loss) per share	0.34	(0.84)	(0.65)	(0.09)

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

	As of December 31,		
	2021	2022	
	RMB	RMB	US$ (Note 2.5)
Deferred tax assets:			
Net operating loss carryforward	380,695	792,602	114,916
Depreciation and amortization of property, equipment, software and intangible asset, net	41,020	39,189	5,682
Share-based compensation expenses	59,296	127,950	18,551
Accrual expense	30,172	30,210	4,380
Less: valuation allowance	(493,233)	(972,118)	(140,944)
Total deferred tax assets	17,950	17,833	2,585
Deferred tax liabilities:			
Acquired intangible assets	17,950	17,833	2,585
Total deferred tax liabilities	17,950	17,833	2,585
Deferred tax assets, net	—	—	—

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13. INCOME TAXES (CONTINUED)

China (continued)

Movement of the valuation allowance is as follows:

	Year Ended December 31			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Balance as of January 1	(165,497)	(100,204)	(493,233)	(71,512)
Additions	(36,061)	(393,029)	(478,885)	(69,432)
Utilization and reversal of valuation allowances	89,154	—	—	—
Decrease due to the change of tax rate	12,200	—	—	—
Balance as of December 31	(100,204)	(493,233)	(972,118)	(140,944)

As of December 31, 2022, the Group had a majority of net operating losses of approximately RMB3,834,455 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 2023 to 2032 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, 2021 and 2022.

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, 2021 and 2022, the Group did not have any significant unrecognized uncertain tax positions.

14. ORDINARY SHARES

As of December 31, 2018 and 2019, 500,000,000 ordinary shares had been authorized by the Company. Each ordinary share is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors of the Company.

On October 29, 2019, the Company's shareholders and board of directors approved that immediately prior to the completion of initial public offering, the Company's authorized share capital will be changed into US$80,000 divided into 800,000,000 ordinary shares of a par value of US$0.0001 each.

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.

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14. ORDINARY SHARES (CONTINUED)

On January 17, 2020, the Company also issued 6,078,571 ordinary shares to Everest.

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, 2021.

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 15(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. All of the warrants were exercised by the Investors during the year ended December 31, 2021.

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 Ireland Unlimited Group ("AbbVie") (see Note 17) 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).

On August 23, 2022, the Company announced, that it plans to implement share repurchases pursuant to the share repurchase program previously authorized by its board of directors. Under the share purchase plans, the Company and the senior management may purchase up to US$40 million of ADSs in aggregate. As of December 31, 2022, the Company had purchased 1,652,541 ordinary shares in an aggregate amount of approximately US$3 million (equivalent to RMB21,249) under the authorized share purchase program. These repurchased shares are considered not outstanding and therefore were accounted for under the cost method and includes such treasury stock as a component of the shareholder's equity. For the year ended December 31, 2022, no treasury stock was used for exercise of option. As of December 31, 2022, 1,652,541 shares were not in use and not outstanding.

As of December 31, 2022, 16,915,104 stock options were exercised, and 7,235,959 restricted share units were issued as ordinary shares.

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15. WARRANTS

As mentioned in Note 14, 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.

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). The Investor Warrants will remain exercisable at the election of the Investors within 12 months after the closing of the private placement. 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. All of the warrants were exercised by the Investors during the year ended December 31, 2021.

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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16. SHARE-BASED COMPENSATION

(a) 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.

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.

The Group did not grant any stock options to employees for the years ended December 31, 2020, 2021 and 2022. 2,569,017 and 1,782,617 stock options were exercisable as of December 31, 2021 and 2022, respectively.

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16. SHARE-BASED COMPENSATION (CONTINUED)

(a) 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 , 2019	9,812,881	0.93	7.76	47,671
Forfeited	(338,876)	1.00	—	—
Exercised	(1,439,373)	0.72	—	—
Surrendered (Note 16(h))	(332,566)	1.00	—	—
Outstanding as of December 31 , 2020	7,702,066	0.97	6.75	150,415
Exercised	(5,122,549)	0.96	—	—
Forfeited	(10,500)	1.00	—	—
Outstanding as of December 31 , 2021	2,569,017	1.00	5.79	50,361
Exercised	(786,400)	1.00	—	—
Outstanding as of December 31 , 2022	1,782,617	1.00	4.75	1,457
Exercisable as of December 31, 2022	1,782,617	1.00	4.75	1,457

All the stock options were vested as of December 31, 2021.

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 prior to the Company's IPO in 2020.

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, RMB69,214 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, totalling 332,566 unvested options, for no consideration, and these stock options were cancelled immediately.

Share-based compensation expenses related to the stock options of 2017 Plan are included in:

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	69,214	(225)	—	—
Administrative expenses	52,802	2,835	—	—
Equity in loss of affiliates	4,277	516	—	—
	126,293	3,126	—	—

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16. SHARE-BASED COMPENSATION (CONTINUED)

(b) 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.

The following table sets forth the stock options activities of 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
Exercised	(402,000)	1.00	—	—
Surrendered (Note 16 (h))	(2,544,917)	1.00	—	—
Outstanding as of December 31, 2020	10,589,671	1.00	8.15	206,499
Exercised	(3,036,435)	1.00	—	—
Outstanding as of December 31, 2021	7,553,236	1.00	7.15	148,076
Exercised	(6,044,843)	1.00	—	—
Outstanding as of December 31, 2022	1,508,393	1.00	6.15	1,233
Exercisable as of December 31, 2022	1,508,393	1.00	6.15	1,233

All the stock options were vested as of December 31, 2021.

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.

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16. SHARE-BASED COMPENSATION (CONTINUED)

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

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.

Share-based compensation expenses related to the stock options of 2018 Plan are included in:

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	65,656	55	—	—
Administrative expenses	48,055	4,478	—	—
Equity in loss of affiliates	226	257	—	—
	113,937	4,790	—	—

(c) 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 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. 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). 24,000 and 48,000 options were exercisable as of December 31, 2021 and 2022, respectively.

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16. SHARE-BASED COMPENSATION (CONTINUED)

(c) 2019 Share Incentive Plan ("2019 Plan") (continued)

The following table sets forth the stock options activities of 2019 Plan for 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
Granted	—	—	—	—
Outstanding as of December 31, 2021	72,000	6.09	8.05	1,045
Granted	—	—	—	—
Outstanding as of December 31, 2022	72,000	6.09	7.05	—
Exercisable as of December 31, 2022	48,000	6.09	7.05	—

A summary of non-vested stock options activity for the year ended December 31, 2022 is presented below:

	Number of shares	Weighted average grant-date fair value US$
Non-vested at December 31, 2021	48,000	4.50
Vested	(24,000)	4.50
Non-vested at December 31, 2022	24,000	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	—
Time to maturity (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. Time to maturity equals to the contract life of the option.

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16. SHARE-BASED COMPENSATION (CONTINUED)

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

Share-based compensation expenses related to the stock options of 2019 Plan are included in:

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	—	—	—	—
Administrative expenses	1,171	707	288	42
Equity in loss of affiliates	—	—	—	—
	1,171	707	288	42

(d) 2020 Plan

On July 15, 2020, the Group adopted 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 years ended December 31, 2020, 2021 and 2022, the Group granted 1,068,733, 133,913 and 2,026,300 stock options to its employees, respectively. 192,340 options and 353,949 options were exercisable as of December 31, 2021 and 2022, respectively.

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
Granted	133,913	18.85	—	—
Exercised	(68,859)	5.91	—	—
Expired	(154)	5.91	—	—
Forfeited	(111,495)	6.23	—	—
Outstanding as of December 31, 2021	997,773	7.61	8.68	12,967
Granted	2,026,300	9.20	—	—
Exercised	(14,645)	5.91	—	—
Expired	(69,051)	6.74	—	—
Forfeited	(170,490)	7.65	—	—
Outstanding as of December 31, 2022	2,769,887	8.81	8.76	—
Exercisable as of December 31, 2022	353,949	7.00	7.67	—

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16. SHARE-BASED COMPENSATION (CONTINUED)

(d) 2020 Plan (Continued)

A summary of non-vested stock option activities for the year ended December 31, 2022 is presented below:

	Number of shares	Weighted average grant-date fair value US$
Non-vested at December 31, 2021	805,433	9.44
Granted	2,026,300	1.35
Vested	(245,305)	9.40
Forfeited	(170,490)	7.39
Non-vested at December 31, 2022	2,415,938	0.53

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	2021	2022
Expected volatility	56.51 %	50.78%-51.84%	53.66 %
Risk-free interest rate (per annum)	0.86 %	1.32%-1.88%	1.88 %
Exercise multiple	2.20-2.80	2.20-2.80	2.20-2.80
Expected dividend yield	—	—	—
Time to maturity (in years)	10	10	10

The expected volatility was estimated based on the historical volatility of comparable peer public companies with a time horizon close to the expected term of the Group's options. The risk-free interest rate was estimated based on the yield to maturity of U.S. treasury bonds denominated in US$ for a term consistent with the expected term of the Group's options in effect at the option valuation date. The expected exercise multiple was estimated as the average ratio of the stock price to the exercise price when employees would decide to voluntarily exercise their vested options. As the Group did not have sufficient information of past employee exercise history, it was estimated by referencing to a widely-accepted academic research publication. Expected dividend yield is zero as the Group has never declared or paid any cash dividends on its shares, and the Group does not anticipate any dividend payments in the foreseeable future. Time to maturity equals to the contract life of the option.

Share-based compensation expenses related to the stock options of 2020 Plan are included in:

	Year Ended December 31,			
	2020	2021	2021	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	10,435	14,915	17,068	2,475
Administrative expenses	4,357	8,702	25,897	3,755
Equity in loss of affiliates	1,619	3,262	2,846	413
	16,411	26,879	45,811	6,643

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16. SHARE-BASED COMPENSATION (CONTINUED)

(d) 2020 Plan (Continued)

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

(1) 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.

(2) 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.

(3) 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 years ended December 31, 2020, 2021 and 2022, the Group granted 4,093,079, 1,649,045 and 755,734 restricted share units to employees, respectively.

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16. SHARE-BASED COMPENSATION (CONTINUED)

(d) 2020 Plan (Continued)

The following table sets forth the restricted share units of 2020 Plan for the periods presented:

	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
Granted	1,649,045	—	—	—
Vested	(4,048,000)	—	—	—
Forfeited	(198,872)	—	—	—
Outstanding as of December 31, 2021	1,481,791	—	8.95	30,531
Granted	755,734	—	—	—
Vested	(720,232)	—	—	—
Forfeited	(270,482)	—	—	—
Outstanding as of December 31, 2022	1,246,811	—	8.55	2,266

A summary of non-vested restricted share units activities for the year ended December 31, 2022 is presented below:

	Number of restricted share units	Weighted average grant-date fair value US$
Non-vested at December 31, 2021	1,481,791	17.80
Granted	755,734	10.11
Vested	(720,232)	19.71
Forfeited	(270,482)	14.52
Non-vested at December 31, 2022	1,246,811	2.98

Share-based compensation expenses related to the aforementioned restricted share units of 2020 Plan are included in:

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	71,945	118,368	18,055	2,618
Administrative expenses	76,663	227,392	37,399	5,422
Equity in loss of affiliates	7,500	8,512	4,214	611
	156,108	354,272	59,668	8,651

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. All the restricted share units were vested as of December 31, 2021.

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16. SHARE-BASED COMPENSATION (CONTINUED)

(d) 2020 Plan (continued)

The following table sets forth the restricted share units subject to terms and conditions under 2020 Plan for the periods presented:

	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
Vested	(762,920)	1.00	—	—
Outstanding as of December 31, 2021	—	—	—	—

Share-based compensation expenses related to these restricted share units are included in:

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	67,181	4,156	—	—
Administrative expenses	25,985	54,011	—	—
Equity in loss of affiliates	19,085	720	—	—
	112,251	58,887	—	—

(e) 2021 Share Incentive Plan ("2021 Plan")

On May 28, 2021, the Group adopted 2021 Plan. Under the 2021 Plan, the maximum aggregate number of shares authorized to be issued is 12,023,618 ordinary shares, provided that the maximum number of shares to be issued in the form of restricted share units shall not exceed 6,011,809 ordinary shares.

Stock options granted to employees under the 2021 Plan are graded vesting in four years with 25% vesting each year. For the years ended December 31, 2021 and 2022, the Group granted 2,698,245 and 2,787,738 stock options to its employees, respectively. Nil options and 519,377 were exercisable as of December 31, 2021 and 2022, respectively.

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16. SHARE-BASED COMPENSATION (CONTINUED)

(e) 2021 Share Incentive Plan ("2021 Plan") (continued)

The following table sets forth the stock options activities of 2021 Plan for the year ended December 31,2022:

	Number of shares	Weighted average exercise price US$	Weighted average remaining contractual term	Aggregate intrinsic value US$
Outstanding as of December 31, 2020	—	—	—	—
Granted	2,698,245	26.43	—	—
Forfeited	(253,805)	26.39	—	—
Outstanding as of December 31, 2021	2,444,440	26.44	9.57	—
Granted	2,787,738	9.20	—	—
Forfeited	(880,304)	18.21	—	—
Expired	(46,202)	26.39	—	—
Outstanding as of December 31, 2022	4,305,672	17.32	8.89	—
Exercisable as of December 31, 2022	519,377	26.46	8.53	—

A summary of non-vested stock option activities for the year ended December 31, 2022 is presented below:

	Number of shares	Weighted average grant-date fair value US$
Non-vested at December 31, 2021	2,444,440	14.12
Granted	2,787,738	2.70
Vested	(565,579)	14.18
Forfeited	(880,304)	7.64
Non-vested at December 31, 2022	3,786,295	1.76

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,	
	2021	2022
Expected volatility	51.77%-54.37 %	53.66%-58.97%
Risk-free interest rate (per annum)	1.44%-1.68 %	1.88%-3.53%
Exercise multiple	2.20-2.80	2.20-2.80
Expected dividend yield	—	—
Time to maturity (in years)	10	10

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16. SHARE-BASED COMPENSATION (CONTINUED)

(e) 2021 Share Incentive Plan ("2021 Plan") (continued)

The expected volatility was estimated based on the historical volatility of comparable peer public companies with a time horizon close to the expected term of the Group's options. The risk-free interest rate was estimated based on the yield to maturity of U.S. treasury bonds denominated in US$ for a term consistent with the expected term of the Group's options in effect at the option valuation date. The expected exercise multiple was estimated as the average ratio of the stock price to the exercise price when employees would decide to voluntarily exercise their vested options. As the Group did not have sufficient information of past employee exercise history, it was estimated by referencing to a widely-accepted academic research publication. Expected dividend yield is zero as the Group has never declared or paid any cash dividends on its shares, and the Group does not anticipate any dividend payments in the foreseeable future. Time to maturity equals to the contract life of the option.

Share-based compensation expenses related to the stock options of 2021 Plan are included in:

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	—	20,430	36,104	5,234
Administrative expenses	—	35,226	75,980	11,016
Equity in loss of affiliates	—	—	2,715	393
	—	55,656	114,799	16,643

Restricted share units granted to employees under the 2021 Plan will be exercisable under the following items:

(1) 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.

(2) 1/3 of the awarded restricted share units shall vest based on the Group's weighted average share price during any consecutive 90 days within one year after the adoption date of 2021 Plan (the "Share Price Based Awards"):

i. a vesting of 75% of the Share Price Based Awards on the first anniversary of the adoption date of 2021 Plan, if the Group's weighted average share price reaches the first share price level as approved by the Board;

ii. a vesting of 100% of the Share Price Based Awards on the first anniversary of the adoption date of 2021 Plan, if the Group's weighted average share price reaches the second share price level as approved by the Board;

In the event that any share issuance in connection with any share split, share dividend, reclassification or other similar event occurs, the target share price herein shall be adjusted accordingly with the proportion of additional share issuance. In the event that the average market value of NASDAQ Biotechnology Index falls by more than 20% from the adoption date of the 2021 Plan, it shall be deemed as a decline of the market, and the Group shall adjust the vesting schedule as appropriate.

(3) 1/3 of the awarded restricted share units shall vest based on the performance conditions as approved by the Board (the "Performance Conditions Based Awards"):

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16. SHARE-BASED COMPENSATION (CONTINUED)

(e) 2021 Share Incentive Plan ("2021 Plan") (continued)

i. a vesting of 75% of the Performance Conditions Based Awards if more than nine (including nine) but less than twelve of the fifteen performance conditions have been met on or before the first anniversary of the adoption date;

ii. a vesting of all of Performance Conditions Based Awards if more than twelve (including twelve) of the fifteen performance conditions have been met on or before the first anniversary of the adoption date;

As of December 31, 2021, it is probable that the 2/3 of the awarded restricted share units are fully vested because it is probable that the Group's weighted average share price can reach the second share price level as approved by the Board during any consecutive 90 days within one year after the adoption date of 2021 Plan, and more than twelve of the fifteen performance conditions will be met on or before the first anniversary of the adoption date.

The following table sets forth the restricted share units of 2021 Plan for the period presented:

	Number of restricted share units	Weighted average exercise price US$	Weighted average remaining contractual term	Aggregate intrinsic value US$
Outstanding as of December 31, 2020	—	—	—	—
Granted	1,827,166	—	—	—
Forfeited	(170,913)	—	—	—
Outstanding as of December 31, 2021	1,656,253	—	9.57	34,126
Granted	821,215	—	—	—
Vested	(1,139,587)	—	—	—
Forfeited	(301,908)	—	—	—
Outstanding as of December 31, 2022	1,035,973	—	8.55	2,266

A summary of non-vested restricted share units activities for year ended December 31, 2022 is presented below:

	Number of restricted share units	Weighted average grant-date fair value US$
Non-vested at December 31, 2021	1,656,253	26.45
Granted	821,215	9.18
Vested	(1,139,587)	26.41
Forfeited	(301,908)	17.85
Non-vested at December 31, 2022	1,035,973	5.19

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16. SHARE-BASED COMPENSATION (CONTINUED)

(e) 2021 Share Incentive Plan ("2021 Plan") (continued)

Share-based compensation expenses related to the restricted share units of 2021 Plan are included in:

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	—	44,227	46,649	6,763
Administrative expenses	—	73,332	99,708	14,456
Equity in loss of affiliates	—	—	4,077	591
	—	117,559	150,434	21,810

(f) 2022 Share Incentive Plan ("2022 Plan")

On June 17, 2022, the Group adopted 2022 Plan. Under the 2022 Plan, the maximum aggregate number of shares authorized to be issued is 13,148,594 ordinary shares, provided that the maximum number of shares to be issued in the form of restricted share units shall not exceed 7,670,017 ordinary shares.

As of December 31, 2022, no options or restricted share units were granted under 2022 Plan.

(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.

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16. SHARE-BASED COMPENSATION (CONTINUED)

(h) Surrender of stock options (continued)

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,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
Research and development expenses	284,431	201,926	117,876	17,090
Administrative expenses	209,033	406,683	239,272	34,691
Equity in loss of an affiliate	32,707	13,267	13,852	2,008
	526,171	**621,876**	**371,000**	**53,789**

17. 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, 2022.

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.

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17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

A. In-Licensing Arrangements (continued)

Licensing Agreement with MorphoSys AG ("MorphoSys") (continued)

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 years ended December 31, 2020, 2021 and 2022 as no milestone has been achieved.

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, 2020, 2021 and 2022. 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, 2020, 2021 and 2022.

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17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

A. In-Licensing Arrangements (continued)

Licensing Agreement with Genexine, Inc. ("Genexine") (continued)

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. For the year ended 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, 2021, the costs incurred for the development of this new indication was RMB13.2 million and thus RMB8.8 million expense was recorded in the consolidated statement of comprehensive loss. For the year ended December 31, 2022, the costs incurred for the development of this new indication was RMB7.0 million and thus RMB4.7 million expense was recorded in the consolidated statement of comprehensive loss.

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. In January 2021, the project achieved the second milestone and the Group paid US$1.5 million (equivalent to approximately RMB9.7 million) of milestone fees to Morphosys and the related withholding tax of RMB1.1 million, which was recorded as research and development expenses in the consolidated financial statements of comprehensive loss for the year ended December 31, 2021. 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, 2020, 2021 and 2022.

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17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

A. In-Licensing Arrangements (continued)

Licensing Agreement with MorphoSys (continued)

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
2022	—	—	—	—	—
2021	—	US$ 1,500	—	—	—
2020	—	US$ 1,000	—	—	—

In June 2022, Morphosys entered into an equity participation agreement and license agreements to allow HIBio to develop and commercialize MorphoSys' felzartamab, an anti-CD38 antibody, and MOR210, an anti-C5aR1 antibody. Under the terms of the agreements, HIBio will obtain exclusive rights to develop and commercialize felzartamab and MOR210 across all indications worldwide, with the exception of Greater China for felzartamab and Greater China and South Korea for MOR210. Upon signing, MorphoSys also receives an upfront payment of US$15 million for MOR210. Subject to the terms agreed in the C5aR Agreement, I-Mab is entitled to share certain economics upon certain clinical milestones in the U.S. Accordingly, the Group received US$0.9 million from MorphoSys and recorded RMB6.0 million in revenue in the consolidated statement of comprehensive loss for the year ended December 31, 2022.

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.

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17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

A. In-Licensing Arrangements (continued)

Licensing Agreement with MacroGenics (continued)

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. In September 2021, the project achieved the first milestone and the Group paid around US$4.5 million (equivalent to approximately RMB28.9 million) of milestone fees to MacroGenics, which was recorded as research and development expenses in the consolidated statement of comprehensive loss for the year ended December 31, 2021. No additional payments were made in the year ended December 31, 2022.

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 the remaining milestones are still not probable as of December 31, 2020 and 2021.

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
2022	—	—	—	—	—
2021	—	US$ 4,484	—	—	—
2020	—	—	—	—	—

In July 2022, due to an unexpected high incidence of fatal bleeding, MacroGenenics terminated a phase 2 study of enoblituzumab as a combination therapy with PD-1 antibody or PD-1/LAG3 bispecific antibody in patients with head and neck cancers (NHSCC). The Company has exercised its termination right under the license and collaboration agreement with MacroGenics by serving a termination notice to MacroGenics on August 29, 2022. The termination took effect in February 2023.

Licensing Agreement with Ferring

In November 2016, the Company, as the licensee, entered into a license and sublicense agreement with Ferring International Center SA (“Ferring”), with respect to Olamkicept (TJ301), a potential highly differentiated IL-6 blocker for ulcerative colitis and other autoimmune diseases (the “Ferring In-licensing Agreement”). Under the Ferring Agreement, Ferring granted to I-Mab an exclusive license to research, commercially develop, make, import, use, sell, dispose of, offer to sell or dispose of the licensed product in China (including Hong Kong, Macau), Taiwan and Korea. In July 2018, the Company sub-licensed the above license to I-Mab Hong Kong.

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17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

A. In-Licensing Arrangements (continued)

Licensing Agreement with Ferring (continued)

In September 2020, I-Mab Hong Kong agreed to assign all rights and obligations/ownership of Target Pipelines (including TJ301) to I-Mab Hangzhou (see Note 10 (a)). The Group entered into a sublicense agreement with I-Mab Hangzhou ("TJ301 Sublicense Agreement"), under which the Group sublicensed to I-Mab Hangzhou an exclusive, sublicensable license to develop, manufacture and commercialize olamkicept in mainland China, Hong Kong, Macau, Taiwan and South Korea.

In the second half year of 2021, I-Mab Hangzhou achieved one of the development milestones by completing the Phase IIA study report in China. Upon the achievement of the milestone, I-Mab Hangzhou made a milestone payment with the amount of US$3 million to I-Mab Hong Kong. As I-Mab Hangzhou's payment of US$3 million is just passthrough payment to I-Mab, and will be eventually paid to Ferring, which does not have any financial impact to I-Mab. The Company recorded it as a payable to Ferring in the consolidated balance sheets for the year ended December 31, 2021 . The US$3 million payable was settled in December 2022.

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$3.1 million (equivalent to approximately RMB21.3 million) milestone payment during the year ended December 31, 2020. The Group recorded US$1.1 million (equivalent to approximately RMB6.8 million) upfront payment and US$2.9 million (equivalent to approximately RMB19.8 million) milestone payment as research and development expenses during the year ended December 31, 2021. The Group recorded RMB0.5 million (US$0.07 million) upfront payment and RMB2.8 million (US$0.4 million) milestone payment as research and development expenses during the year ended December 31, 2022. As of December 31, 2022, under the terms of the agreements, the licensors are eligible to receive from the Group up to an aggregate of approximately US$173.4 million (equivalent to approximately RMB1,207.8 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.

B.Out-Licensing and Collabration Arrangement

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.

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17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

B. Out-Licensing and Collabration Arrangements (continued)

Collaboration Agreement with ABL Bio (continued)

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). 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. For the year ended December 31, 2021, RMB27.9 million expenses were incurred by the Group and RMB20.7 million expenses were incurred by ABL Bio. Accordingly, the Group recorded RMB24.3 million (50% cost sharing) of expenses in the Group's consolidated statement of comprehensive loss for the year ended December 31, 2021. For the year ended December 31, 2022, RMB63.1 million expenses were incurred by the Group and RMB33.7 million expenses were incurred by ABL Bio. Accordingly, the Group recorded RMB48.4 million (50% cost sharing) of expenses in the Group's consolidated statement of comprehensive loss for the year ended December 31, 2022.

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. The Group has recorded US$0.03 million (equivalent to approximately RMB0.17 million), US$0.02 million (equivalent to approximately RMB0.11 million), nil of research and development costs in the consolidated statement of comprehensive income for the year ended December 31, 2020, 2021 and 2022.

In April 2020, Tracon issued a notice of dispute with respect to the TJD5 Agreement and the BsAbs Agreement. The disputes relating to the TJD5 Agreement and the BsAbs Agreement are the subject of a binding arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce before an arbitration tribunal.

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17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

B. Out-Licensing and Collabration Arrangements (continued)

Collaboration Agreements with Tracon Pharmaceuticals, Inc. (Continued)

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. The Group accrued and recorded this termination fee of US$9.0 million (equivalent to approximately RMB58.0 million) as administrative expenses in the consolidated financial statements of comprehensive loss for the year ended December 31, 2021.

On April 25, 2023, the arbitration award determined that the TJD5 Agreement has been terminated for a pre-agreed termination fee of $9.0 million plus interest payable pursuant to the original agreement. For the year ended December 31, 2022, the Group accrued and recorded the interest for the termination fee with an amount of US$0.6 million (equivalent to approximately RMB4.2 million) as administrative expenses in the consolidated financial statements of comprehensive loss. The tribunal also confirmed the termination of the BsAb Agreement. Based on the arbitration award, I-Mab will bear a portion of Tracon's legal fees and costs, totaling approximately US$13.5 million (equivalent to approximately RMB91.3 million), which was recorded as administrative expenses in the consolidated financial statements of comprehensive loss for the year ended December 31, 2022.

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. On January 31, 2022, the Group and CSPC entered into an amendment to revise the second milestone payment from RMB10 million to RMB8.5 million.

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. The second milestone was achieved in November 2021 and RMB8.5 million was recognized as revenue in the consolidated statements of comprehensive loss for the year ended December 31, 2021. No revenue was recognized in the consolidated statements of comprehensive loss for the year ended December 31, 2022.

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17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

B. Out-Licensing and Collabration 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, 2021 and 2022, no revenue was recognized during the years ended December 31, 2020, 2021 and 2022.

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.

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.

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 has received milestone payment of US$20 million from AbbVie and is 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 double-digit percentages on global net sales outside of Mainland China, Macau, and Hong Kong.

I-MAB

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

17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

B. Out-Licensing and Collabration Arrangements (continued)

Global Strategic Partnership with AbbVie (continued)

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 years ended December 31, 2020 and 2021 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 and 2021 as the Group deemed that the achievement of the second milestone event is probable as of December 31, 2020 and 2021 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 2021, 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.

As of December 31, 2020 and 2021, 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 (RMB 227.4 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. As of December 31, 2021, the cumulative percentages complete in the cost-to-cost input method for Study I and Study II were estimated to approximate 53% and 51% respectively. As a result, US$4.0 million (equivalent to approximately RMB25.6 million) and US$0.9 million (equivalent to approximately RMB6.0 million) were recognized as revenue for the year ended December 31, 2021 in the consolidated financial statements of comprehensive loss for Study I and Study II respectively, resulting in an addition of contract asset of US$4.9 million (equivalent to approximately RMB31.6 million) for this agreement, and the total contract asset related to this agreement was US$39.7 million (RMB 253.8 million) as of December 31, 2021.

17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

B. Out-Licensing and Collabration Arrangements (continued)

Global Strategic Partnership with AbbVie (continued)

In August 2022, the Group and AbbVie entered into an amendment to the original license and collaboration agreement dated September 3, 2020. The Group will be eligible to receive, and AbbVie will pay, up to US$1.295 billion in the development, regulatory, and sales milestone payments, and the tiered royalties at rates from mid-to-high single-digit percentages on global net sales outside of Greater China for certain new anti-CD47 antibodies currently in development, or the original milestone payments and tiered royalties for other licensed products. The Group has the exclusive right to develop and commercialize all licensed products under the agreement in Greater China. AbbVie discontinued the global Phase 1b study of lemzoparlimab combination therapy with AZA and venetoclax in patients with MDS and acute myeloid leukemia (AML), and a Phase 1b study of lemzoparlimab in patients with relapsed/refractory multiple myeloma. As a result of the amendment to the original collaboration arrangement in the second half of 2022, the Group estimated the amount of consideration to which it will be entitled to under the amended agreement and determined the probability of achieving the second milestone payment of US$50 million is lowered. The Group concluded it is not probable that a significant reversal of revenue will not occur once the uncertainty associated with the milestone payment is resolved, the variable consideration of US$50 million associated with the second milestone is excluded from the transaction price at the amendment date. The consideration of US$200 million was re-allocated to the three performance obligations based on the relative stand-alone selling price at the amendment date. The allocated price for the grant of lemzoparlimab license, Study I and Study II is US183.0 million, US$8.8 million and US$ 8.2 million, respectively. As of the amendment date, based on the updated transaction price and the progress of each performance obligation, the Group recorded a cumulative catch-up adjustment which resulted in a reduction of revenue of US$48.0 million (equivalent to RMB 314.2 million), a reversal of contract assets of US$39.8 million, and a recognition of contract liabilities of US$8.2 million in the second half of 2022. Offsetting this amount, the revenue of US$5.8 million (equivalent to RMB 39.9 million) was recorded for the ongoing Study I and Study II initial development services for the year ended December 31, 2022. As of December 31, 2022, the cumulative percentages complete in the cost-to-cost input method for Study I and Study II were estimated to be approximate 84% and 88%, respectively. The accumulated revenue recognized for Study I and Study II was US$7.4 million and US$7.2 million, respectively, as of December 31, 2022. As of December 31, 2022, the balance of contract assets related to the collaboration arrangement with AbbVie was nil, while the balance of contract liabilities was US$2.4 million (RMB16.6 million).

Strategic collaboration with Jumpcan

On November 10, 2021, the Group entered into a strategic collaboration agreement (the "Jumpcan Agreement") with Jumpcan Pharmaceutical Group ("Jumpcan"), a China pharmaceutical company specialized in and committed to pediatric medicines, for the development, manufacturing and commercialization of I-Mab's highly differentiated long-acting recombinant human growth hormone, eftansomatropin alfa (the "TJ101" and "Licensed Product") in mainland China (the "Territory").

Under the collaboration agreement, I-Mab will continue to lead the ongoing registrational Phase 3 clinical trial of eftansomatropin alfa in pediatric growth hormone deficiency (PGHD). The two companies will share costs of manufacturing tech transfer, process optimization and new formulation development. I-Mab will be the marketing authorization holder (MAH) of the product and supply the product at agreed cost to Jumpcan. Jumpcan will be responsible for commercializing the product and developing new indications in collaboration with I-Mab in mainland China. I-Mab will provide clinical, manufacturing and academic support.

According to the terms of the collaboration agreement, Jumpcan will make an upfront payment of RMB 224 million to I-Mab and, upon achievement of development, registration and sales milestones, certain milestone payments of up to RMB 1.792 billion, making the non-royalty payments a total of up to RMB 2.016 billion. In addition, I-Mab and Jumpcan will share profits generated from commercialization of the product in mainland China on a 50/50 basis, pursuant to which I-Mab will be entitled to receive tiered low double-digit royalties on net sales.

I-MAB

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

17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

B. Out-Licensing and Collabration Arrangements (continued)

Strategic collaboration with Jumpcan (continued)

The Group performed assessment and concluded that all the promise identified, including the grant of the license to Jumpcan, Phase III clinical trial in PGHD and CMC development under the Jumpcan Agreement have been bundled into a single performance obligation. The amounts of the transaction price allocable to this performance obligation are deferred until the control of the manufactured commercial drug product has begun to transfer to Jumpcan. For the year ended December 31, 2021, the Group received the upfront fee of RMB224 million from Jumpcan and recorded it as contract liabilities in the consolidated balance sheet as of December 31, 2021. According to the terms of the collaboration agreement, Jumpcan shall undertake to bear 50% proportion of the CMC cost occurred by I-Mab after the effective date of this agreement. these costs. For the year ended December 31, 2022, the Group received the payment of RMB22.0 million from Jumpcan related to the cost sharing and recorded it as contract liabilities in the consolidated balance sheet.

Cell Line Collaboration with Ferring

In May 2022, the Group entered into an amended and restated license and sublicense agreement and a cell line and manufacturing collaboration agreement ("Cell Line Collaboration Agreement") with Ferring, under which the Group granted to Ferring an exclusive, perpetual and transferrable sublicense, with the right to grant further sublicenses to sublicensees, under all of the intellectual properties licensed to I-Mab by I-Mab's business partner to research, develop, make, import, use and sell olamkicept as expressed by or produced by cell lines created by I-Mab's business partner and its affiliates, in any human indications in the territories other than Greater China and Korea. The Group also granted to Ferring an exclusive, perpetual and royalty-free license, with right of sublicense to sublicensees, under the intellectual property owned or controlled by I-Mab which relates to cell lines created by I-Mab's business partner and its affiliates, for the research, development, making, using or selling of olamkicept, including prespecified patents and know-how and improvements thereto. As of December 31, 2022, Ferring paid to the Group the milestone payment as specified in the Cell Line Collaboration Agreement. This payment was recorded in revenue in the consolidated statements of comprehensive loss for the year ended December 31, 2022. Ferring also agreed to make milestone payments to us, conditioned on the achievement of certain development milestones in Ferring's licensed territory.

In May 2022, the Group entered into a supplementary sublicensing agreement to the TJ301 Sublicense Agreement ("TJ301 Supplemental Sublicense Agreement") with I-Mab Hangzhou. Pursuant to the TJ301 Supplemental Sublicense Agreement, I-Mab Hong Kong should pay I-Mab Hangzhou US$2.75 million (equivalent to approximately RMB18.6 million) to reimburse the effort and contribution from I-Mab Hangzhou in the development of Wuxi Cell Line, which was recorded as the reduction of revenue in the consolidated financial statements of comprehensive loss for the year ended December 31, 2022.

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

17. LICENSING AND COLLABORATION ARRANGEMENTS (CONTINUED)

Breakdown of licensing and collaboration revenue

The breakdown of licensing and collaboration revenue was as follows:

	Year Ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$(Note 2.5)
Recognition in the year	*1,542,668*	*31,615*	*39,891*	*5,784*
Reduction in the year	—	—	*(314,181)*	*(45,552)*
Revenues from AbbVie	1,542,668	31,615	(274,290)	(39,768)
Revenues from other partners	—	8,500	24,625	3,570
	1,542,668	**40,115**	**(249,665)**	**(36,198)**

18. OTHER INCOME (EXPENSES), NET

The following table summarizes other income (expenses), net recognized for the years ended December 31, 2020, 2021 and 2022:

		Year Ended December 31			
		2020	2021	2022	
	Notes	RMB	RMB	RMB	US$ (Note 2.5)
Income of incentive payment from depository bank	11	2,348	2,395	2,821	409
Fair value change of short-term and other investments		11,288	30,360	(13,549)	(1,964)
Fair value change of put right liabilities		3,024	16,628	34,260	4,967
Net foreign exchange gains (losses)		(22,126)	25,373	(175,391)	(25,429)
Subsidy income [(3)]		11,633	9,216	25,470	3,693
Gains on deconsolidation of a subsidiary	10	407,598	—	—	—
Others		(873)	(810)	(198)	(29)
		412,892	83,162	(126,587)	(18,353)

(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. For the year ended December 31, 2021, subsidy income primarily consists of an amount of RMB2.9 million related to the paycheck protection program loan forgiveness approved by the U.S. Small Business Administration in April 2021, and an amount of RMB4.5 million recognized in connection with the completion of a project related to one of the Group's pipelines. For the year ended December 31, 2022, subsidy income consists primarily of the government grant of RMB18.9 million. The government grant was granted by the project management office of Shanghai Zhangjiang Science City and the management committee of Shanghai Free Trade Zone to support the research and development activities in the local region.

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

19. 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			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
	(in thousands, except for share and per share data)			
Numerator:				
Net income (loss) attributable to I-Mab	470,915	(2,331,541)	(2,507,317)	(363,526)
Net income (loss) attributable to ordinary shareholders	470,915	(2,331,541)	(2,507,317)	(363,526)
Denominator:				
Denominator for basic calculation-weighted average number of common shares outstanding	134,158,824	174,707,055	189,787,292	189,787,292
Dilutive effect of convertible preferred shares	4,373,047	—	—	—
Dilutive effect of ordinary shares to be issued to Everest	266,458	—	—	—
Dilutive effect of convertible promissory notes	865,479	—	—	—
Dilutive effect of restricted shares units	778,130	—	—	—
Dilutive effect of stock options	16,789,714	—	—	—
Denominator for diluted income (loss) per share calculation	157,231,652	174,707,055	189,787,292	189,787,292
Net income (loss) per share - basic	3.51	(13.35)	(13.21)	(1.92)
Net income (loss) per share - diluted	3.00	(13.35)	(13.21)	(1.92)

The effects of all outstanding restricted shares, certain stock options and warrants have been excluded from the computation of diluted loss per share for the years ended December 31, 2021 and 2022 as their effects would be anti-dilutive. 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	
	2021	2022
Restricted shares	3,150,881	484,395
Stock options	14,584,833	2,939,322
Warrants	648,359	—

20. 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 RMB10,049, RMB26,426 and RMB35,332 for the years ended December 31, 2020, 2021 and 2022, respectively.

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

21. 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 17). In April 2020, Tracon issued a notice of dispute with respect to the TJD5 Agreement and the BsAbs Agreement. The disputes relating to the TJD5 Agreement and the BsAbs Agreement are the subject of a binding arbitration proceeding under the Rules of Arbitration of the International Chamber of Commerce before an arbitration tribunal. In April 2023, the Group received the result of the arbitration, which is further discussed in Note 17.

The Group did not have significant long-term obligations, or guarantees as of December 31, 2021 and 2022.

Capital commitments

The capital expenditures related to property, equipment and software contracted for as of December 31, 2021 and 2022 but not recognized in the Group's consolidated financial statements were RMB24,426 and RMB4,392, respectively.

22. RELATED PARTY BALANCES AND TRANSACTIONS

The table below sets forth the major related parties and their relationships with the Group for the years ended December 31, 2020, 2021 and 2022:

Name of related parties	Relationship with the Group
CMAB Biopharma (Suzhou) Inc.	Controlled by the ultimate controlling party of a principal shareholder of the Group before April 30, 2021
Jiangsu Taslydiyi Pharmaceutical Co., Ltd.	Controlled by the ultimate controlling party of a principal shareholder of the Group before December 9, 2021
I-Mab Biopharma (Hangzhou) Co., Limited	Subsidiary of the Group before September 15, 2020; Affiliate of the Group after September 15, 2020

Details of related party balances as of December 31, 2021 and 2022 are as follows:

Prepayments and other receivables

	As of December 31,		
	2021	2022	
	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou	8,079	8,231	1,193

Accruals and other payables

	As of December 31,		
	2021	2022	
	RMB	RMB	US$ (Note 2.5)
Jiangsu Taslydiyi Pharmaceutical Co., Ltd.	5,092	—	—
I-Mab Hangzhou	—	64,782	9,393

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

22. RELATED PARTY BALANCES AND TRANSACTIONS (CONTINUED)

Details of related party transactions for the years ended December 31, 2020, 2021 and 2022 are as follows:

Receipt of CRO and CMC services - recognized in research and development expenses

	For the year ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
CMAB Biopharma (Suzhou) Inc.	681	—	—	—
Jiangsu Taslydiyi Pharmaceutical Co., Ltd.	2,395	2,697	—	—
I-Mab Hangzhou	—	2,465	84,673	12,276

Revenue sharing - recognized as deduction of revenue

	For the year ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou (Note 17)	—	—	18,583	2,694

Collection of loan to an affiliate

	For the year ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou [4]	52,000	—	—	—

[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,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou	21,212	17,649	—	—

Provision of FTE and other services - recognized in other income

	For the year ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou	—	11,691	—	—

Amounts received on behalf of an affiliate

	For the year ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou	—	281	—	—

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

22. RELATED PARTY BALANCES AND TRANSACTIONS (CONTINUED)

Amounts received related to the sublicense agreement

	For the year ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou (Note 17)	—	19,102	—	—

Amounts paid by an affiliate on behalf of the Group

	For the year ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US$ (Note 2.5)
I-Mab Hangzhou	—	25,448	837	121

23. 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, accounts receivable, contract assets, and other receivables. The carrying amounts of cash and cash equivalents, short-term investments and contract assets represent the maximum amount of loss due to credit risk. As of December 31, 2021 and 2022, 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 and other receivables, 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)

24. 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, 2020, 2021 and 2022, 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, 2022, 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.

THE SYMBOL "[REDACTED]" DENOTES PLACES WHERE CERTAIN INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (1) NOT MATERIAL, AND (2) THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

August 15, 2022

I-Mab Biopharma Co., Ltd.
天境生物科技(上海)有限公司
Suite 802, West Tower, OmniVision
88 Shangke Road, Pudong District
Shanghai, 201210
P.R. China
Attn: Legal

I-Mab Biopharma US Limited
Suite 516, 2275 Research Boulevard,
Rockville, Maryland, 20850
United States
Attention: Claire Xu, Site Head and US Clinical R&D Head

RE: Amendment No.1 to License and Collaboration Agreement

AbbVie Global Enterprises Ltd. (as assignee from AbbVie Ireland Unlimited Company) ("**AbbVie**") and I-Mab Biopharma Co., Ltd. ("**I-Mab Shanghai**", 天境生物科技(上海)有限公司) and I-Mab Biopharma US Limited ("**I-Mab US**" and collectively with I-Mab Shanghai, "**I-Mab**") are parties to that certain License and Collaboration Agreement entered into September 3, 2020 (the "**Agreement**"). Capitalized terms used but not defined in this letter have the respective meanings set forth in the Agreement. Each of AbbVie and I-Mab may be referred to in this letter individually as a "**Party**" and collectively as the "**Parties**".

The Parties have agreed to amend (a) the anti-shelving provision under the Agreement and (b) certain amounts payable under the Agreement with respect to any Other Licensed Product (as defined below) and in each case ((a) and (b)) desire to memorialize such agreement in this letter. In consideration of the mutual representations, warranties and covenants contained in this letter, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows under the terms of this letter agreement and amendment to the Agreement ("**Amendment No.1**"). This Amendment No.1 is entered into and shall become effective on the date of the last signature (the "**Effective Date**").

Cessation of Development and Commercialization

1. Section 2.6.1 of the Agreement is hereby amended by deleting the word "clinical" from "material clinical Development".

Financials for Other Licensed Product

2. The following new definition is hereby added to Article 1 of the Agreement:

   a. "**Other Licensed Product**" means any Licensed Product that (a) does not contain the [REDACTED], and (b) contains a Licensed Compound that is [REDACTED] as the sole Licensed Compound.

3. Section 10.3.1 and Section 10.4.1 of the Agreement are hereby amended as set forth in **Exhibit A** of this letter.

General Provisions

4. **Exhibit B** sets forth the public disclosures agreed to by the Parties with respect to this letter. Neither Party shall make any other public disclosure regarding this letter without complying with its obligations under Section 12.5 of the Agreement.

5. Each Party represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under Applicable Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this letter; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents or any other agreement by which it is bound or requirement of Applicable Laws; and (d) this letter is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to Applicable Laws of bankruptcy and moratorium).

6. This letter shall be governed under, and subject to, the terms of Article 12 (Confidentiality and Non-Disclosure) (and the terms of this letter shall be the Confidential Information of both Parties) and Article 16 (Miscellaneous) (other than Section 16.17) of the Agreement as if such terms were expressly set forth in this letter.

7. Except as expressly amended hereby, all of the terms and conditions of the Agreement shall remain in full force and effect. This Amendment No.1, together with the Agreement and the exhibits and schedules hereto and thereto, constitute the full and entire understanding and agreement between the Parties with regard to the subjects hereof. This Amendment No.1 may be executed in any number of counterparts, each of which is enforceable against the parties that execute such counterparts, and all of which together constitute one instrument.

[Signature page follows.]

If this letter accurately sets forth our understanding, kindly execute this letter and return it to the undersigned.

Best regards,

AbbVie Global Enterprises Ltd.

By: /s/ Jonathan C. Clipper
Jonathan C. Clipper

Date: August 15, 2022

Accepted and agreed:

I-Mab Biopharma Co., Ltd.

By: /s/ Jingwu Zhang Zang
Jingwu Zhang Zang
Legal Representative
Date: August 15, 2022

I-Mab Biopharma US Limited

By: /s/ Jingwu Zhang Zang
Jingwu Zhang Zang
Director
Date: August 15, 2022

Exhibit A
Amendments to Certain Financial Terms

1. Section 10.3.1 of the Agreement is hereby amended and replaced in its entirety as follows:

10.3.1 Development, Regulatory and First Commercial Sale Milestones. Subject to the terms and conditions of this Agreement, with respect to each of the following Milestone Events, AbbVie shall pay to I-Mab a one (1)-time non-refundable and non-creditable Milestone Payment within [REDACTED] after such Milestone Event is first achieved by or on behalf of AbbVie or its Affiliates or Sublicensees during the Term as follows:

	Milestone Event	**Milestone Payment**
1.	Fulfillment of the success criteria (as set forth in **Schedule 10.3.1(a)**) in conjunction with the AML/MDS monotherapy Phase 1 dose escalation study identified as "study 2" in the Initial Development Plan as of the Execution Date at the 10mg/kg dose level	Twenty Million Dollars ($20,000,000)* * Milestone Payment for Milestone Event 1 previously paid by AbbVie.
2.	[REDACTED]	[REDACTED]
3.	[REDACTED]	[REDACTED]
4.	[REDACTED]	[REDACTED]
5.	[REDACTED]	[REDACTED]
6.	[REDACTED]	[REDACTED]
7.	[REDACTED]	[REDACTED]
8.	[REDACTED]	[REDACTED]
9.	[REDACTED]	[REDACTED]
10.	[REDACTED]	[REDACTED]
11.	[REDACTED]	[REDACTED]

For clarity, each of the Milestone Payments set forth in this Section 10.3.1 shall be payable only once upon the first achievement of the corresponding Milestone Event, and any subsequent or repeated achievement of the same Milestone Event, whether by the same Licensed Product or by a Licensed Product different from the first Licensed Product used in the same Milestone Event, shall not result in any additional payment obligation for AbbVie under this Section 10.3.1.

[REDACTED]

2. Section 10.4.1 of the Agreement is hereby amended and replaced in its entirety as follows:

10.4.1 Royalty Rates. Subject to the terms and conditions of this Agreement, AbbVie shall pay to I-Mab, with respect to each Licensed Product, a tiered royalty on Net Sales of such Licensed Product by AbbVie or any of its Affiliates or Sublicensees in the AbbVie Territory in each Calendar Year during the Royalty Term with respect to such Licensed Product and each country or jurisdiction in the AbbVie Territory, at the following rates:

Aggregate Net Sales in a Calendar Year for such Licensed Product	**Royalty Rate**
For that portion of aggregate Net Sales of such Licensed Product in the AbbVie Territory in a Calendar Year less than [REDACTED]	[REDACTED]
For that portion of aggregate Net Sales of such Licensed Product in the AbbVie Territory in a Calendar Year equal to or greater than [REDACTED] but less than [REDACTED]	[REDACTED]
For that portion of aggregate Net Sales of such Licensed Product in the AbbVie Territory in a Calendar Year equal to or greater than [REDACTED] but less than [REDACTED]	[REDACTED]
For that portion of aggregate Net Sales of such Licensed Product in the AbbVie Territory in a Calendar Year equal to or greater than [REDACTED] but less than [REDACTED]	[REDACTED]
For that portion of aggregate Net Sales of such Licensed Product in the AbbVie Territory in a Calendar Year equal to or greater than [REDACTED]	[REDACTED]

With respect to each Licensed Product in each country (or jurisdiction) in the AbbVie Territory, from and after the expiration of the Royalty Term for such Licensed Product in such country or jurisdiction, Net Sales of such Licensed Product in such country or jurisdiction shall be excluded for purposes of calculating the Net Sales thresholds and ceilings set forth in this Section 10.4.1. For purposes of this Section 10.4.1, with respect to a particular country, Net Sales shall include sales without the receipt of Regulatory Approval for a Licensed Product in such country, such as so-called "treatment IND sales" or "named patient sales" if such sales are the primary means of Commercialization of such Licensed Product in such country and Regulatory Approval for such Licensed Product in such country will not be sought.

Exhibit B
Agreed Public Disclosures

I-Mab Provides Updates on Its Global Strategic Partnership with AbbVie

I-Mab (the "Company") (Nasdaq: IMAB) today announced that the Company and AbbVie Global Enterprises Ltd. (as assignee of AbbVie Ireland Unlimited Company) ("AbbVie") have entered into an amendment to the original license and collaboration agreement dated September 3, 2020 among I-Mab Biopharma (Shanghai) Co., Ltd. and I-Mab Biopharma US Limited, each a wholly-owned subsidiary of the Company, and AbbVie (as amended, the "Agreement").

The parties will continue to collaborate on the global development of anti-CD47 antibody therapy under the Agreement. The Company will be eligible to receive, and AbbVie will pay, up to US$1.295 billion in the development, regulatory and sales milestone payments, and the tiered royalties at rates from mid-to-high single digit percentages on global net sales outside of Greater China for certain new anti-CD47 antibodies currently in development, or the original milestone payments and tiered royalties previously disclosed in the Company's Form 20-F for the fiscal year 2021 for other licensed products. The Company has the exclusive right to develop and commercialize all licensed products under the Agreement in Greater China.

AbbVie will discontinue the global Phase 1b study of lemzoparlimab combination therapy with azacitidine ("AZA") and venetoclax, in patients with myelodysplastic syndrome ("MDS") and acute myelocytic leukemia ("AML"). This decision was not based on any specific or unexpected safety concerns.

The Company continues its commitment on lemzoparlimab development with a near-term focus on the initiation of a Phase 3 clinical trial in patients with MDS in China, which is supported by the safety and efficacy data from its Phase 2 study of combination therapy of lemzoparlimab and AZA in patients with higher risk MDS. The detailed data will be presented in a proffered paper at the European Society for Medical Oncology (ESMO) Congress in September 2022. To date, Phase 1 and Phase 2 clinical studies of lemzoparlimab in the U.S. and China with nearly 200 patients enrolled have shown a good safety profile without the need for a priming dosing regimen.

The Company has a strong cash position (US$671 million in cash, cash equivalents and short-term investments as of December 31, 2021) to support the ongoing and planned clinical development of lemzoparlimab, in addition to other critical late-stage clinical assets.

Exhibit 4.23

English translation

I-Mab Biopharma (Hangzhou) Co., Ltd.

Investment Agreement

July 16, 2022

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INVESTMENT AGREEMENT

This INVESTMENT AGREEMENT (this "**Agreement**") is entered into in the PRC on July 16, 2022 (the "**Signing Date**") by and among the following parties:

1. **I-Mab Biopharma (Hangzhou) Co., Ltd.**, a limited liability company legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330100MA2GNANB49 (the "**Company**");

2. **I-Mab Biopharma Co., Ltd.**, a limited liability company legally established and existing in accordance with the PRC laws, whose unified social credit code is 91310115MA1K3G0E1F ("**I-Mab Shanghai**");

3. **I-MAB BIOPHARMA HONGKONG LIMITED**, a company limited by law established in accordance with the laws of the Hong Kong Special Administrative Region of the PRC, whose registration number is 2400410 ("**I-Mab HK**");

4. **Pingtan Wenzhou Ruihe Investment Partnership (Limited Partnership) (平潭文周瑞和投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91350128MA8TQEYH30 ("**Wenzhou Ruihe**");

5. **Huzhou Jingyun Equity Investment Partnership (Limited Partnership) (湖州静耘股权投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330501MA2JL1G07W ("**Huzhou Jingyun**");

6. **Pingtan Wenzhou Ruizhi Investment Partnership (Limited Partnership) (平潭文周瑞致投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91350128MA8TQFP85C ("**Wenzhou Ruizhi**");

7. **Jiaxing Hongtong Investment Partnership (Limited Partnership) (嘉兴鸿桐创业投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330402MA7GF15T8Q ("**Jiaxing Hongtong**");

8. **Qingdao Zhongou Industry Investment Partnership (Limited Partnership) (青岛中欧创新产业投资基金合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91370202MA3WNGTEXK ("**Qingdao Zhongou**");

9. **Qingdao Haiyang Innovation Investment Co., Ltd. (青岛海洋创新产业投资基金有限公司)**, a limited liability company legally established and existing in accordance with the PRC laws, whose unified social credit code is 91370282MA3N5L323R ("**Qingdao Haiyang Innovation**");

10. **Ningbo Yijing Management Partnership (Limited Partnership) (宁波市伊境企业管理合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330205MA7JC3H09J ("**Ningbo Yijing**");

11. **Ningbo Hangjing Management Partnership (Limited Partnership) (宁波市杭境企业管理合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330205MA7HXY278M ("**Ningbo Yijing**");

12. **Ningbo Zhengjing Management Partnership (Limited Partnership) (宁波市正境企业管理合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330205MA7GQY2K5F ("**Ningbo Zhengjing**", together with Ningbo Zhengjing, Wenzhou Ruihe, Huzhou Jingyun, Wenzhou Ruizhi, Jixing Hongtong, Qingdao Zhongou, Qingdao Haiyang Innovation, Ningbo Yijing, Ningbo Hangjing, the "**Investors**"); (for the avoidance of doubt, Investors does not include series A round investors)

13. **Lili Qian**, a Chinese citizen, whose ID number is ***;

14. **Zhengsong Zhang**, a Chinese citizen, whose ID number is ***;

15. **Yunfei Zhang**, a Chinese citizen, whose ID number is ***;

16. **Lihong Lou**, a Chinese citizen, whose ID number is ***;

17. **Kai Zhou**, a Chinese citizen, whose ID number is ***;

18. **Fang Yin**, a Chinese citizen, whose ID number is *** (together with Lili Qian, Zhengsong Zhang, Yunfei Zhang, Lihong Lou and Kai Zhou, collectively referred to as the "**Management**");

19. **Hangzhou Yijing Biotech Partnership (Limited Partnership) (杭州伊境生物科技合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330100MA2HY0AEXX ("**Hangzhou Yijing**"); and

20. **Hangzhou Lanjing Biotech Partnership (Limited Partnership) (杭州阑境生物科技合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330100MA2HY07T3Q ("**Hangzhou Lanjing**"; together with I-Mab HK, the Series A Round Investors, and Hangzhou Yijing, collectively referred to as the "**Existing Shareholders**").

The above parties are hereinafter collectively referred to as the "**Parties**". When any party hereto is referred to as a "**Party**", the other parties hereto will be referred to as the "**Other Parties**".

WHEREAS:

1. The Company is a limited liability company legally established and existing in accordance with PRC laws, which was established on 26 June, 2019. The Company's unified social credit code is 91330100MA2GNANB49, its current registered capital is USD 30 million, and its business scope is: technology development, technology services, technology consulting, and transfer of results: biotechnology, pharmaceutical technology (with respect to the above, except for the development and application of human stem cells, gene diagnosis and treatment technology); production: drugs; drugs, pharmaceutical intermediates, Category I medical device wholesale and import and export business (except for those subject to special access control regulations stipulated by the state).

2. As of the Signing Date of this Agreement, I-Mab HK holds 45% of the equity in the Company, represented by the Company's registered capital of USD 13.50 million, of which the paid-in registered capital is USD 13.50 million. I-Mab HK is a wholly owned Subsidiary of I-Mab 天境生物 (NASDAQ: IMAB; hereinafter referred to as "**I-Mab**").

3. As of the Signing Date of this Agreement, the Series A Round Investors hold a total of 40% of the Company's equity, of which Fushi Capital holds 8.33% of the Company's equity, corresponding to USD 2.5 million in registered capital of the Company, and a paid-in capital of USD 2.5 million; Heda Investment holds 6.67% of the Company's equity, corresponding to USD 2 million in registered capital of the Company, and a paid-in capital of USD 2 million; Tsingsong Shenzhen holds 5.52% of the Company's equity, corresponding to USD 1.655 million in registered capital of the Company, and a paid-in capital of USD 1.655 million; Ronghui Derun holds 3.33% of the Company's equity, corresponding to USD 1 million in registered capital of the Company, and a paid-in capital of USD 1 million; Tsingsong Nanjing holds 2.82% of the Company's equity, corresponding to USD 845,000 in registered capital of the Company, and a paid-in capital of USD 845,000; Guochuang Junyao holds 2.33% of the Company's equity, corresponding to USD 700,000 in registered capital of the Company, and a paid-in capital of USD 700,000; Hanhai Qianyuan holds 2.33% of the Company's equity, corresponding to USD 700,000 in registered capital of the Company, and a paid-in capital of USD 700,000; Yanchuang Yangming holds 1.07% of the Company's equity, corresponding to USD 320,000 in registered capital of the Company, and a paid-in capital of USD 320,000; Haibang Yigu holds 1% of the Company's equity, corresponding to USD 300,000 in registered capital of the Company, and a paid-in capital of USD 300,000; Jialiang Shan holds 1% of the Company's equity, corresponding to USD 300,000 in registered capital of the Company, and a paid-in capital of USD 300,000; Silu Fund holds 1% of the Company's equity, corresponding to USD 300,000 in registered capital of the Company, and a paid-in capital of USD 300,000; Yanyuan Dongfang holds 0.93% of the Company's equity, corresponding to USD 280,000 in registered capital of the Company, and a paid-in capital of USD 280,000; Rongshun Yanyuan holds 0.83% of the Company's equity, corresponding to USD 250,000 in registered capital of the Company, and a paid-in capital of USD 250,000; Yanyuan Innovation holds 0.83% of the Company's equity, corresponding to USD 250,000 in registered capital of the Company, and a paid-in capital of USD 250,000; Yanyuan Chanrong holds 0.67% of the Company's equity, corresponding to USD 200,000 in registered capital of the Company, and a paid-in capital of USD 200,000; Viva Biotech holds 0.67% of the Company's equity, corresponding to USD 200,000 in registered capital of the Company, and a paid-in capital of USD 200,000; Huatian Enterprise Management holds 0.42% of the Company's equity, corresponding to USD 125,000 in registered capital of the Company, and a paid-in capital of USD 125,000; Qingdao Xinneng holds 0.25% of the Company's equity, corresponding to USD 75,000 in registered capital of the Company, and a paid-in capital of USD 75,000.

4. As of the date of signing of this Agreement, Hangzhou Yijing holds 10% of the Company's equity, corresponding to USD 3 million in registered capital of the Company, and a paid-in capital of USD 750,000. Hangzhou Yijing is the Management Holdco of the Company, and the Executive Affairs Partner is Lili Qian. Hangzhou Lanjing holds 5% of the Company's equity, corresponding to USD 1.5 million in registered capital of the Company, and a paid-in capital of USD 0. Hangzhou Lanjing is the ESOP Holdco of the Company, and the Executive Affairs Partner is Lili Qian.

5. The Investors intend to invest a total of RMB 292.43 million into the company through capital increase and share expansion to subscribe for new registered capital of the Company totaling to USD 3.445758 million ("**New Registered Capital**")("**This Capital Increase**").

6. the Parties will also sign a Shareholders Agreement (the "**Shareholders Agreement**") on or before Closing Date to further provide for the rights and obligations of the shareholders of the Company after the Closing Date.

THEREFORE, the Parties have entered into the following agreement through negotiation:

Article 1 Definitions

1.1 **Definitions**. Definitions The following terms shall have the following meanings when used in this Agreement:

Affiliate	With respect to a Party, refers to any enterprise that controls or is controlled by such Party, or is under common control by the same entity with such Party. "**Control**" means directly or indirectly owning more than fifty percent (50%) of equity, voting rights, or directly or indirectly owning more than fifty percent (50%) of any other equivalent assets of the enterprise, or other power or right that can independently determine the management of the enterprise. "Entities" may include but are not limited to individuals, partnerships, companies and other legal entities.
Senior Officers	Refer to general manager, deputy general manager, financial controller and other VP or above level officers.
Working Day	Refers to any day except Saturdays, Sundays or Chinese legal holidays.
Qualified IPO	The public offering of the Company's shares on the China Stock Exchange's Science and Technology 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 the Company in accordance with provisions of the Shareholders Agreement.

Transaction Documents	Refer to this Agreement, the Shareholders Agreement, the Amended and Restated Articles of Association of the Company reflecting This Capital Increase (referred to as the "**Amended Articles of Association**"), and any other agreement or document in connection with the transactions contemplated hereunder which is entered into pursuant to any of the foregoing documents.
Person	Refers to any natural person, legal person, partnership, limited liability company, company limited by shares, association, trust, unincorporated organization, or any other legal entity of any nature established in accordance with any Applicable Law, or any Government Agency.
MOFCOM	Refers to the Ministry of Commerce of China and its counterparts at all levels that exercise similar powers.
Market Regulation Bureau	Refers to the PRC's State Administration for Market Regulation and its local counterparts that exercise similar powers at all levels.
Applicable Law	With respect to any Person, refers to any public, valid and applicable treaties, laws, administrative regulations, local regulations, rules, decisions, orders, judicial interpretations, judgments, rulings, arbitration awards or other normative documents that is applicable to that Person or binding on that Person or any of its assets.
Subsidiary	With respect to any Person, refers to any legal person, partnership, limited liability company, company limited by shares, association, trust, or other entity in which the Person (alone or through or in collaboration with any other Person) directly or indirectly owns securities or other interests in it, so that the Person generally has more than fifty percent (50%) of the voting rights in the election of the board of directors or other similar decision-making bodies, or in which the Person is given the right to control by other means.
I-Mab Shanghai	I-Mab Biopharma Co., Ltd.
Beijing Sanjing	Sanjing (Beijing) Biotechnology Co., Ltd.
I-Mab Tianjin	I-Mab Bio-tech (Tianjin) Co., Ltd.
Series A Round Investment Agreement	On September 15, 2020, the Existing Shareholders, the Management and the Company except for Qingdao Xinneng entered into that certain Equity Transfer and Investment Agreement.

Series A Round Investors	Refers to the entities listed in row #2 to row #19 in Schedule 2 attached hereto.
the Management	Lili Qian, a Chinese citizen, whose ID number is ***; Zhengsong Zhang, a Chinese citizen, whose ID number is ***; Yunfei Zhang, a Chinese citizen, whose ID number is ***; Lihong Lou, a Chinese citizen, whose ID number is ***; Kai Zhou, a Chinese citizen, whose ID number is ***; Fang Yin, a Chinese citizen, whose ID number is ***.
Management Holdco	Refers to the entity listed in row #20 in Schedule 2 attached hereto.
ESOP Holdco	Refers to the entity listed in row #21 in Schedule 2 attached hereto.
Existing Shareholders	Refers to I-Mab HK, the Series A Round Investors, the Management, ESOP Holdco and Management Holdco.
Intellectual Property	Refers to patents, trademarks, service marks, registered designs, domain names, utility models, copyrights, inventions, confidential information, trade secrets, proprietary production processes and equipment, brand names, database rights, trade names, or a right similar to any of the above, and the interest of any of the above (whether registered or unregistered, and including the application for the authorization of the above items and the right to apply for any of the above items anywhere in the world).
OXIF	Refer to the OX40-IFNα bispecific antibody fusion protein introduced by the Company in December 2020.
A3	Refers to the Target Pipeline TJA3 listed in Schedule 1 of the Series A Round Investment Agreement.
T6	Refers to the Target Pipeline TJT6 listed in Schedule 1 to the Series A Round Investment Agreement.
L1A3	Refers to the Target Pipeline TJL1A3 listed in Schedule 1 of the Series A Round Investment Agreement.
Material Adverse Change	Refers to any material adverse impact or change that has caused a significant adverse effect on the Company's Target Pipelines, business, management, financial condition, Intellectual Property, debt, governmental approval, or qualifications (but in each case does not include any such material adverse impact or change that has been remedied or corrected); in case the Company incurs or is reasonable expected to incur a loss of RMB 5 million or more, it shall be deemed as a Material Adverse Change.

Government agency	Refers to any government or its affiliates with jurisdiction, any department or agency of any government or its affiliates, any legislative body, court or arbitral tribunal, and any stock exchange regulatory agency.
PRC	Refers to the People's Republic of China. For the purpose of this Agreement, it does not include the Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan.
Greater China	Refers to the People's Republic of China. For the purposes of this Agreement, it includes the Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan.
Force Majeure Event	Refers to any objective event or circumstance that is unforeseeable, inevitable and unavoidable, including without limitation earthquake, typhoon, flood, fire or other natural disasters, strike, pandemic (including COVID-19), riot, war. For the avoidance of doubt, any change of laws, regulations, policies, government orders of any national, regional or local Government Agency that is unforeseeable on the Signing Date hereof shall be deemed as Force Majeure.

Article 2 This Capital Increase

2.1 On the Signing Date of this Agreement, the Company's registered capital is USD 30 million, and the paid-in registered capital is USD 26.25 million. The amount of registered capital respectively subscribed by current the shareholders of the Company and their respective shareholding percentage in the Company are reflected in **Schedule 2**.

2.2 The Investors agree to subscribe for the New Registered Capital of the Company of USD 3.445758 million at a price of RMB 292.43 million on the Closing Date in order to acquire 5.00% equity in the Company after This Capital Increase, of which USD 3.445758 million is credited to the registered capital of the Company and the remaining USD 4.2497683 million is credited to the capital reserve of the Company in accordance with the terms and conditions agreed herein.

2.3 The Existing Shareholders agree to This Capital Increase and agree to waive their Pre-emptive Rights to subscribe to This Capital Increase in accordance with the articles of association, Shareholders Agreement or other agreements between Existing Shareholders currently in force.

Article 3 Closing Conditions

3.1 **Conditions Precedent**. The obligation of the Investors to complete its obligation to subscribe for the New Registered Capital and to pay the consideration of their investments ("**Closing**") shall be subject to the following conditions (each of which is referred to as a "**Condition Precedent**") being satisfied or waived in writing by the Investors on or prior to the Closing Date:

(1) The Investors have completed the business, legal, and financial due diligence on the Company;

(2) The representations and warranties made by the Company herein are true, accurate, complete and not misleading in all material respects on the Signing Date and the Closing Date, there is no Material Adverse Change in the Company, and the Company shall have delivered a Closing Certificate to the Investors in the form and substance as attached hereto as **Schedule 3**;

(3) Except the relevant Market Regulation Bureau Registration (as defined below), tax registration, MOFCOM foreign invested companies' information reporting and change of foreign exchange registration, the Company has obtained and completed all necessary authorizations, consents and approvals required to be obtained by the Company for the execution, delivery and performance of the Transaction Documents and the transactions contemplated thereunder;

(4) This Agreement has been duly executed and delivered by the Parties, has become effective, and remains fully effective on the Closing Date;

(5) A Shareholders Agreement satisfactory to the Investors has been duly executed and delivered by the Parties, and shall take effect on and from the Closing Date;

(6) The Parties shall have duly executed and delivered other Transaction Documents (if any) which, according to terms thereof, shall be executed on or prior to the Closing Date;

(7) The Investors have obtained all necessary internal approvals and authorizations for the purpose of signing this Agreement and other Transaction Documents and completing the transactions and other related matters under this Agreement and other Transaction Documents.

3.2 **Long-Stop Date**. All Parties shall exert their best efforts to ensure that all Conditions Precedent be satisfied no later than September 30, 2022. If any of the Conditions Precedent is not met within such time limit and is not waived by the Investors in writing, any Party has the right to terminate this Agreement by giving a written notice to the Other Parties. The termination of this Agreement shall be effective on and from the date of such written notice of termination. Notwithstanding the foregoing, the Party who bears the main responsibility or fault to which the failure of satisfaction of any Condition Precedent within the above-mentioned deadline is attributable shall not have the right to terminate this Agreement in accordance with the provisions of this Article 3.2. At the Closing, if any of the Conditions Precedent are waived by the Investors in writing, unless expressly and permanently waived by Investors, such Condition Precedent shall automatically become post-Closing obligations under Article 4.3 of this Agreement, and such obligations shall be fulfilled within the time limit otherwise agreed in writing by the Investors.

Article 4 Closing and Related Matters

4.1 **Time of Closing**. Closing shall be made (1) on the date on which the Conditions Precedent set forth in Article 3.1 of this Agreement (except for those which by their nature must be achieved on such Closing Date) are fully achieved or waived by the Investors in writing, and (2) within ten (10) Working Days (the "**Closing Date**") after the date that Wenzhou Ruihe and Wenzhou Ruizhi shall complete the private fund filing ("**Fund Filing**") with the Asset Management Association of China (whichever is later).

4.2 **Closing**. The Parties agree that the Investors shall remit the investment amount due from its investors by wire transfer to the Company's designated bank account on the Closing Date. If, as of September 30, 2022, Wenzhou Ruihe and Wenzhou Ruizhi has not completed the Fund Filing, the Company, Wenzhou Ruihe and Wenzhou Ruizhi each have the right to cancel This Capital Increase, in which case, the rights and obligations of Wenzhou Ruihe and Wenzhou Ruizhi under this Agreement automatically terminate and are not subject to the Article 8 "Liability for Breach of Contract; Indemnification" of this Agreement. The amount of Investors Investment Amount payable by the Investors shall be as follows:

(1) Qingdao Zhongou shall pay RMB 20 million to the Company to fulfill its obligation to contribute to the New Registered Capital subscribed. Among such investment amount, RMB equivalent to USD 235,664 shall be booked to the Company's registered capital, and the remaining RMB equivalent to USD 2,906,520 shall be booked to the Company's capital reserve as a premium.

(2) Qingdao Haiyang Innovation shall pay RMB 20 million to the Company to fulfill its obligation to contribute to the New Registered Capital subscribed. Among such investment amount, RMB equivalent to USD 235,664 shall be booked to the Company's registered capital, and the remaining RMB equivalent to USD 2,906,520 shall be booked to the Company's capital reserve as a premium.

(3) Wenzhou Ruihe shall pay RMB 50 million to the Company to fulfill its obligation to contribute to the New Registered Capital subscribed. Among such investment amount, RMB equivalent to USD 589,159 shall be booked to the Company's registered capital, and the remaining RMB equivalent to USD 7,266,301 shall be booked to the Company's capital reserve as a premium.

(4) Huzhou Jingyun shall pay RMB 48.58 million to the Company to fulfill its obligation to contribute to the New Registered Capital subscribed. Among such investment amount, RMB equivalent to USD 572,427 shall be booked to the Company's registered capital, and the remaining RMB equivalent to USD 7,059,937 shall be booked to the Company's capital reserve as a premium.

(5) Wenzhou Ruizhi shall pay RMB 30 million to the Company to fulfill its obligation to contribute to the New Registered Capital subscribed. Among such investment amount, RMB equivalent to USD 353,496 shall be booked to the Company's registered capital, and the remaining RMB equivalent to USD 4,359,780 shall be booked to the Company's capital reserve as a premium.

(6) Jiaxing Hongtong shall pay RMB 25 million to the Company to fulfill its obligation to contribute to the New Registered Capital subscribed. Among such investment amount, RMB equivalent to USD 294,580 shall be booked to the Company's registered capital, and the remaining RMB equivalent to USD 3,633,150 shall be booked to the Company's capital reserve as a premium.

(7) Ningbo Yijing shall pay RMB 37.6 million to the Company to fulfill its obligation to contribute to the New Registered Capital subscribed. Among such investment amount, RMB equivalent to USD 443,048 shall be booked to the Company's registered capital, and the remaining RMB equivalent to USD 5,464,258 shall be booked to the Company's capital reserve as a premium.

(8) Ningbo Hangjing shall pay RMB 41.5 million to the Company to fulfill its obligation to contribute to the New Registered Capital subscribed. Among such investment amount, RMB equivalent to USD 489,002 shall be booked to the Company's registered capital, and the remaining RMB equivalent to USD 6,031,029 shall be booked to the Company's capital reserve as a premium.

(9) Ningbo Zhengjing shall pay RMB 19.75 million to the Company to fulfill its obligation to contribute to the New Registered Capital subscribed. Among such investment amount, RMB equivalent to USD 232,718 shall be booked to the Company's registered capital, and the remaining RMB equivalent to USD 2,870,189 shall be booked to the Company's capital reserve as a premium.

4.3 Post-Closing Covenants

I-Mab HK (for Article 4.3 (3), (4) and (10) to (16) only), the Company, Hangzhou Yijing, Hangzhou Lanjing, and the Management hereby represent and covenant to the Investors (including the Series A Round Investors) as follows:

(1) The Company shall, within two (2) months after the Closing, complete the registration of changes with the Market Regulation Bureau (including the registration of change of registered capital, shareholders change and shareholding percentage change, as well as filing for the Amended Articles of Association and the Company's new Board of Directors, collectively referred to as the "**Market Regulation Bureau Registration**") for the transactions contemplated hereunder, obtain an updated business license, and complete the necessary tax registration, MOFCOM foreign invested companies information reporting, change of foreign exchange registration, and other registrations or filings required by Applicable Laws of the PRC. The company shall, within fifteen (15) Working Days after the investment payment by the Investor, conduct capital verification on the Investors Investment Amount by an accounting firm approved by the Investors in advance, and issue a capital verification report on the full payment of Investors Investment Amount in the current period, and submit the original capital verification report to the Investors.

(2) After the Closing, the Company shall prompt Hangzhou Yijing and Hangzhou Lanjing to complete the paid-in capital contribution to I-Mab Hangzhou on time, and to fulfill the aforementioned capital contribution obligations no later than before the company's listing equity division reform.

(3) Before the company applies for Qualified IPO, the company shall cooperate with the engaged intermediaries at that time to eliminate potential independence issues.

(4) After the Closing, the Company and the Management shall, prior to the Company's application for Qualified IPO, cooperate with the then engaged IPO intermediaries in eliminating circumstance that may constitute obstacles to the Qualified IPO; transactions between the Company and its Affiliated Company(ies), and between the Company and its directors, officers, managers, shareholders or other Affiliates, shall be conducted in compliance with requirements of relevant securities regulatory rules such as reasonableness, necessity, fairness, etc.

(5) After the Closing, the Company will apply for, renew and obtain all licenses, authorizations, approvals, recognitions or filings (hereinafter referred to as "**Business Qualifications**") from governmental authorities or regulatory authorities required to carry out its business activities within 6 months after the Closing Date in accordance with the provisions of laws and regulations, including, but are not limited to, drug manufacturing licenses, drug registration approval letters, Good Manufacturing Practice certification, and Good Supply Practice for Drugs certification.

(6) After the Closing, the Company will gradually establish its own brand name and trademark system, and apply for registration of trademarks used in the operation of its existing business and/or proposed business.

(7) The Company will promptly fulfill its notification obligations to Bank of Communications, Hangzhou Huansha Sub-Branch after the Closing.

(8) After the Closing, the Company shall construct the project of Hangzhou manufacture base in accordance with the applicable laws or requirements of Government Agencies, and shall, based on process of the construction, complete procedures required by the applicable laws such as relevant approval, registration or filing, ensure that all material aspects of the Company's construction, fire protection, environmental protection and production safety comply with the requirements of laws and regulations.

(9) After the Closing, the Company will gradually set up subsidiaries in different locations, and the subsidiaries in different locations will pay social security and provident fund for employees in different locations to gradually standardize the social security and provident fund contributions.

(10) Subject to the completion of the Closing of This Capital Increase, I-Mab HK covenants to make its reasonable commercial efforts to reduce the proportion of equity held in the Company by no more than 30% within 3 months after the Closing of This Capital Increase (to the extent that the equity in the Company is sufficiently diluted at that time), in the specific manner to be determined by subsequent consultation between the Parties, and the other parties undertake to cooperate with their reasonable commercial efforts. If due to market reasons or other subjective reasons not subjective to I-Mab HK, it is unable to complete the above-mentioned equity proportion adjustment within 3 months after the Closing of This Capital Increase, such period may be postponed to a period agreed upon by all Parties after consultation between the Parties. For the avoidance of doubt, an increase in Proportion of Shares resulting from the performance of Article 3.5 of the Shareholders Agreement shall not be deemed to be a breach by I-Mab HK of its obligations under this subparagraph.

(11) The Parties are willing to cooperate in making reasonable commercial efforts to make the Management Holdco (including the ESOP Holdco) the largest shareholder of the Company when the Series C Round of financing of the Company is completed.

(12) In view of the fact that the Company takes the clinical development and commercialization of drugs for autoimmune disease indications as its main business and future key development direction, I-Mab HK and I-Mab Shanghai and their affiliates guarantee that I-Mab Shanghai will not focus on autoimmune disease as its business development in the future, and in the event of any new business or business opportunities in such field, they shall communicate with the Company for its consent, and give priority to deliver such relevant business opportunities to the Company under the same conditions. With respect to the relevant business of drugs for autoimmune disease indications in stock at I-Mab Shanghai as of the date of signing this Agreement (see Schedule 5 Disclosure Schedules to this Agreement for details), I-Mab HK and I-Mab Shanghai shall make their best commercial efforts to actively seek arrangements such as external authorization or transfer before the company applies for Qualified IPO, and give priority to deliver such relevant business opportunities to the Company under the same conditions.

(13) In view of the fact that I-Mab Shanghai takes the clinical development and commercialization of oncology drug development as its main business, the Company guarantees that in principle no new target development of oncology drugs will be added in the future. For the currently available oncology drug development targets L1A3, T6, A3 and OXIF, the Company will actively seek arrangements such as external authorization or transfer, and give priority to transferring such commercial opportunities to I-Mab Shanghai or its affiliates under the same conditions. If the above-mentioned targets of the Company are indeed the same or similar to the other target indications of I-Mab Shanghai and its affiliates in the oncology drug development pipeline indications, I-Mab Shanghai and the Company shall negotiate and determine the solution separately at that time. However, I-Mab HK and the Company shall address the same issues with respect to oncology drug indications no later than before the Company applies for Qualified IPO, so as to ensure that the Company meets the relevant requirements of Qualified IPO for horizontal competition at that time. Notwithstanding the foregoing, I-Mab HK and I-Mab Shanghai covenant to make their best efforts not to take actions that increase the matter of inter-sector competition between the Company and I-Mab Shanghai and violate the circumstances agreed in this Agreement, so as to reduce the issue of horizontal competition with the Company since the Closing of This Capital Increase.

(14) I-Mab HK and I-Mab Shanghai guarantee that they will, based on the actual situation of the equity in the Company held by I-Mab HK at that time, cooperate with the then engaged IPO intermediaries by the Company to provide the necessary cooperation in eliminating the circumstances that constitute a material impediment to the Qualified IPO of the Company, including but not limited to: 1) issue a Letter of Commitments to avoid horizontal competition (if required) and cooperate with the signing of relevant written agreements (if involved) in accordance with the audit requirements at that time and the proportion of shares of I-Mab HK at that time when the Company applies for a Qualified IPO; 2) make its best commercial efforts to cooperate in reducing connected transactions with the Company in accordance with the audit requirements at that time when the Company applies for a Qualified IPO, and ensure that its connected transactions with the Company shall be conducted in compliance with requirements of relevant securities regulatory rules such as reasonableness, necessity, and fairness; 3) in order to meet the audit requirements of the independence of the Company's personnel when applying for the Qualified IPO, I-Mab HK shall cooperate with the Company to improve the independence of the Company's personnel by June 30, 2023, including but not limited to make the relevant personnel of I-Mab HK no longer participate in the operation and management of the Company as members of the management of the Company and to maintain mutual independence with the management of the Company.

(15) Except for force majeure, I-Mab HK and I-Mab Shanghai guarantee that the interests in the Target Pipeline L1A3 as listed in Schedule 1 to Series A Round Investment Agreement shall be fully transferred to the Company by June 30, 2022 and the relevant conditions set out in Article 3.1 (8) and (9) of the Series A Round Investment Agreement have been fully satisfied (collectively referred to as the "**Transfer of Interests Obligations of Series A Round Investment Agreement**"). Unless otherwise agreed with the Company, I-Mab HK and I-Mab Shanghai guarantee that regardless of whether or not the Transfer of Interests Obligations of Series A Round Investment Agreement have been completed, neither I-Mab HK nor I-Mab Shanghai shall further advance the arrangements for the clinical development and commercialization of the intangible assets listed in Schedule 1 to the Series A Round Investment Agreement and the related product pipeline utilizing or involving such intangible assets. In order to meet the Company's Qualified IPO filing or submission requirements, the Company warrants, and I-Mab HK and I-Mab Shanghai warrant that the Company shall consummate a complete Phase 1 human clinical trial of at least one drug by June 30, 2023.

(16) I-Mab HK guarantees that, although it always insists on the truthfulness and accuracy of the content in its information disclosure, for the sake of clarity of its obligations, I-Mab HK shall neither expressly or impliedly disclose the Company still as a controlled subsidiary of I-Mab HK nor bring the Company's business and products into the scope of control of I-Mab HK at that time for publicity and disclosure, from the date when the proportion of equity of I-Mab HK in the Company is reduced to within 30% (to the extent that the equity in the Company is sufficiently diluted at that time).

Article 5 Representations and Warranties

5.1 **Company's Representations and Warranties**. The Company, Hangzhou Yijing, Hangzhou Lanjing and the Management (collectively referred to as the "**Warrantors**") jointly make the representations and warranties to the Investors as follows: except for the exceptional circumstances as disclosed by the Company to the Investors in the disclosure schedules attached hereto as Schedule 5 ("**Disclosure Schedules**", the specific items set forth in the Disclosure Schedules shall qualify the corresponding representations and warranties hereunder), the Warrantors make the following representations and warranties in connection with this Agreement on the Signing Date and the Closing Date of this Agreement (or, for representations and warranties made on a specific date, such representations and warranties are deemed to be made on that specific date), and the Warrantors acknowledge and agree that the Investors rely on the authenticity, completeness and accuracy of these representations and warranties to sign this Agreement and consummate the transactions contemplated under this Agreement.

(1) Due Organization. The Company is a limited liability company established and validly established in accordance with the conditions and legal procedures prescribed by the PRC laws. It has obtained all necessary approvals and permits from Government Agencies for its establishment.

(2) Constitutional Documents. The constitutional documents of the Company that have been delivered to the Investors are true and complete. On the Signing Date and the Closing Date of this Agreement, the above-mentioned constitutional documents are valid and have not been replaced by other documents (provided that at Closing, such constitutional documents will be superseded by the Amended Articles of Association). All legal and procedural requirements and other procedures related to the above-mentioned constitutional documents have been properly complied with and performed in accordance with the law.

(3) Authorization and Enforceability. After the execution, delivery and performance of this Agreement and the other Transaction Documents are duly authorized and this Agreement and the other transaction documents to which the Company, Hangzhou Yijing, Hangzhou Lanjing and the Management are a Party shall be executed by the relevant parties, they shall constitute valid and legally binding agreements on the Company, Hangzhou Yijing, Hangzhou Lanjing and the Management. The form of this Agreement is lawful, and is enforceable upon the Company, Hangzhou Yijing, Hangzhou Lanjing and the Management. The Company, Hangzhou Yijing, Hangzhou Lanjing and the Management's execution, delivery and performance of this Agreement and other Transaction Documents to which they are a Party, and the rights and obligations under such Transaction Documents, will not violate laws and regulations of the PRC nor the articles of association or other constitutional documents of the Company, Hangzhou Yijing, Hangzhou Lanjing and the Management, will not violate court judgments, rulings, arbitral awards, administrative decisions, orders which are binding on or applicable to the Company, Hangzhou Yijing, Hangzhou Lanjing and the Management, and will not violate any document, contract or agreement to which the Company, Hangzhou Yijing, Hangzhou Lanjing and the Management are a Party.

(4) Capital Contribution. As of the Signing Date of this Agreement, the registered capital of the Company has been paid in full, except for the registered capital owned by Hangzhou Lanjing and Hangzhou Yijing.

(5) Government Approval. As of the Closing Date, the Company has full power and authority to hold, lease or operate its property (including without limitation Intangible Assets of the Licensed Pipelines) and operate its existing business (including without limitation the Licensed Pipelines), and has all the required approvals, permits, licenses, certificates, consents, or other approval documents from government agencies ("**Approval Documents**") for holding, leasing or operating its property (including without limitation Intangible Assets of the Licensed Pipelines) and operating its existing business (including without limitation the Licensed Pipelines), there is no ongoing or potential government agency Approval Documents that may be suspended or revoked, unless the absence of such Approval Documents of the government agency, or the potential revocation or cancellation of such Approval Documents from the government agency will not prevent the Company from fulfilling this Agreement or cause material negative effects. The Company has always complied with the requirements of these Approval Documents, and has not violated these Approval Documents in any material respect. The Company has never received any written or oral notice from any government department informing it that it has violated any provisions under any such Approval Documents.

(6) Company's External Investment. The Company does not have any domestic subsidiaries, branches or entities invested in other forms, nor any other investment commitments, except for holding 100% of the equity in Yijing Biotech (Beijing) Co., Ltd. and Lanjing Biotech (Shanghai) Co., Ltd., and holding I-Mab Biopharma (Hangzhou) Co., Ltd. Shanghai Branch.

(7) Financial Statements; Off-Balance Sheet Liabilities. The Company has delivered the unaudited Company's balance sheet and related income statement and cash flow statement (hereinafter collectively referred to as "**Management Statements**") as of the financial statement date (that is, November 30, 2021). The Management Statements (a) are prepared based on the Company's books and other financial records,(b) in material respects fairly reflect the Company's financial status and operating results as of the financial statement date or the corresponding period, and (c) have been prepared in accordance with China's general accounting principles and following the principle of consistency in line with the Company's previous practice.

The Company does not have any other material off-balance sheet transactions, debts, arrangements and obligations, including but not limited to relationships with non-consolidated reporting entities.

(8) Related Party Transactions. There are no material transactions between the Company and the Company and/or Affiliated Companies and their directors, officers, managers, shareholders, or other related parties (hereinafter collectively referred to as "**Related Parties**") that contain terms different from those terms entered into with unrelated third parties based on the fair trade. As of the Closing Date, except for the Transaction Documents (including the agreement or documents required or contemplated by the Transaction Documents) and labor-related contracts, there is no contract, agreement or other transaction between the Company and any Related Parties that is still within the validity period or has not been completed, and there are no due or outstanding debts, liabilities nor any other payables and receivables with the Related Parties, except for those that will not cause Material Adverse Changes in the Company's production and operation.

(9) No Material Adverse Change. From the financial statement date to the Closing Date, the Company's business operations are normal, specifically:

(a) There is no Material Adverse Change to the Company's financial situation, assets, liabilities, and net business value, except for changes in the ordinary course of operation;

(b) There are no strikes, labor disputes, or any new or continuation of events or circumstances that cause or may cause Material Adverse Change to the Company;

(c) There is no cancellation or waiver of right that may have a material adverse impact on the business operations, nor is there cancellation or waiver of any rights or claims with material value, nor is there cancellation or waiver of any rights or claims against Related Parties;

(d) No Material Adverse Change to the relationship between the Company and its suppliers, clients or customers has occurred or may occur;

(e) No Material Adverse Change in the accounting or bookkeeping methods or accounting practices related to or affecting the business of the Company has occurred;

(f) There is no sale, transfer or lease of any material property or asset (whether tangible or intangible), nor any incumbrance created on such assets, and there is no payment, loan or prepayment obligation related to such material property or asset.

(10) Tax Matters. All tax statements, reports and forms ("**Tax Reports**") that need to be submitted by the Company have been provided to the competent government authorities in a timely manner, and all Tax Reports accurately reflect the Company's tax burden in all material respects for the period, property, or event recorded. All taxes, including tax in Tax Reports or taxes that any government agency believes shall be paid by the Company, or taxes levied on the Company's property, assets, capital, turnover, or income have been paid in full (except for taxes fully reserved in the relevant Tax Reports). At present, there is no unfinished or potential inspection, inquiry or audit by a competent department on the Company. The tax that the Company shall withhold in accordance with the law has been withheld and handed over to the competent government agency, or the Company shall keep it properly. The Company does not have any material tax liability or obligation of any nature, unless such tax liability or obligation is (a) fully reflected in the Tax Reports; or (b) occurs during the normal operating activities of the Company since its establishment.

(11) Property Ownership/No Incumbrance. Except for the cases listed in Article 1.1 of the Disclosure Schedules and the leased real estate, the Company has the complete and marketable rights of all other real estate (if any), and there is no liens or other incumbrances over these rights. With respective to the leased real estate, all leases of the Company are fully effective; all the rent and additional payments due have been paid; since the beginning of the original lease period, the Company has occupied properly, and there has not been any material violation of the provisions of the lease contract, nor has there been any material breach of contract or any event, situation or behavior that may lead to violation of the lease contract. The Company's leased real estate is in good maintenance condition, and is sufficient to meet the current purpose of use (except for normal wear and tear).

The Company legally owns the material tangible movable property (or have legal right to use such tangible movable property) required to engage in the main business and is able to operate its tangible movable property independently. To the knowledge of the Warrantors, there is no contracts, agreements, commitments, documents or laws and regulations, government regulations, government requirements, measures, litigation or other legal procedures that may affect the Company's legal and complete ownership or use of its tangible movable property in material respects. To the knowledge of the Warrantors, the Company's use of the tangible movable property for business operation is in compliance with PRC laws and will not infringe the rights and interests of any third parties.

(12) Employees. The Company does not violate the applicable PRC labor laws in any material respects (including but not limited to labor contracts, wages, working hours, social insurance and housing provident fund payment, etc.) nor is there any material liabilities, contingent liabilities or unpaid fees due to the requirements of applicable PRC labor laws. The Company has paid withholding tax on behalf of the employees to the relevant Government Agency, or has withheld and reserved on behalf of its employee payable amount that is not yet due for these Government Agencies, and the Company does not have any material amounts of unpaid wages, taxes, penalties or any material payments due to violation of the above-mentioned obligations. The Company does not have any unpaid economic compensation that should be paid for the termination of labor relations or other material payment obligation for similar compensation or compensation costs related to the employment relationship.

Except for social insurance and housing provident funds as required by the PRC laws and commercial insurance for its employees, the Company has not participated and is not subject to any other pension, retirement, profit sharing, deferred compensation or other employee benefit plan, arrangement, agreement or understanding, nor is there any other pension, retirement, profit sharing, deferred compensation, or other employee benefit plan, arrangement, agreement, or understanding that any employee or former employee (or its beneficiaries, if any) has the right to participate in or enjoy. The Company has been paying social insurance and housing provident funds for all employees in accordance with the law.

There are no pending labor controversy or disputes between the Company and its existing or former employees, and to the knowledge of the Warrantors, there are no potential labor controversy or disputes.

The Company has not entered into any collective contract or similar contract or arrangement with employees.

(13) Material Contracts. Any Material Contract was executed under normal commercial conditions. Any Material Contract is a contract that is valid and binding in accordance with its terms (except for those that cannot be enforced due to bankruptcy, liquidation, reorganization or other similar laws that affect the general rights of creditors); there is no violation or breach of any Material Contracts in material respects by the Company, nor is there any matter that will constitute a material breach of contract by the Company; the Company has not received any notice on termination or cancellation of any Material Contract or in connection with breach under any Material Contract; and to the knowledge of the Warrantors, there is no violation or breach of any Material Contracts in material respects by the counter party(ies) thereof, nor is there any matter that will constitute a material breach of contract by the counter party(ies); in addition, the consummation of the transaction contemplated in this Agreement will not (and will not give anyone the right to) terminate or modify the Company's rights under any Material Contracts, or accelerate the performance or increase the Company's obligations under any Material Contracts, or create any liens or other incumbrances therefrom. There is no contract, agreement or other arrangement that grants to any person any priority to purchase the material assets or property of the Company (excluding purchases made in the normal course of business consistent with past practice).

"**Material Contracts**" refer to any material contracts to which the Company is a party, or involving any property or assets of the Company, including: (a) contract under which any party has obligation to pay RMB 5 million or more; (b) real estate lease contract; (c) exclusive cooperation/license contract, or contract involving non-compete or other clauses that restrict or interfere with the Company's capacity of operation in any manner or in any jurisdiction; (d) contract stipulating line of credit; (e) contract stipulating securities provided by the Company; (f) contract granting power of attorney or similar authorization to any person; (g) contract involving right of first refusal; (h) contract involving any transaction between the Company and its Related Party(ies); (i) collective contract or contract providing severance (except statutory severance) to any officers, directors or employees, (j) contract that materially affects operation of the Company, or contract that is material to the Company's operation; (k) contract stipulating that the Company shall make payment or provide benefits to third party(ies) as a result of consummation of the transactions contemplated under this Agreement; (l) material license agreement (including agreement under which the Company licenses Intellectual Property to other person(s), and agreement under which the other person(s) license Intellectual Property to the Company) or transfer agreement in connection with Intellectual Property; (m) contract that is not entered into in normal commercial terms; (n) contract to transfer, sell or dispose of material assets of the Company; (o) contract involving equity sale, equity acquisition, investment, financing, joint venture, merger and acquisition, restructure, profit sharing or change in control; (p) contract that creates incumbrances on the equity or material property of the Company; (q) strategic cooperation agreement entered into with any partner that is material to the operation and development of the Company; and (r) any memorandum of understanding, letter of intent, contract or agreement entered into with government departments (including enterprises solely owned or controlled by the State).

(14) Intellectual Property.

(a) As of the Closing Date, all Intellectual Property in connection with the business operation of the Company and the Licensed Pipelines are legally and beneficially owned by the Company or legally used with the permission of the owner(s) (as the case may be), and there are no incumbrances over such Intellectual Property. The Company's Intellectual Property is sufficient to enable it to operate its business in its current state.

(b) Article 1.2 of the Disclosure Schedules sets forth a list of Intellectual Property of the main Pipelines of the Company and Intellectual Property transferred to the Company. To the knowledge of the Warrantors as of the Signing Date, there are no notices, statements, claims, opposition, cancellation or litigation by third parties that allege the Intellectual Property used by the Company as invalid.

(c) All licenses of Intellectual Property used by the Company are fully effective. The Company has not, as of the Signing Date and the Closing Date, breached any of the material terms of the licenses, and the counter party(ies) to the licenses have not stated in writing that it will breach the contract.

(d) To the knowledge of the Warrantors as of the Signing Date, the Company has not interfered with, infringed, improperly used or violated the Intellectual Property of third parties due to the use of Intellectual Property or licensed Intellectual Property, nor has it received any allegations, complaints, claims, demands or notices claiming any such interference, infringement, improper use or violation. In addition, to the knowledge of the Warrantors, no third party has interfered with the Company's Intellectual Property, or infringed, improperly used or violated the same.

(15) Litigation. There are no pending or threatened litigation, arbitration or other legal proceedings against the Company or its property or rights by any court or arbitral tribunal, and there are no pending or threatened administrative or other proceedings by any Government Agency (including investigations by such Government Agency), which may cause Material Adverse Changes to the Company's right or ability to continue its current business, or to the Company's financial or other conditions, property or assets; there is no valid basis for initiating such litigation, arbitration, legal proceedings, administrative and other procedures or investigations. The Company is not bound by any judgment, order or ruling made in any litigation, arbitration or other legal proceedings that may cause Material Adverse Changes to its operations. The Company has not received any notice of material disputes or claims under any contract.

(16) Compliance. The Company has not (a) materially violated the law; (b) materially violated approval of any relevant Government Agency; (c) violated the provisions of its articles of association, or (d) failed to perform or comply with any material obligations, agreements, covenants or conditions in any contract on which it is a party or which binds it or any of its property. The Company has not received any notification of such breach of contract, violation or omission, whether have occurred or may occur.

(17) Books and records. The Company's books and records are true and accurate in all material respects, without any material inaccuracies or inconsistencies, and are prepared and maintained in accordance with applicable laws and good business practices, so as to enable the Company to prepare its financial statements in accordance with the generally accepted accounting principles of the PRC. The Company's meeting minutes book accurately reflects in all material aspects all the important actions and legal procedures that have been taken by the Company's shareholders and the Board of Directors as of the record date.

(18) External Shareholdings and External Working by Senior Officers. Except as expressly stated in Article 1.3 of the Disclosure Schedules, to the knowledge of the Warrantors, no Senior Officers of the Company directly or indirectly own, manage, control, or invest in any business that competes with the business of the Company ("**Competing Business**"), act as a director, management, advisor or employee of any company or entity engaged in such business, or hold any equity or share in any company or entity engaged in such business (except holding not more than 5% of all outstanding shares of a listed company).

(19) Disclosures. All documents, materials and information provided by the Company in the course of due diligence by the Investors are true, accurate, complete and valid, and are not misleading. Documents, statements and information related to the Company that would be reasonably expected to materially affect the Investors' intention to consummate the transaction contemplated hereunder have been disclosed to the Investors without material omissions.

5.2 Representations and Warranties of Series A Round Investors, Investors and I-Mab HK. Series A Round Investors, Investors and I-Mab HK) separately but not jointly represent and warrant to Other Parties as follows:

(1) Legal or Corporate Status. Such party is a partnership or company legally established and effectively existing according to the law of its place of registration, or a natural person with full capacity for civil rights and civil conduct.

(2) Authorization and Enforceability. This Agreement is duly authorized, and after executed by the Parties, shall constitute a valid and legally binding agreement on such party; the form of this Agreement is lawful, and is enforceable upon such party in the PRC.

Article 6 Transitional Period Covenants

6.1 Business Operation

(1) From the Signing Date of this Agreement to the Closing Date, except for implementing the transactions contemplated hereunder, the Company and the Management shall take the following actions:

(a) In the normal course of business, conduct business in a manner that is in compliance with Applicable Laws and is consistent with past practices and prudent business practices;

(b) Ensure the integrity of existing business organization;

(c) Maintain all operating assets and equipment (including any owned or licensed Intellectual Property) in normal operation and good maintenance;

(d) Renew and update registered Intellectual Property rights in the normal course of business;

(e) Promptly notify the Investors of any material violation of the Company's representations and warranties, or any material violation of other terms of this Agreement.

(2) The Company and the Management covenant that from the Signing Date of this Agreement to the Closing Date, except for implementing the transactions contemplated hereunder, none of the Company and the Management shall take any of the following actions without the Investors' prior written consent:

(a) Terminate the operation of the Company's existing business or substantially change any part of its business behavior;

(b) Sell or dispose of all or most of the Company's intangible assets or assets;

(c) Distribute any profits among shareholders through the distribution of dividends, capitalization of provident funds and otherwise;

(d) Create or amend terms and conditions of any employee equity incentive plan without the written consent of the Investors;

(e) Amend the Company's previously adopted financial rules or change the Company's fiscal year;

(f) Increase or reduce registered capital, change of equity (except for matters for purposes of the transactions contemplated hereunder), or attract any investment or obtain any investment commitments other than those contemplated hereunder;

(g) Change the company form;

(h) Sell, transfer, license, mortgage, create any incumbrance or otherwise dispose of any trademarks, patents, copyrights or other Intellectual Property owned by the Company;

(i) Adopt any resolution to terminate the Company or conduct any merger, division, bankruptcy, reorganization, liquidation, dissolution or designation of receiver or similar events of the Company;

(j) Except for purpose of performing this Agreement, amend or restate the Company's articles of association;

(k) Approve any transfer of equity of the Company; or

(l) Enter into commercial cooperation with any third party on the Pipelines to be injected into the Company, including but not limited to joint development, external licensing and other cooperation.

6.2 **Exclusivity**. The Company and the Management covenant that from the Signing Date of this Agreement to the earlier to occur of: (1) the Closing Date; (2) the date of termination of this Agreement, without the Investors' prior written consent or unless otherwise agreed in this Agreement, the Company and the Management may not, and shall procure their Affiliates and their respective directors, supervisors, senior officers, employees, representatives or agents not to:

(1) Initiate, induce or instigate sale or other disposal of equity in the Company, or any inquiry, quotation or offer related to acquisition or merger of the Company (each referred to as an "**Alternative Transaction**");

(2) Participate in any discussions or negotiations on any Alternative Transactions, or provide or disclose any information about the Company or the business for any Alternative Transactions; or

(3) Enter into any binding or non-binding written or oral agreement, arrangement or understanding for any Alternative Transactions.

6.3 **Notification of Specific Matters**. Each Party to this Agreement covenants that from the Signing Date to the Closing Date of this Agreement, it shall notify the Other Parties and provide the corresponding supporting documents immediately after knowledge of the following matters:

(1) Any facts or circumstances that constitute a material violation of its representations and warranties made in this Agreement; or

(2) Become aware of the occurrence of certain facts or circumstances after the Signing Date of this Agreement, and the occurrence of these facts or circumstances will or may cause material violation of such representations and warranties made by the Party.

Article 7 Other Agreements and Covenants

7.1 **Equity Incentive Plan**. The Parties agree that within 5 months after the completion of the Closing, the Company will implement the Company's employee equity incentive plan (the "**ESOP**") by way of additional subscription of the Company's registered capital by Hangzhou Lanjing or a separately established ESOP Holdco to acquire 8% equity in the Company after the capital increase at that time. For such ESOPs: (a) the unit exercise price for equity represented by per USD 1 of registered capital is the RMB equivalent of USD 1, (b) subject to the grantees of incentives continuing to work in the Company and passing the relevant annual performance assessment tests, 50% of the relevant award granted under the ESOP will be vested on the two (2) years' anniversary of the grant date (i.e. the date when the Company and the grantee of incentives signed the equity incentive award document), and 100% of the relevant award will be vested on the three (3) years' anniversary of the grant date; however, upon occurrence of a Deemed Liquidation Event (as defined in the Shareholders Agreement), all unvested award then held by the grantees of equity incentive will be fully vested. Adoption and amendment of the ESOP and its specific implementation plan shall be subject to approval by the Company's Board of Directors as agreed in the Shareholders Agreement. The Parties hereby acknowledge and agree that any equity held by the ESOP Holdco in the Company shall only be used for grant of equity incentives under equity incentive plan in accordance with the decision of the Board of Directors, and unless for the purpose of implementing the equity incentive plan and approved by resolution of the Board of Directors, the ESOP Holdco shall not directly or indirectly transfer, pledge, create incumbrance or otherwise dispose of any equity held by it in the Company.

7.2 **Intellectual Property Protection**. After the Closing, the Company shall exert all commercially reasonable efforts to obtain lawful ownership or right of use of Intellectual Property (including but not limited to patents, trademarks, copyrights, know-how, domain names and trade secrets, etc.) required for the Company's business and operation activities, and exert all efforts to protect the Company's Intellectual Property from infringement by any third party.

7.3 **Operation in Compliance with Laws.** After the Closing, the Company shall comply with relevant Applicable Laws in all material aspects, continuously improve corporate governance of the Company in various aspects (including without limitation clinical trials, human generic resources, environmental protection, health and security, finance, labor, Intellectual Property, social insurance, housing provident fund, taxes and business) and maintain the validity of the licenses required to operate its business. If, after the Closing Date, in accordance with the relevant Applicable Laws or the requirements of Government Agencies, there is a need to obtain relevant concessions, licenses, permits, approvals, waivers, consents, authorizations, registrations or filings ("**Government Licenses**") for any matter or action involved in the Company's business or its business operations, the Company shall take all necessary measures and actions to obtain such Government Licenses in a timely manner. The Company shall maintain insurance for its business and Target Pipelines in compliance with the laws.

7.4 **Tax Payment**. Each Party shall be responsible for the taxes in connection with the transactions contemplated hereunder on which it is levied or which it is responsible to pay. The Company will conduct business operation in compliance with the laws and regulations, and shall not engage in any activities or behaviors that involve violations of laws and regulations, including but not limited to any violations of laws and regulations related to taxation and tax collection.

Article 8 Liability for Breach of Contract; Indemnification

8.1 **Default of contract**. If any Party fails to duly or fully fulfill its obligations, covenants or other agreements under this Agreement or other Transaction Documents, or the representations and warranties made by the Party under this Agreement and other Transaction Documents are untrue, inaccurate or incomplete, then such Party shall be regarded as having breached the contract.

8.2 **Liability for Breach of Contract; Indemnification**. When the breach of contract described in Article 8.1 above occurs, the breaching Party shall indemnify the non-breaching Parties for any direct losses suffered by the non-breaching Parties as a result of the breach by the breaching Party ("**Loss**"). The breaching Party's indemnification against the non-breaching Parties' Loss or taking of liability for breach shall not affect the non-breaching Parties' right to require the breaching Party to continue to perform the Agreement or their rights to terminate this Agreement. Subject to other provisions of the Transaction Documents, in the event the Company fails to close a Qualified IPO as a result of I-Mab HK's rejection to perform its obligations, covenants or other agreement under this Agreement or under other Transaction Documents to resolve issues of horizontal competition and/or related party transactions to the extent such issues create obstacles to the Qualified IPO, provided that other Parties agree to cooperate, notwithstanding provisions of Article 3.5 (1) of the Shareholders Agreement, the repurchase price which the Investors are entitled to will be the higher of the repurchase price set forth in Article 3.5 (1) of the Shareholders Agreement, and the value of relevant equity based on appraisal by an appraiser to be jointly designated by the Parties at that time.

Article 9 Effectiveness, Amendment and Termination of the Agreement

9.1 **Effectiveness**. This Agreement shall take effect on the date when it is executed by the Parties or their authorized representatives (Chinese legal persons and unincorporated organizations must also affix their official seals).

9.2 **Amendment**. This Agreement shall take effect on the date when it is executed by the Parties or their authorized representatives (Chinese legal persons and unincorporated organizations must also affix their official seals).

9.3 **Termination**. This Agreement may be terminated prior to the Closing Date under any of the following circumstances:

(1) With the unanimous written consent of all Parties;

(2) Terminated pursuant to Article 3.2;

(3) Any Party breaches this Agreement as described under Article 8 hereof, and does not cure the breach within thirty days (30), or the breach have occurred for twice or more cumulatively, then the non-breaching Parties shall have the right to unilaterally terminate this Agreement;

(4) If force majeure occurs and as a result the fundamental purpose of this Agreement cannot be achieved, any Party may terminate this Agreement.

9.4 **Effect of Termination**. When this Agreement is terminated in accordance with Article 9.3, except Article 1 (Definitions), Article 8 (Liability for Breach of Contract; Indemnification), Article 10 (Miscellaneous) and this Article 9.4, this Agreement shall be invalid and shall no longer be binding or effective on the Parties who terminate the Agreement, and such Parties will be no longer required to bear the responsibilities and obligations under this Agreement; provided, however, despite termination of this Agreement, a Party shall still be liable for any losses incurred by the Other Parties as a result of its breach of this Agreement before the termination. For the avoidance of any doubt, in case of termination due to circumstances under Article 9.3 (2) or Article 9.3 (3) hereof, such termination of the Agreement shall take effect only between the Investor(s) to who such termination is related and the Company, and effectiveness of the Agreement between the other Investor(s) and the Company shall not be impacted; in such case, this Agreement shall be correspondingly adjusted so as to remove the Investors to whom the termination is related.

Article 10 Miscellaneous

10.1 **Fees**. The Investors shall respectively bear the transaction costs that are incurred due to transactions contemplated under this Agreement, including but not limited to, professional services fees incurred by the Investors and their consultant (including but not limited to accountants, lawyers, etc.) to carry out due diligence, draft Transaction Documents, or participate in negotiations; provided, however, the Company agrees that,(a) if the Closing is completed successfully, or (b) if the Closing fails to occur due to reasons attributable to the Company, then the Company will bear the Investors' transaction costs up to an aggregate amount of RMB Fifty Thousand (50,000). Subject to the Company's receipt of a legal invoice for the relevant fees provided by a third-party service organization, the Company will pay such fees to the third-party service organization.

10.2 **Notice**.

(1) All notices, claims, requests, consents, waivers and other communications required or permitted under this Agreement shall be in writing (including telegram, fax or similar written form) and shall be sent, delivered or mailed, e-mailed or faxed to the following addresses:

Company, Hangzhou Yijing and Hangzhou Lanjing:	**I-Mab Biopharma (Hangzhou) Co., Ltd.**	
	Attention:	***
	Phone:	***
	E-mail:	***
	Address:	***
I-Mab Shanghai:	**I-Mab Biopharma Co., Ltd.**	
	Attention:	***
	Phone:	***
	E-mail:	***
	Address:	***

Investors: **Pingtan Wenzhou Ruihe Investment Partnership (Limited Partnership)**

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Huzhou Jingyun Equity Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Pingtan Wenzhou Ruizhi Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Jiaxing Hongtong Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Qingdao Zhongou Industry Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Qingdao Haiyang Innovation Investment Co., Ltd.

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Ningbo Yijing Management Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Ningbo Hangjing Management Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Ningbo Zhengjing Management Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Existing Shareholders:	**I-MAB BIOPHARMA HONGKONG LIMITED**	
	Attention:	***
	Phone:	***
	E-mail:	***
	Address:	***

(2) Each notice, request or other communication delivered or served in accordance with the provisions of Article 10.2 (1) shall be deemed as delivered or served as follows: (a) if sent by a courier company or personally delivered, it shall be deemed as delivered when the relevant notice, request or communication is sent to the above-mentioned address; (b) if sent by fax, then the relevant notice, request or communication shall be deemed as delivered when it is transmitted to the above fax number and the report of successful fax transmission is obtained; (c) if sent by e-mail, it shall be deemed as delivered twenty-four hours after the date on which the e-mail containing the relevant notice, request or communication as recorded by the sender's computer is sent, provide, however, if the sender does not receive the recipient's confirmation of receipt of the above e-mail within twenty-four hours (except for automatic email confirmation of receipt), the above notice, request or other communication shall be sent by courier or fax by the end of the same day. The addresses and e-mails provided by the Parties be used as the address for service of dispute resolution under this Agreement. The confirmed address for service applies to all stages of dispute resolution, including arbitration, first instance, second instance, retrial, and execution, etc.

10.3 **Governing law**. This Agreement shall be governed by and be construed in accordance with the PRC (for the purposes of this Article only, it does not include the Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan) laws.

10.4 **Dispute Resolution**. In the event of is a dispute over the interpretation or performance of this Agreement, the Parties shall firstly attempt to resolve the dispute through friendly consultation. If the dispute cannot be resolved through consultation within thirty (30) days after one Party delivers written notice to the Other Parties requesting the commencement of consultation, then any Party may submit the dispute to the China International Economic and Trade Arbitration Commission for arbitration, and the arbitration shall be conducted in Hangzhou according to the said commission's arbitration rules then in force. The arbitration award shall be final and binding on all Parties and cannot be appealed. The arbitration costs shall be borne by the losing party unless the arbitration award provides otherwise. When any dispute occurs and when any dispute is under arbitration, except the matter under disputes, the Parties shall continue to exercise their other rights and perform their other obligations under this Agreement.

10.5 **Confidentiality**. Each of the Parties shall not, and shall cause its respective Affiliates, shareholders, directors, senior officers, employees, representatives or agents not to, directly or indirectly disclose the existence of this Agreement or any information related to the transactions contemplated hereunder (including any information obtained by the Party during the course of the negotiation and execution of this Agreement), unless (a) it has obtained the prior written consent of the non-disclosing Parties, or (b) such information is required to be disclosed by the applicable laws and is only disclosed to the extent necessary to comply with the applicable laws or any regulations or policies of any stock exchange, provided, however that the disclosing Party shall, within a reasonable time before the disclosure or submission of the relevant information, seek opinions of the Other Parties on such disclosure and submission, and that if required by the Other Parties, the disclosing Party shall seek for confidential treatment of the disclosed or submitted information to the extent possible. Before the Closing, without the written consent of the Investors, the Company shall not disclose the investment that the Investors intend to make to the Company according to this Agreement to the public through press conferences, industry or professional media, marketing materials or other means; however, each Investor has the right to disclose to the investors of its fund or its consultant in a non-public manner about the investment that such Investor intends to make in the Company under this Agreement, provided that the recipients shall have agreed to maintain the confidentiality of the relevant confidential information. Notwithstanding the foregoing, I-Mab 天境生物, I-Mab HK's parent company, being a company listed in the United States, shall have the right to disclose the Company's financing information in accordance with the requirements of U.S. securities laws without the need for separately obtaining the Parties' consent. After the Closing, each of the Company, I-Mab HK and the Investors shall have the right to disclose the existence of the Investors' investment in the Company to third parties or the public; provided, however, the Investors shall seek the opinions of I-Mab HK when disclosing information related to the Company's investment matters, with a view to comply with the information disclosure requirements under the U.S. securities laws.

10.6 **Severability**. The obligations under this Agreement shall be regarded as separate obligations and be independently enforceable. When one or more obligations of this Agreement are unenforceable, the enforceability of other obligations shall not be affected. If this Agreement is not enforceable against any Party, the enforceability of this Agreement among the Other Parties shall not be affected. If one or more of the provisions of this Agreement are found to be invalid, illegal or unenforceable in any respect according to any applicable law, or a government agency requests amendment of one or more provisions of this Agreement, the validity, legality and enforceability of the remaining provisions shall not be affected or damaged in any way. The Parties shall endeavor to replace these invalid, illegal or unenforceable provisions with valid provisions through sincere consultations, and the economic effects of such valid provisions shall be as similar as possible to those of the invalid, illegal or unenforceable provisions.

10.7 **Entire Agreement**. This Agreement (including the other Transaction Documents and any other documents referred to or contemplated hereunder or thereunder) constitutes the entire agreement among the Parties with regard to the subjects hereof, and supersedes any other agreements or intentions previously reached by the Parties on the same subjects.

10.8 **Assignment**. Prior to completion of its capital contribution obligations, an Investor may assign its rights and obligations under this Agreement to its Affiliates, and such assignment does not require prior consent of Other Parties or the Company. After completion of its capital contribution obligations, an Investor has the right to assign its rights and obligations under this Agreement to any third party along with the sale or transfer (if any) of its equity in the Company to such third party; provided, however, such equity transfer shall be subject to the other Investors' right of first refusal under the Shareholders Agreement. Notwithstanding anything to the contrary herein, after completion of its capital contribution obligation, any Investor may transfer its then effective rights and obligations under the Agreement to its Affiliates along with the sale or transfer (if any) of its equity in the Company, which transfer or assignment shall not be subject to any other shareholders' consent, right of first offer, right of first refusal, co-sale rights or similar rights. Except the foregoing, without the prior written consent of each other Party, no Party shall assign its rights or obligations under this Agreement; any assignment without the Other Parties' consent shall be invalid.

10.9 **Counterparts**. This Agreement is written in Chinese. This Agreement shall be signed in 20 original copies. Each Party shall hold one (1) original copy, and the remaining original copies shall be held by the company. Each copy of this Agreement shall be equally effective.

10.10 **Priority**. If, in order to request any government agency to carry out any specific act, separate agreements in connection with the transactions contemplated hereunder (including but not limited to, the Investment Agreement, the Company's articles of association or amendments to the articles of association, as may be amended from time to time, etc.) have to be signed in accordance with the standard templates or requirements of the government agency, this Agreement shall control over any such agreements, and such agreements shall only be used to request the government agency to implement the specific act, and shall not be used to establish or as an evidence of any rights or obligations of the relevant parties on matters that may be stipulated in such agreements.

(No text below)

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Company:

I-Mab Biopharma (Hangzhou) Co., Ltd.
(Seal)

/s/Lili Qian
Name: Lili Qian
Position: General Manager

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

I-Mab Shanghai:

I-Mab Biopharma Co., Ltd.
(Seal)

/s/ JINGWU ZHANG ZANG
Name: JINGWU ZHANG ZANG
Position: CHAIRMAN

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Investor:

Pingtan Wenzhou Ruihe Investment Partnership (Limited Partnership)
(Seal)

/s/ Shuguang Wang
Name: Shuguang Wang
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Investor:

Huzhou Jingyun Equity Investment Partnership (Limited Partnership)
(Seal)

/s/ Danjun Kong
Name: Danjun Kong
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Investor:

Pingtan Wenzhou Ruizhi Investment Partnership (Limited Partnership)
(Seal)

/s/ Shuguang Wang
Name: Shuguang Wang
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Investor:

Jiaxing Hongtong Investment Partnership (Limited Partnership)
(Seal)

/s/ Haifang Wang
Name: Haifang Wang
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Investor:

Qingdao Zhongou Industry Investment Partnership (Limited Partnership)
(Seal)

/s/ Yuanyi Ji
Name: Yuanyi Ji
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Investor:

Qingdao Haiyang Innovation Investment Co., Ltd
(Seal)

/s/ Bingbing Liu
Name: Bingbing Liu
Position: Delegated Representative of Legal Representative

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Investor:

Ningbo Yijing Management Partnership (Limited Partnership)
(Seal)

/s/ Lili Qian
Name: Lili Qian
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Investor:

Ningbo Hangjing Management Partnership (Limited Partnership)
(Seal)

/s/ Lei Wang
Name: Lei Wang
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Investor:

Ningbo Zhengjing Management Partnership (Limited Partnership)
(Seal)

/s/ Daling Zhang
Name: Daling Zhang
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

I-MAB BIOPHARMA HONGKONG LIMITED

/s/ JINGWU ZHANG ZANG
Name: JINGWU ZHANG ZANG
Position: DIRECTOR

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Hangzhou Yijing Biotech Partnership (Limited Partnership)
(Seal)

/s/ Lili Qian
Name: Lili Qian
Position: Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Hangzhou Lanjing Biotech Partnership (Limited Partnership)
(Seal)

/s/ Lili Qian
Name: Lili Qian
Position: Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Lili Qian
Lili Qian

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Zhengsong Zhang
Zhengsong Zhang

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Yunfei Zhang
Yunfei Zhang

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Lihong Lou
Lihong Lou

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Kai Zhou
Kai Zhou

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Fang Yin
Fang Yin

Schedule 1:

Amended Articles of Association

Schedule 1

Schedule 2:

Shareholding Structures of the Company

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Schedule 3:

Closing Certificate

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List of Key Employees

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English translation

I-Mab Biopharma (Hangzhou) Co., Ltd.

Shareholders Agreement

July 16, 2022

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SHAREHOLDERS AGREEMENT

This SHAREHOLDERS AGREEMENT (this "**Agreement**") is entered into in the PRC on July 16, 2022 by and among the following parties:

1. **I-Mab Biopharma (Hangzhou) Co., Ltd.**, a limited liability company legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330100MA2GNANB49 (the "**Company**");

2. **I-Mab Biopharma Co., Ltd.**, a limited liability company legally established and existing in accordance with the PRC laws, whose unified social credit code is 91310115MA1K3G0E1F ("**I-Mab Shanghai**");

3. **I-MAB BIOPHARMA HONGKONG LIMITED**, a company limited by law established in accordance with the laws of the Hong Kong Special Administrative Region of the PRC, whose registration number is 2400410 ("**I-Mab HK**");

4. **Hangzhou Fushi Investment Management Partnership (Limited Partnership) (杭州赋实投资管理合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330102MA2AYYBD4Q ("**Fushi Capital**");

5. **Shenzhen Tsingsong Shengrui Investment Partnership (Limited Partnership) (深圳市青松晟睿投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91440300MA5FYAQD4R ("**Tsingsong Shenzhen**");

6. **Nanjing Tsingsong Healthcare Investment Partnership (Limited Partnership) (南京清松医疗健康产业投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91320113MA21DH7W5M ("**Tsingsong Nanjing**");

7. **Hangzhou Heda Biotech Investment Partnership (Limited Partnership) (杭州和达生物医药创业投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330101MA2AXNXM21 ("**Heda Investment**");

8. **Xiamen Ronghui Derong Equity Investment Partnership (Limited Partnership) (厦门融汇德润股权投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91350211MA34071K50 ("**Ronghui Derong**");

9. **Ningbo Yanyuan Yaoshang Chanrong Equity Investment Partnership (Limited Partnership) (宁波燕园姚商产融股权投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330281MA2AF01K1J ("**Yanyuan Chanrong**");

10. **Ningbo Yanchuang Yaoshang Yangming Investment Partnership (Limited Partnership) (宁波燕创姚商阳明创业投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330281MA2H6M3084 ("**Yanchuang Yangming**");

11. **Jiangsu Yanyuan Dongfang Investment Partnership (Limited Partnership) (江苏燕园东方创业投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91320300MA1UQURD8F ("**Yanyuan Dongfang**");

12. **Ningbo Rongshun Yanyuan Investment Partnership (Limited Partnership) (宁波荣舜燕园投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330201MA2AJPJ617 ("**Rongshun Yanyuan**");

13. **Ningbo Yanyuan Innovation Investment Partnership (Limited Partnership) (宁波燕园创新创业投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330201340622519X ("**Yanyuan Innovation**");

14. **Zhuzhou Guochuang Junyao Investment Partnership (Limited Partnership) (株洲市国创君垚投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91430200MA4RGB014A ("**Guochuang Junyao**");

15. **Ningbo Hanhai Qianyuan Equity Investment Partnership (Limited Partnership) (宁波瀚海乾元股权投资基金合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330212MA2GW05H0A ("**Hanhai Qianyuan**");

16. **Hangzhou Haibang Yigu Investment Partnership (Limited Partnership) (杭州海邦羿谷创业投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330101MA2B02RD4R ("**Haibang Yigu**");

17. **Jialiang Shan**, a Chinese citizen, whose ID number is ***;

18. **Zhejiang Silu Industry Investment Fund Partnership (Limited Partnership) (浙江丝路产业投资基金合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330101MA28WHW02L ("**Silu Fund**");

19. **Viva Biotech (Shanghai) Ltd. (维亚生物科技(上海)有限公司)**, a limited company legally established and existing in accordance with the PRC laws, whose unified social credit code is 91310115677881436W ("**Viva Biotech**");

20. **Tianjin Huatian Enterprise Management Consultation Limited Partner (Limited Partner) (天津华天企业管理咨询合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91120118MA0727C0X0 ("**Huatian Enterprise Management**");

21. **Qingdao Xinneng Property Management Co., Ltd.**, a limited liability company legally organized and existing in accordance with the PRC laws, whose unified social credit code is 91330100MA2GNANB49 ("**Qingdao Xinneng**"; together with Fushi Capital, Tsingsong Shenzhen, Tsingsong Nanjing, Heda Investment, Ronghui Derong, Yanyuan Chanrong, Yanchuang Yangming, Yanyuan Dongfang, Rongshun Yanyuan, Yanyuan Innovation, Guochuang Junyao, Hanhai Qianyuan, Haibang Yigu, Jialiang Shan, Silu Fund, Viva Biotech, Huatian Enterprise Management, collectively referred to as the "**Series A Round Investors**");

22. **Lili Qian**, a Chinese citizen, whose ID number is ***;

23. **Zhengsong Zhang**, a Chinese citizen, whose ID number is ***;

24. **Yunfei Zhang**, a Chinese citizen, whose ID number is ***;

25. **Lihong Lou**, a Chinese citizen, whose ID number is ***;

26. **Kai Zhou**, a Chinese citizen, whose ID number is ***;

27. **Fang Yin**, a Chinese citizen, whose ID number is *** (together with Lili Qian, Zhengsong Zhang, Yunfei Zhang, Lihong Lou and Kai Zhou, collectively referred to as the "**Management**");

28. **Hangzhou Yijing Biotech Partnership (Limited Partnership) (杭州伊境生物科技合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330100MA2HY0AEXX (the "**Management Holdco**");

29. **Hangzhou Lanjing Biotech Partnership (Limited Partnership) (杭州阑境生物科技合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330100MA2HY07T3Q (the "**ESOP Holdco**"; together with I-Mab HK, the Series A Round Investors, the Management Holdco, collectively referred to as the "**Existing Shareholders**");

30. **Pingtan Wenzhou Ruihe Investment Partnership (Limited Partnership) (平潭文周瑞和投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91350128MA8TQEYH30 ("**Wenzhou Ruihe**");

31. **Hangzhou Jingyun Equity Investment Partnership (Limited Partnership) (湖州静耘股权投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330501MA2JL1G07W ("**Huzhou Jingyun**");

32. **Pingtan Wenzhou Ruizhi Investment Partnership (Limited Partnership) (平潭文周瑞致投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91350128MA8TQFP85C ("**Wenzhou Ruizhi**");

33. **Jiaxing Hongtong Investment Partnership (Limited Partnership) (嘉兴鸿桐创业投资合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330402MA7GF15T8Q ("**Jiaxing Hongtong**");

34. **Qingdao Zhongou Industry Investment Partnership (Limited Partnership) (青岛中欧创新产业投资基金合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91370202MA3WNGTEXK ("**Qingdao Zhongou**");

35. **Qingdao Haiyang Innovation Investment Co., Ltd. (青岛海洋创新产业投资基金有限公司)**, a limited liability company legally established and existing in accordance with the PRC laws, whose unified social credit code is 91370282MA3N5L323R ("**Qingdao Haiyang Innovation**");

36. **Ningbo Yijing Management Partnership (Limited Partnership) (宁波市伊境企业管理合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330205MA7JC3H09J ("**Ningbo Yijing**");

37. **Ningbo Hangjing Management Partnership (Limited Partnership) (宁波市杭境企业管理合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330205MA7HXY278M ("**Ningbo Hangjing**");

38. **Ningbo Zhengjing Management Partnership (Limited Partnership) (宁波市正境企业管理合伙企业(有限合伙))**, a limited partnership legally established and existing in accordance with the PRC laws, whose unified social credit code is 91330205MA7GQY2K5F ("**Ningbo Zhengjing**", together with Ningbo Zhengjing, Wenzhou Ruihe, Huzhou Jingyun, Wenzhou Ruizhi, Jixing Hongtong, Qingdao Zhongou, Qingdao Haiyang Innovation, Ningbo Yijing, Ningbo Hangjing, the "**Series B Round Investor**");

(The Series B Round Investor and the Series A Round Investors are collectively referred to as the "**Investors**")

The above parties are hereinafter collectively referred to as the "**Parties**". When any party hereto is referred to as a "**Party**", the other parties hereto will be referred to as the "**Other Parties**".

WHEREAS:

1. The Company is a limited liability company legally established and existing in accordance with PRC laws, which was established on June 26, 2019. The Company's unified social credit code is 91330100MA2GNANB49, its registered capital is USD$30 million, and its business scope is: technology development, technology services, technology consulting, and transfer of results: biotechnology, pharmaceutical technology (with respect to the above, except for the development and application of human stem cells, gene diagnosis and treatment technology); production: drugs; drugs, pharmaceutical intermediates, Category I medical device wholesale and import and export business (except for those subject to special access control regulations stipulated by the state).

2. On September 15, 2020, the Existing Shareholders, the Management and the Company except for Qingdao Xinneng entered into that certain Equity Transfer and Investment Agreement (the "**Series A Round Investment Agreement**"). According to the Series A Round Investment Agreement, the Series A Round Investors collectively acquired 40% of the equity of the Company from I-Mab HK, corresponding to the unpaid registered capital of the Company in the amount of USD$12 million, and invest a total amount in RMB equivalent to USD$120 million (collectively referred to as the "**Series A Round Investors Investment Amount**"; the equity acquired by the Series A Round Investor in such transactions is the "**Series A Round Equity**") to the Company after acquiring such equity; the Management acquired, through the Management Holdco, 10% of the equity of the Company from I-Mab HK, corresponding to the unpaid registered capital of the Company in the amount of USD$3 million, and invest a total amount in RMB equivalent to USD$3 million to the Company after acquiring such equity; the ESOP Holdco acquired 5% of the equity of the Company from I-Mab HK, corresponding to the unpaid registered capital of the Company in the amount of USD$1.5 million, which equity will be used to implement the Company's employee equity incentive plan; I-Mab HK transferred to the Company the Intangible Assets agreed in the Series A Round Investment Agreement with a total valuation of USD$105 million and pay to the Company USD$30 million in cash, so as to complete its capital contribution obligations with respect to the 45% remaining equity of the Company held by I-Mab HK (corresponding to registered capital of the Company in the amount of USD$13.5 million). On the same day, the aforementioned Parties signed a Shareholders Agreement (the "**Series A Round Shareholders Agreement**"). On January 13, 2021, Qingdao Xinneng acquired 0.25% of the equity of the Company from Huatian Enterprise Management, corresponding to registered capital of USD$75,000, such equity is the Series A Round Equity.

3. On the same day as this Agreement is signed, the Parties jointly signed an Investment Agreement (the "**Investment Agreement**"). According to the Investment Agreement, the Series B Round Investor agreed to subscribe for the new registered capital of the Company by RMB¥292.43 million (the "**Series B Round Investor Investment Amount**", and Series A Round Investors Investment Amount are collectively referred to as the "**Investors Investment Amount**") for the Company's new registered capital of USD$344.5758 million. The aforementioned transactions are collectively referred to as the "**Transactions**", in which the equity acquired by the Series B Round Investor is "**Series B Round Equity**"; the Series B Round Equity and the Series A Round Equity are collectively referred to as "**Investors' Equity**". Immediately after the completion of the Transactions, the Company's shareholding structure is reflected in **Schedule 1**.

THEREFORE, in order to further stipulate the rights and obligations of the shareholders of the Company after completion of the Transactions, the Parties have entered into the following agreement (unless otherwise provided in this Agreement, the terms used in this Agreement shall have the same meaning as that of the terms in the Investment Agreement):

Article 1 Information and Inspection Rights

1.1 **Information and Inspection Rights**. The Parties agree that, as long as an Investor holds equity in the Company, the Investor or person designated by the Investor in writing shall have the right, to (a) inspect the assets and account capital flow records, financial statements, financial books, financial documents and other related documents of the Company and its Subsidiaries during the Company's normal office hours, or (b) communicate with directors, supervisor(s), senior officers, key employees, employees of the Company, and professional service organizations engaged by the Company such as auditors and legal consultants on affairs of the Company; in each case, provided that notice is delivered to the Company five (5) Working Days in advance. At the same time, the Company shall provide such Investor with the following information with respect to the Company and its Subsidiaries:

(1) Within twenty-one (21) days after the end of each fiscal month, provide Investors with unaudited monthly financial statements;

(2) Within one hundred and twenty (120) days after the end of each fiscal year, provide Investors with annual financial statements and annual audit report audited by an auditor acceptable to the Investors;

(3) Within thirty (30) days before the commencement of each fiscal year, provide Investors with the financial budget for such fiscal year;

(4) Provide copies of documents and other materials given to any other shareholders;

(5) Other information and materials reasonably requested by the Investors.

The aforesaid financial statements shall be prepared in accordance with China's generally accepted accounting principles, and shall include balance sheets, profit and loss statements, and cash flow statements.

The Investors shall have the right to inspect the company and its subsidiaries.

1.2 **Termination**. The above-mentioned information and inspection right will terminate upon completion of the Qualified IPO (as defined in the Investment Agreement).

Article 2 Equity Lockup

2.1 I-Mab HK, the Management, the Management Holdco and the ESOP Holdco hereby agree that before the Qualified IPO of the Company and as long as the Investors still hold equity in the Company, without consent of the Majority Investors (i.e., Investors whose total proportion of subscribed capital among each Investor exceeds two-thirds of the total subscribed capital contribution of all Investors, the same hereinafter) and the Investors who have the rights to appoint Investors Directors in accordance with the provisions of Article 4.1 of this Agreement, none of I-Mab HK, the Management, the Management Holdco and the ESOP Holdco shall dispose of any equity of the Company directly or indirectly held by them through transfer, gift, pledge or otherwise, or create any incumbrance on such equity in favor of any third party. However, (i) I-Mab HK may transfer equities in the Company to its Affiliated Company(ies), provided that such equity transfer shall not affect I-Mab HK's obligations hereunder. For the avoidance of doubt, in such case, the equity transfer shall not take effect unless and until the relevant Affiliated Company(ies) of I-Mab HK have agreed to assume all covenants, representations, obligations and responsibilities which are owed by I-Mab HK to the Investors hereunder; (ii) I-Mab HK shall not be subject to the Articles 2.1, 3.2 and 3.3 of this Agreement for the purpose of fulfilling its obligation under Article 4.3 (10) of the Investment Agreement to reduce its equity in the Company to within 30% (to the extent that the equity in the Company is sufficiently diluted at that time). Notwithstanding this paragraph, for the avoidance of ambiguity, I-Mab HK shall not directly or indirectly transfer all or part of the company's equity to a competitor of the Company; (iii) in the event of an increase in the management team, an existing Management may transfer equity to a newly joined member of the management team. For the avoidance of doubt, in such case, the equity transfer between the Management members shall not take effect unless and until the new Management member(s) have agreed to subject themselves to the provisions of this Article 2.1 and have executed relevant joinder agreement; (iv) for purposes of implementing the ESOP or other incentive arrangement that may be approved by the Investors Directors, the grantee(s) of incentives may be granted option or may accept transfer of equity; (v) any member of the Management may exercise the repurchase rights in accordance with Article 2.2, and (vi) the transfer of equity in the Company by I-Mab HK for the purpose of implementation of a repurchase under Article 3.5 (the foregoing are collectively referred to as the "**Exempt Transfer**"). The Exempt Transfer shall not be subject to the Company's, the Investors' or other shareholders' consent, the right of first refusal, the co-sale rights or similar rights. For the avoidance of doubt, a change in shares at the level of I-Mab 天境生物 (NASDAQ: IMAB; hereinafter referred to as "**I-Mab**"), the parent company of I-Mab HK, is not considered an indirect transfer of the equity in the company.

2.2 The Parties hereby acknowledge and agree that the Share of Equity held by each member of Management through the Management Holdco shall be restricted equity. After each member of the Management pays in an installment of capital contribution for his/her Share of Equity in accordance with the provisions of Article 4.3 (8) of the Series A Round Investment Agreement, such paid-in portion of Share of Equity shall be vested one (1) year from the relevant paid-in date (however, if the date on which such member of the Management paid in the relevant installment is earlier than the due date of such installment as provided in Article 4.3 (8) of the Series A Round Investment Agreement, the relevant portion of Share of Equity shall be vested one (1) year from such due date as provided in Article 4.3 (8) of the Series A Round Investment Agreement instead) (for the avoidance of doubt, the Share of Equity, after being vested, shall still be subject to the provisions of Article 2.1 hereof), till all portion of the Share of Equity is vested. However, upon a successful Qualified IPO of the Company or occurrence of a Deemed Liquidation Event, then all unvested Share of Equity held by the Management shall be immediately and fully vested. If, before the Share of Equity held by a member of the Management is fully vested, (a) such member of the Management departs for any reason, or (b) the Board of Directors has determined that there is a material violation of labor contract, or non-compete and intellectual property assignment agreement by such member of the Management, or material failure to perform his/her duties, or other material fault of such member of the Management, and therefore resolves to forfeit his/her Share of Equity, then other members of Management shall have the pro rata rights to purchase all Share of Equity directly or indirectly held by such member of the Management who departed or committed a material fault, which pro rata rights are in proportion to the Share of Equity then held by the relevant members of the Management. The purchase price shall be calculated based on the amount actually paid by the selling member of Management plus interest accrued at an annualized simple interest of 5%. Upon occurrence of aforesaid termination of employment or material fault of any Management member before his/her Share of Equity is fully vested, if the other Management members fail to exercise their repurchase rights or fail to fully exercise their pro rata repurchase rights in proportion to their respective Share of Equity, then Lili Qian and Zhengsong Zhang shall be responsible for repurchasing Share of Equity of the said Management member that are not repurchased. For the avoidance of doubt, in such case, the other shareholders of the Company do not have any right of first refusal, co-sale right or any other similar rights with respect to such purchase.

2.3 The Parties hereby acknowledge and agree that any equity held by the ESOP Holdco in the Company shall only be used for grant of equity incentives under equity incentive plan in accordance with the decision of the Board of Directors, and unless for the purpose of implementing the equity incentive plan and approved by resolution of the Board of Directors, the ESOP Holdco shall not directly or indirectly transfer, pledge, create incumbrance or otherwise dispose of any equity held by it in the Company.

Article 3 Investors' Preferred Rights

3.1 **Pre-emptive Rights**.

(1) From the Closing Date of the Transactions and prior to the Qualified IPO of the Company, if the Company intends to increase its registered capital or issue new shares in any form, arrangement shall be made in accordance with provisions of this Agreement and the Company's articles of association, and the Investors shall have the right to subscribe for the Company's new registered capital or new shares at the same price and conditions up to a percentage of such new registered capital or new shares equal to its then shareholding percentage in the Company ("**Pre-emptive Rights**").

(2) If the Company intends to increase registered capital or issues new shares in any form, the Company shall serve a written notice ("**Capital Increase Notice**") to all Investors at least fifteen (15) Working Days in advance. The Capital Increase Notice shall include the price and conditions of the plan to increase registered capital or issue new shares (including the amount/number of new registered capital/shares), and at the same time, issue an offer to invite Investors to subscribe for the Company's new registered capital or new shares at such price and conditions.

(3) An Investor shall notify the Company in writing within ten (10) Working Days after receipt of the above offer (the "**Participation Period**") whether to exercise its Pre-emptive Rights. If the Investor decides to exercise its Pre-emptive Rights, a written commitment to exercise the Pre-emptive Rights shall also be made, in which the amount to be exercised shall be indicated.

(4) Within ninety (90) Working Days after the expiration date of the above-mentioned Participation Period (if applicable, as the case may be), the Company may enter into a corresponding capital increase contract or similar agreement for the remaining part of the proposed new registered capital or proposed new shares which are not subject to the above-mentioned Pre-emptive Rights or against which no Pre-emptive Rights are exercised; provided, however, such capital increase contract or similar agreement cannot stipulate terms and conditions that are more favorable than those stated in the Capital Increase Notice. If the Company fails to enter into a capital increase contract or a similar agreement within ninety (90) Working Days, then the remaining part of the above-mentioned new registered capital or new shares shall again be subject to the Pre-emptive Rights in accordance with the provisions of this Article 3.1.

(5) This Article 3.1 does not apply to any capital increase for purposes of implementation of employee equity incentive plans or other incentive plan approved by the Investors Directors, capital increase for purposes of adjustments under Article 3.6, nor capital increase allocated to all shareholders on a pro rata basis for realization of profits or for converting capital reserve to registered capital as approved by resolution of the Shareholders.

3.2 **Right of First Refusal**.

(1) Subject to the provisions of Article 2 of this Agreement, if any shareholder of the Company (the "**Selling Shareholder**") wishes to transfer any equity of the Company directly or indirectly held by it (the "**Offered Equity**") to any third party (the "**Proposed Transferee**"), the Selling Shareholder shall issue a written notice to the Company and the Investors (the "**Transfer Notice**"), indicating its transfer intention, transfer price and conditions, and identity of the Proposed Transferee. The Investors (except for the Investor who is a Selling Shareholder) have the right of first refusal to purchase all or part of the Offered Equity at the same price and conditions with priority over other shareholders of the Company and the Proposed Transferee, in proportion to the amount of equity then held by them in the Company (the "**Right of First Refusal**"). The Investors have the right to, within ten (10) Working Days after receiving the Transfer Notice (the "**RoFR Exercise Period**"), respond in writing to the Company and the Selling Shareholder requesting to exercise the Right of First Refusal. If the Investors have responded in writing requesting to exercise the Right of First Refusal within the RoFR Exercise Period, such Investors have the right to purchase all or part of the Offered Equity at the same price and conditions with priority over other shareholders of the Company other than the Investors and any third parties.

(2) Within ninety (90) Working Days after the expiration of above-mentioned RoFR Exercise Period (if applicable, as the case may be), the Selling Shareholder may enter into a corresponding equity transfer contract for the remaining part (if any) of the Offered Equity which is not subject to the above-mentioned Right of First Refusal or against which no Right of First Refusal is exercised; provide, however, the equity transfer contract cannot stipulate terms and conditions that are more favorable than the prices and conditions stated in the Transfer Notice. If the Selling Shareholder fails to enter into an equity transfer contract within the above-mentioned ninety (90) Working Days' period, then the remaining part of the above-mentioned Offered Equity shall again be subject to the Right of First Refusal under this Article 3.2.

(3) For the avoidance of any doubt, the Parties confirm that transfer equity held by any Investor in the Company to its Affiliates is not subject to the Company's or other shareholders' consent, the Right of First Refusal, the co-sale rights or similar rights. Without the prior written consent of I-Mab HK, each shareholder shall not, and shall cause its respective Affiliates not to, directly or indirectly transfer all or any part of equity of the Company to any person who directly competes with the Company's principal business (i.e., early stage discovery, development and commercialization of innovative biological drugs in the field of immune diseases) (the "**Competitors of the Company**"; the number of Competitors of the Company shall be not greater than 20). The initial list of the Competitors of the Company is set forth in Schedule 2 hereto, which list may be updated by approval of the Board (including consent of both Investors Directors).

(4) This Article 3.2 does not apply to any Exempt Transfer listed in Article 2.1.

3.3 Co-Sale Right.

(1) Subject to Article 2.1 hereof, when I-Mab HK (including any Affiliate of I-Mab HK who acquires equity of the Company through Exempt Transfer pursuant to Article 2.1 (i) hereof) and/or any the Management member and/or the Management Holdco and/or the ESOP Holdco propose to transfer any equity of the Company held by them, if any Investor decides not to exercise the Right of First Refusal specified in Article 3.2 of this Agreement, such Investor shall have the right to, within five (5) Working Days after expiration of the First RoFR Exercise Period, respond in writing to the Company and I-Mab HK and/or any Management member and/or the Management Holdco and/or the ESOP Holdco (as the Selling Shareholder(s)) requesting to participate in the sale of equity of the Company by such Selling Shareholder(s) under the same conditions of sale (the "**Co-Sale Rights**"). Except for the situation described in Article 3.3 (2), the amount of equity that any Investor who intends to exercise the Co-Sale Rights by participating in the sale shall not exceed the product of the following: (i) the quantity of the Offered Equity, multiplied by (ii) a fraction, the numerator of which is the amount of equity of the Company held by the Investor who intends to exercise the Co-Sale Rights, the denominator of which is the total number of equity of the Company held by all Investors of the same round who intend to exercise the Co-Sale Rights and the amount of equity of the Company held by the said Selling Shareholder(s) at that time. The said Selling Shareholder(s) shall procure the Proposed Transferee to agree to the above-mentioned co-sale by the Investors; if the Proposed Transferee does not agree to the above-mentioned co-sale, the said Selling Shareholder(s) shall not transfer Offered Equity to the Proposed Transferee unless prior written consent of the Investors who intend to exercise the Co-Sale Rights is obtained or the said Selling Shareholder(s) agree to purchase the equity to be sold by the Investors who intend to exercise the Co-Sale Rights at the same price and conditions.

(2) Subject to other terms of this Agreement, when I-Mab HK (including any Affiliate of I-Mab HK who acquires equity of the Company through Exempt Transfer pursuant to Article 2.1 (i) hereof) and/or the Management and/or the Management Holdco and/or the ESOP Holdco have already cumulatively sold equity held by them in the Company in excess of 6% of the then total registered capital of the Company, and I-Mab HK and/or the Management and/or the Management Holdco and/or the ESOP Holdco wish to further sell equity directly or indirectly held by them in the Company to any Proposed Transferee, and any Investor decides not to exercise its Right of First Refusal as specified in Article 3.2 of this Agreement, then such Investor has the right to, within five (5) Working Days after expiration of the RoFR Exercise Period, respond in writing to the Company and I-Mab HK and/or the Management and/or the Management Holdco and/or the ESOP Holdco (as the Selling Shareholder(s)), requesting to sell any part or all equity of the Company held by it to the Proposed Transferee under the same conditions of sale (the "**Full Co-Sale Rights**"). If the Proposed Transferee does not agree to purchase any part or all equity that any Investor requests to sell by exercising the Fully Co-Sale Rights, I-Mab HK and/or the Management and/or the Management Holdco and/or the ESOP Holdco (as the Selling Shareholder(s)) shall purchase all equity requested to be sold by the Investors who intend to exercise the Full Co-Sale Rights at the same conditions, otherwise they shall not transfer Offered Equity to the Proposed Transferee.

(3) This Article 3.3 does not apply to any Exempt Transfer listed in Article 2.1.

3.4 <u>Liquidation Preference</u>.

Before the Qualified IPO of the Company, in the event of the Company's liquidation, dissolution, or occurrence of a Deemed Liquidation Event (as defined below), the Company's property shall be used to pay off liquidation expenses, employee salaries and social insurance expenses, statutory compensation, taxes owed by the Company and the Company debts in the order prescribed by law. If there is any remaining property after the Company's liquidation property is liquidated in accordance with the abovementioned provisions, or in case of a Deemed Liquidation Event, the Company or all shareholders have surplus after deduction of relevant taxes (collectively referred to as the "**Remaining Property**"), the Remaining Property shall be allocated in the following order:

(1) An Investor has the right to take precedence over the Existing Shareholders of the Company except for the Series A Round Investors to receive the higher of ("**Liquidation Preference Amount**"): (i) x) the Investors Investment Amount paid by the Investor, plus y) investment return accrued from the date on which the Investor actually paid the relevant Investors Investment Amount until the payment date of the relevant Liquidation Preference Amount, calculated on the basis of the annualized 10% simple interest rate on the Investor Investment Amount so paid, plus z) the Company's undistributed profits (if any) corresponding to the Investor's equity; or (ii) among the Remaining Property, the part that the Investor would be entitled to receive base on its shareholding percentage in the Company. If the Remaining Property is insufficient to pay all Investors their Liquidation Preference Amount in full, the Company shall allocate the Remaining Property among the Investors in proportion of each Investor's Liquidation Preference Amount. The aforesaid Liquidation Preference Amount shall be paid to the Investors by RMB cash.

(2) If there are any assets remaining after the Liquidation Preference Amount has been paid in full, the Remaining Property shall be distributed ratably among the other shareholders of the Company according to the relative proportion of equity held by them in the Company.

(3) The Parties shall take all effective measures in compliance with the applicable PRC laws to ensure that the Investors obtain their priority proceeds from the distributable Remaining Property in the above-mentioned order, in a manner consistent with applicable PRC laws. The Parties shall cooperate with the completion of the procedures that are required under the applicable laws for performance of obligations under this Article 3.4.

(4) For the purposes of this Agreement, "**Deemed Liquidation Events**" shall mean (i) all or substantially all of the Company's assets, business or equity are sold, transferred or otherwise disposed of in a transaction or series of related transactions ; or (ii) all or substantially all of the Company's intellectual property rights are transferred or exclusively licensed to third parties for use in a transaction or series of related transactions; or (iii) fifty percent (50%) and above of the Company's equity is sold, transferred to third parties or otherwise disposed of in a transaction to third parties or series of related transactions, or due to the merger, reorganization, business integration, or any other form of transaction between the Company and other entities, resulting in all shareholders of the Company before such transactions no longer hold fifty percent (50%) and above of the Company's voting rights after such mergers, reorganizations, business integration, or any other form of transaction.

3.5 Repurchase

(1) Repurchase Triggering Scenario ("**Repurchase Scenario**"):

(a) on September 15, 2024, the Company fails to close a Qualified IPO;

(b) Serious breach of the relevant commitments and warranties set forth in Article 8.1 of this Agreement and Article 4.3 of the Investment Agreement by the Company, I-Mab HK or I-Mab Shanghai, and creates material obstacles to the Qualified IPO of the Company resulting in the Company's Qualified IPO application being rejected by the stock exchange or securities regulatory authority, or the intermediary institutions such as the Company's sponsor, lawyer believe that such problems cannot be solved and the purpose of Qualified IPO cannot be achieved;

(c) other shareholders of the Company, other than the Repurchase Scenario (d), require the Company, the controlling shareholder(s) or other subject to repurchase their equity in the Company as set forth in Article 3.5 (1);

(d) subject to the requirements of the regulatory review of A-shares, upon written notice from I-Mab HK, and the consent of the board of directors of the Company (which shall include directors appointed by all Investors and shall be actively pursued by all Parties and shall not be unreasonably withheld or delayed after I-Mab HK has provided reasonable material explanation) or the written request of the A-shares review regulatory authority (Shanghai Stock Exchange or the China Securities Regulatory Commission), for the purpose of A-shares listing of I-Mab, I-Mab HK is unable to continue to perform its repurchase obligations under this Article 3.5.

(2) Within three (3) years of the occurrence of the Repurchase Scenario (a), within forty-five (45) days of the occurrence of the Repurchase Scenario (c), which the Investor knows or should know (whichever is the date when the Company, the controlling shareholder(s) or other repurchase obligation subject serves the Investor with the notice as stipulated in Article 8.3), or other period that may then be agreed between I-Mab and the Investors through consultation, any Investor will have the right to elect to request I-Mab HK to repurchase all or any part of the equity held by such Investor in the Company by cash. The repurchase price of the corresponding equity represented by per 1 U.S. dollar of registered capital of the Company Investors' Equity shall be (a) the Investor's Original Unit Investment Price (as defined below; or if the Original Unit Investment Price has been adjusted in accordance with Article 3.6, the Adjusted Unit Investment Price shall be applied instead), plus (b) accrued from the date that the Investor actually paid the relevant Investors Investment Amount till the date when the repurchase price is paid, interest calculated at the annualized 10% simple interest rate on the Original Unit Investment Price (or the Adjust Unit Investment Price), plus (c) the Company's undistributed profits (if any) corresponding to such equity (collectively referred to as the "**Repurchase Price**"). The total Repurchase Price that an Investor is entitled to shall be a product obtained by multiplying the unit Repurchase Price of per 1 U.S. dollar of registered capital calculated pursuant to the preceding provisions, by the total amount of registered capital corresponding to the Investors' Equity which the Investor requests to be repurchased.

(3) Within three (3) years of the occurrence of the Repurchase Scenario (b), within forty-five (45) days of the occurrence of the Repurchase Scenario (d), or other period that may then be agreed between I-Mab and the Investors through consultation, any Investor will have the right to elect to request I-Mab HK to repurchase all of the equity held by such Investor in the Company by cash. The Repurchase Price of the corresponding equity represented by per 1 U.S. dollar of registered capital of the Company Investor's Equity shall be repurchased in accordance with the valuation of the corresponding equity assessment by an evaluation institution jointly designated by the Parties at that time, and such Repurchase Price shall not be less than the Repurchase Price as stipulated in Article 3.5 (2) of the Shareholders Agreement.

(4) If the Investor fails to exercise the right of repurchase as stipulated under this Article 3.5 within forty-five (45) days of the occurrence of the Repurchase Scenario (d), I-Mab HK shall no longer assume any repurchase obligations, and the Company shall assume the repurchase obligations under this Article 3.5. Where the Company assumes the repurchase obligation, the Existing Shareholders shall, and the Company and I-Mab HK and the Management shall make every effort to cause all shareholders at that time to sign the resolution required for capital reduction and complete the legal procedures for the Company's repurchase.

(5) I-Mab HK and the Investors hereby agree that if any Investor intends to exercise the Repurchase Right in accordance with the provisions of Article 3.5 (1) above, subject to the approval procedures of I-Mab and the then applicable domestic and foreign securities laws and regulatory rules on public companies, if the Parties intend to have I-Mab to use its stock as consideration to repurchase the equity of the Company against which the Investor intends to exercise the Repurchase Right (hereinafter referred to as "**Repurchase by Stock**"), it shall be negotiated separately by the Investors and I-Mab. If the value of I-Mab stock obtained by an Investor through Repurchase by Stock has reached an amount equal to the product obtained by multiplying the unit Repurchase Price under Article 3.5 (2) by the quantity of equity held by such Investor, I-Mab HK shall no longer assume the repurchase obligations under this Article 3.5 with respect to such equity of the Company held by the Investor. From expiration of the four (4) years period after the Closing Date of the Series A Round financing, that is September 15, 2020, and within three (3) years thereafter, or within exercising period that may be otherwise agreed between I-Mab HK and the Investors through consultation, with consent of the Majority Investors, negotiation may be initiated with I-Mab on I-Mab's repurchase of equity of the Company held by the Investors by issuance of I-Mab stock as consideration. If the Investor fails to exercise the right of repurchase as stipulated under this Article 3.5 within forty-five (45) days of the occurrence of the Repurchase Scenario (d), this Article shall automatically terminate.

(6) (i) I-Mab HK and the Company shall complete procedures that are required under the applicable laws for performance of obligations under this Article 3.5. I-Mab HK guarantees that, within 1 year from the date on which any Investor delivers request of repurchase to the Company in writing, the Investor will receive Repurchase Price for all equity with respect to which it has exercised right of repurchase. Before I-Mab HK has paid the Investors the Repurchase Price in full, the Investors shall still be entitled to the full shareholder rights under the laws of the PRC and this Agreement for the equity in which it has not obtained relevant portion of Repurchase Price. (ii) If I-Mab HK disposes of all or substantially all of the equity directly or indirectly held by it in I-Mab Bio-Tech (Tianjin) Co., Ltd. and I-Mab Biopharma Co., Ltd. and such disposal of equity may impact I-Mab HK's capability to perform its repurchase obligations under this Article 3.5, I-Mab HK shall cause other company(ies) within the Group who have capacity of repurchase to jointly covenant to perform the repurchase obligations, so as to make up for deficiency in the Warrantor's capacity of repurchase (If the Investor fails to exercise the right of repurchase as stipulated under this Article 3.5 within forty-five (45) days of the occurrence of the Repurchase Scenario (d), this Article (ii) shall automatically terminate).

(7) The Repurchase Price shall be adjusted according to stock split, dividend distribution, capital reorganization and other similar situations.

(8) In the event that I-Mab HK and/or the Company fails to perform its repurchase obligations, any Investor has the right to require the Company to raise funds to perform its repurchase obligations by selling assets, dividends, liquidation or other means permitted by applicable laws ("**Alternative Means**"), the shareholders of the Company other than the Investor then agree and ensure that they act in concert with the Investor, make relevant resolutions in accordance with the direction of the Investor, and sign all legal documents required to enforce the Alternative Means.

3.6 Anti-Dilution

If, after the Closing Date and before the Company's Qualified IPO, the Company issues new registered capital (or securities that can be converted into or can be exercised as the Company's equity) with a unit price of per 1 U.S. dollar of registered capital (the "**New Unit Price**") that is lower than any Investor's Original Unit Investment Price at its investment in the Company, the Investor will have the right to require the Original Unit Investment Price of its equity held in the Company to be reduced to an amount that is equal to the New Unit Price (the Original Unit Investment Price, after such adjustment, shall be referred to as the "**Adjusted Unit Investment Price**"), and recalculate the amount of equity in the Company that it should have been entitled to obtain based on its Investor Investment Amount. After the recalculation, the amount of Company registered capital held by each Investor shall be equal to the quotient obtained by dividing the Investors Investment Amount paid by such Investor in the Transactions, by the Adjusted Unit Investment Price ("**Investor's Equity after Adjustment**"). The difference between the Investor's Equity after Adjustment and the Investor's then actual equity shall, to the extent permitted by the applicable laws, be compensated by the Company by issuing additional registered capital to the Investor at the lowest price permitted by law. For the avoidance of doubt, the "**Original Unit Investment Price**" of the Series A Round Equity is initially RMB equivalent to USD$10 per USD$1 of registered capital (calculated according to the USD to RMB central parity rate announced by the People's Bank of China on the day of such Investor's payment of its Series A Round Investors Investment Amount); the "**Original Unit Investment Price**" of the Series B Round Equity is initially RMB equivalent to USD$16.6666 per USD$1 of registered capital (calculated according to the USD to RMB central parity rate announced by the People's Bank of China on the day of such Investor's payment of its Series B Round Investor Investment Amount). However, equity/shares issuance for implementation of employee equity incentive plans or other incentive arrangements approved by the Investors Directors shall not trigger the adjustments under this Article 3.6. For the avoidance of doubt, if, in accordance with Shareholders' resolution, the Company uses capital reserve fund to increase the registered capital of all shareholders on a pro rata basis, the Original Unit Investment Price of the anti-dilution right investor under this Article shall be diluted and reduced proportionally.

3.7 **Effect of Preferred Rights**. Unless otherwise agreed in this Agreement, the foregoing special rights of Investors as stipulated in Article 3 of this Agreement shall automatically lapse at the time as necessary for initial public offering of the Company and in accordance with requirements of the regulatory authority for initial public offering; provided, however, such rights shall be automatically reinstated as if such rights had never expired or terminated, when (i) the Company withdraws the application for initial public offering, (ii) the Company fails to successfully complete the issuance with eighteen (18) months after submission of application for initial public offering (this period can be extended by the Parties through written agreement before the expiration), or (iii) the relevant regulatory authority overrules or rejects the Company's application for Qualified IPO (based on the earliest occurrence of the preceding three events).

3.8 **New Shareholders**. If, after execution of this Agreement, any shareholder of the Company intends to transfer all of the equity held by it in the Company to any third party, the transferee of the equity shall sign an agreement with the Parties to this Agreement simultaneously with the transfer of the equity, stipulating that the transferee shall be assigned rights and obligations of the transferring shareholder. If, after execution of this Agreement, any shareholder of the Company intends to transfer a part of the equity held by it in the Company to any third party, the transferee of the equity shall sign an agreement with the Parties to this Agreement simultaneously with the transfer of the equity, stipulating that the transferee and the transferor shall respectively be entitled to the rights of the transferor hereunder immediately prior to the transfer, and be subject to the obligations of the transferor hereunder immediately prior to the transfer, with respect to equity of the Company respectively held by each of them. Rights and obligations of the transferee(s) of equity shall be subject to agreement among the transferee(s) and all shareholders of the Company at that time.

3.9 **Most Favored Nation**. In the event any Investor is entitled to, with respect to its investment in these Transactions, any terms (the "**More Favorable Terms**") that are more favorable than the Series A Round Investors other than those required by the applicable laws and regulations or under the Transaction Documents (as defined in the Investment Agreement), the Series A Round Investors shall automatically be entitled to the same More Favorable Terms. In the event that the Series A Round Investors are entitled any More Favorable Terms than the Series B Round Investor in the Transactions in accordance with any document prior to this Agreement, then the Series B Round Investor shall automatically be entitled to the same More Favorable Terms.

Article 4 Corporate Governance

4.1 **Composition of Board**. The Company shall establish a Board of Directors. As of the Closing Date, the Board of Directors shall consist of seven (7) persons, of which: I-Mab HK has the right to appoint three (3) directors; Fushi Capital has the right to appoint one (1) director; Tsingsong Shenzhen and Tsingsong Nanjing have the right to appoint one (1) director jointly; Wenzhou Ruihe has the right to appoint one (1) director (together with the directors appointed by Fushi Capital, Tsingsong Shenzhen and Nanjing Tsingsong, collectively referred to as the "**Investors Directors**"); the Management Holdco has the right to appoint one (1) director. The Company shall have a Chairman, who shall be a director appointed by I-Mab HK. The Parties hereby unanimously agree that, in accordance with Article 4.3 (10) of the Investment Agreement, if the percentage of equity in the Company held by I-Mab HK falls below 30%, the Parties shall adjust the number of directors that I-Mab HK is entitled to appoint to a number of seats commensurate with the proportion of shares held at the time, and such adjusted number of seats shall be consistent with the purpose of I-Mab HK not having control of the Company at that time.

Each Shareholder of the Company shall exert affirmative votes on election of the aforesaid nominees of Directors, so as to ensure persons nominated by the Parties who are entitled to appoint Directors pursuant to this Article 4.1 be elected as Directors of the Company. Wenzhou Ruihe has the right to appoint one (1) Board observers. Each Board observer shall be entitled to: (i) simultaneously with the Directors of the Company, receive all notices for Board meetings, meeting materials and other documents that the Company delivers to the Directors; (ii) attend Board meetings and make speech, and receive copies of Board resolutions and meeting minutes, provided that the observer shall have no voting rights on any matter reviewed by the Board; and (ii) customary information rights of Directors.

4.2 **Shareholders' Power**. The Shareholders shall exercise the following powers to:

(1) Decide the Company's business policy and investment plan;

(2) Elect and replace directors, and decide on matters related to the remuneration of directors;

(3) Elect and replace supervisors who are representatives of the Shareholders, and determine matters related to the remuneration of supervisors;

(4) Review and approve the report of the Board of Directors;

(5) Review and approve the report of the supervisors;

(6) Review and approve the Company's annual financial budget plan and final account plan;

(7) Review and approve the Company's profit distribution plan and loss make-up plan;

(8) Adopt resolutions on issuance of corporate bonds;

(9) Adopt resolutions on the Company's public offering of shares, determination or amendment of the Company's IPO plan (including without limitation jurisdiction of IPO);

(10) Adopt resolutions on shareholders' transfer of equity interest or change of shareholding structure of the Company (provided that in the event any Party transfers equity in compliance with this Agreement, the other Parties shall cooperate to pass the relevant Shareholders resolutions);

(11) Adopt resolutions on the increase or decrease of the registered capital of the Company or its Subsidiaries;

(12) Adopt resolutions on matters of the Company or its Subsidiaries such as mergers, divisions, changes in organizational form, dissolution, termination, liquidation, ceasing to operate principal business of the Company, or Deemed Liquidation Events;

(13) Amend the Company's or its Subsidiaries' articles of association.

In shareholders meetings, the shareholders shall exercise their voting power in accordance with the proportion of registered capital respectively subscribed by them. When the shareholders adopt resolutions on items (9)-(13) above, such resolutions must be passed by shareholders representing more than two-thirds (2/3) of the voting power (including the consent of I-Mab HK and the Majority Investors (for the avoidance of doubt, shall include consent of the Investors who are entitled to appoint Investors Directors)). Except for the abovementioned circumstances, the resolution of the shareholders shall be passed by shareholders representing more than one-half (1/2) of the voting power.

4.3 **Board of Directors' Power**. The Board of Directors shall exercise the following power to:

(1) Decide the business plan and investment plan of the Company and its Subsidiaries;

(2) Formulate the annual financial budget plan and final account plan of the Company and its Subsidiaries;

(3) Formulate profit distribution plan and loss make-up plan of the Company and its Subsidiaries;

(4) Formulate plans for the Company and/or its Subsidiaries to increase or decrease the registered capital;

(5) Approve, implement or amend the Company's employee equity incentive plan and specific plans thereof;

(6) Formulate merger, division, change of company organization form, and dissolution plan of the Company and/or its Subsidiaries;

(7) Approve, extend or amend related party transactions or agreements between the Company and/or its Subsidiaries and any of its shareholders, directors and Senior Officers or their respective Affiliates (except related party transactions or agreements necessary for the Exempt Transfer described in Article 2.1 hereof, or execution, extension or amendment of any related party transaction or agreement to the extent such execution, extension or amendment is made in accordance with related party transaction/agreement framework plan approved in advance by the Board of Directors (including the Investors Directors);

(8) Approve the Company and/or its Subsidiaries to sell, mortgage, pledge, transfer or dispose of the intellectual property as contributed by I-Mab HK to the Company stipulated in the Series A Round Investment Agreement, or sale or disposal of all or substantially all of assets related to any Target Pipeline of the Company stipulated in the Series A Round Investment Agreement;

(9) Any commercial cooperation between the Company or its Subsidiaries and any third party regarding the intellectual property related to the Target Pipelines as contributed by I-Mab HK to the Company stipulated in the Series A Round Investment Agreement, including but not limited to joint development, external licensing, etc.;

(10) Company's or its Subsidiaries' provision of securities to third parties;

(11) Amendment of the list of the Competitors of the Company as attached to this Agreement;

(12) The Company's obtainment of license from any third party under any Intellectual Property, or the license of any Intellectual Property of the Company to any third party, or change of any existing license agreement or arrangement in connection with any Target Pipeline stipulated in the Series A Round Investment Agreement;

(13) Decide on the establishment of the internal management organization of the Company and its Subsidiaries;

(14) Formulate the Company's basic management policies (including without limitation policies on the Company's provision of securities or lending of loans to third parties, borrowing of loans, related party transactions);

(15) Approve the company and its Subsidiaries as service providers to sign any CRO contracts, contract for CMC development and contract manufacturing of drugs, or contract for contract development or manufacture of drugs of similar nature;

(16) Approve the planning and design (including its modifications and changes) and implementation of the production lines of the Company and its Subsidiaries; and

(17) Other powers granted under the applicable laws, the Company's articles of association, or by the Shareholders.

4.4 Each member of the Board of Directors shall have one vote. The quorum for meetings of Board of Directors shall exceed two-thirds (2/3) of the total number of directors, and the Board of Directors resolutions reached are valid only if with affirmative votes of a majority of the directors. Notwithstanding the foregoing, the Board of Directors shall not adopt resolutions on the matters listed in item (5) above without the affirmative votes of over two-thirds (2/3) of the directors, including affirmative votes of at least one Investor Director; and the Board of Directors shall not adopt resolutions on the mattes listed in items (6) to (12), (15) and (16) above without the affirmative votes of a majority of the directors, including affirmative votes of at least one director appointed by I-Mab HK and all the Investors Directors.

Article 5 Dissolution of Act in Concert

5.1 I-Mab HK, the Management Holdco and the ESOP Holdco unanimously agree to terminate the relationship of act in concert agreed in Article 5 Act in Concert of the Series A Round Shareholders Agreement, and terminate all rights and obligations under such relationship of act in concert.

5.2 From the effective date of this Agreement, I-Mab HK, the Management Holdco and the ESOP Holdco shall, as shareholders of the Company, in accordance with the laws and regulations, the Company's articles of association and provisions of this Agreement, independently exercise all the rights of shareholders including, but not limited to, information rights, dividend rights, economic rights and other rights granted by the laws and regulations, or the Company's articles of association and provisions of this Agreement.

Article 6 Liability for Breach of Contract; Indemnification

6.1 If any Party to this Agreement breaches the provisions of this Agreement, the Other Parties shall have the right to claim indemnification for the losses suffered by them as a result of the breach in addition to other rights that they may be entitled to under this Agreement.

6.2 Subject to other provisions of this Agreement, a Party to this Agreement (hereinafter referred to as the "**Indemnifying Party**") shall indemnify and hold harmless the Other Parties (hereinafter referred to as the "**Indemnified Parties**") against losses or payment incurred in connection with any of the following circumstances: (a) any representation or statement made by the Indemnifying Party in this Agreement is false, untrue or misleading,(b) the Indemnifying Party has violated or failed to fully fulfill the covenants, warranties or obligations under this Agreement, in each case except the circumstances which have been waived by the Other Parties in writing. The Indemnifying Party shall indemnify the Indemnified Parties against any and all losses directly or indirectly suffered by the Indemnified Parties as a result of the foregoing circumstances.

6.3 If any Party to this Agreement breaches the provisions of this Agreement, in addition to any other rights under this Agreement, the Other Parties shall have the right to require the breaching Party to specifically and completely perform the obligations under this Agreement.

6.4 Notwithstanding anything to the contrary herein, the provisions of this Article shall survive termination of the Parties' rights and obligations hereunder, and survive the termination of this Agreement.

Article 7 Effectiveness, Amendment and Termination of the Agreement

7.1 **Effectiveness**. This Agreement shall take effect on the Closing Date, subject to the due execution of this Agreement by the Parties or their authorized representatives (Chinese non-natural persons must also affix their official seals). Upon the entry into force of this Agreement, the Series A Round Shareholders Agreement shall automatically terminate and be superseded in its entirety by this Agreement.

7.2 **Amendment**.

(1) Unless otherwise provided in this Agreement, any amendment or modification of this Agreement shall be negotiated by the Parties separately and shall not take effect until a written contract is signed jointly on the amendment or modification.

(2) Notwithstanding the foregoing, the Parties acknowledge that if the Company establishes any new Management Holdco or ESOP Holdco after the signing of this Agreement (including, but not limited to, the ESOP Holdco established separately in accordance with Article 7.1 of the Investment Agreement, if applicable), the Company shall cause such Management Holdco or ESOP Holdco to sign a reasonable form of Joinder Agreement to the Shareholder Agreement and send such Joinder Agreement to the Other Parties to confirm that such Shareholding Platform has become a Party to this Agreement, and shall have the same rights and obligations as the Management Holdco or ESOP Holdco under this Agreement. The foregoing adjustments shall take effect on the date on which such Shareholding Platform acquires the equity in the Company without the need for a separate written contract between the Parties.

7.3 **Termination**. This Agreement may be prematurely terminated in accordance with the following provisions:

(1) With the unanimous written consent of all Parties;

(2) If force majeure occurs and as a result the fundamental purpose of this Agreement cannot be achieved, any Party may terminate this Agreement.

7.4 **Effect of Termination**. When this Agreement is terminated in accordance with Article 7.3, except the provisions in Article 6 (Liability for Breach of Contract; Indemnification), Article 8 (Miscellaneous) and this Article 7.4, this Agreement shall be invalid and shall no longer be binding or effective, and the Parties will be no longer required to bear the responsibilities and obligations under this Agreement; provided, however, despite termination of this Agreement, a Party shall still be liable for any losses incurred by the Other Parties as a result of its breach of this Agreement before the termination.

Article 8 Miscellaneous

8.1 **Other Commitments from I-Mab HK and I-Mab Shanghai**. I-Mab HK and I-Mab Shanghai undertake that if the Company subsequently starts to prepare for an independent listing, I-Mab HK and I-Mab Shanghai will, based on the actual situation of the equity in the Company held by I-Mab HK at that time, make their reasonable commercial efforts to provide the necessary cooperation to the Company on issues related to the demonstration of independence by means including the cancellation of preferential rights arrangement, adjustment of the equity in the Company held by I-Mab HK and the weight of corporate governance, etc. in due time, including but not limited to the following matters: 1) issue a Letter of Commitments to avoid inter-sector competition (if required) and cooperate with the signing of relevant agreements (if involved) in accordance with the audit requirements at that time and the proportion of shares of I-Mab HK at that time when the Company applies for a Qualified IPO; 2) make its best commercial efforts to reduce connected transactions with the Company in accordance with the audit requirements at that time when the Company applies for a Qualified IPO, and ensure that its connected transactions with the Company shall be conducted in compliance with requirements of relevant securities regulatory rules such as reasonableness, necessity, fairness; 3) in order to meet the audit requirements of the independence of the Company's personnel when applying for the Qualified IPO, I-Mab HK shall cooperate with the Company to improve the independence of the Company's personnel, including, but not limited to, to make the relevant personnel of I-Mab HK no longer participate in the operation and management of the Company as members of the management of the Company and to maintain mutual independence with the management of the Company.

8.2 **Other Commitments of the Company and its Investors**. As a participating subsidiary of I-Mab HK, in the subsequent capital market operations of I-Mab HK or its affiliates, if it needs to conduct necessary due diligence, verification to the Company or require the Company to issue necessary explanations or other documents, the Company and the Investors should make their best commercial efforts to provide necessary cooperation.

8.3 **Notice**.

(1) All notices, claims, requests, consents, waivers and other communications required or permitted under this Agreement shall be in writing (including telegram, fax or similar written form) and shall be sent, delivered or mailed, e-mailed or faxed to the following addresses:

Company: **I-Mab Biopharma (Hangzhou) Co., Ltd.**

Attention: ***

Phone: ***

E-mail: ***

Address: ***

I-Mab Shanghai: **I-Mab Biopharma Co., Ltd.**

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Existing Shareholders: **I-MAB BIOPHARMA HONGKONG LIMITED**

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Hangzhou Fushi Investment Management Partnership (Limited Partnership)

Attention: ***

Phone: ***

Fax: ***

E-mail: ***

Address: ***

Shenzhen Tsingsong Shengrui Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Nanjing Tsingsong Healthcare Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Hangzhou Heda Biotech Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Xiamen Ronghui Derong Equity Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

Fax: ***

E-mail: ***

Address: ***

Ningbo Yanyuan Yaoshang Chanrong Equity Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Ningbo Yanchuang Yaoshang Yangming Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Jiangsu Yanyuan Dongfang Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Ningbo Rongshun Yanyuan Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Ningbo Yanyuan Innovation Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Zhuzhou Guochuang Junyao Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Ningbo Hanhai Qianyuan Equity Investment Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Hangzhou Haibang Yigu Investment Partnership (Limited Partnership)/Jialiang Shan

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Zhejiang Silu Industry Investment Fund Partnership (Limited Partnership)

Attention: ***

Phone: ***

Fax: ***

E-mail: ***

Address: ***

Viva Biotech (Shanghai) Ltd.

Attention: ***

Phone: ***

Fax: ***

E-mail: ***

Address: ***

Tianjin Huatian Enterprise Management Consultation Limited Partner (Limited Partner)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Qingdao Xinneng Property Management Co., Ltd.

Attention: ***

Phone: ***

E-mail: ***

Address: ***

The Management/Hangzhou Yijing Biotech Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Hangzhou Lanjing Biotech Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Series B Round Investor	**Pingtan Wenzhou Ruihe Investment Partnership (Limited Partnership)**	
	Attention:	***
	Phone:	***
	E-mail:	***
	Address:	***
	Huzhou Jingyun Equity Investment Partnership (Limited Partnership)	
	Attention:	***
	Phone:	***
	E-mail:	***
	Address:	***
	Pingtan Wenzhou Ruizhi Investment Partnership (Limited Partnership)	
	Attention:	***
	Phone:	***
	E-mail:	***
	Address:	***
	Jiaxing Hongtong Investment Partnership (Limited Partnership)	
	Attention:	***
	Phone:	***
	E-mail:	***
	Address:	***
	Qingdao Zhongou Industry Investment Partnership (Limited Partnership)	
	Attention:	***
	Phone:	***
	E-mail:	***
	Address:	***
	Qingdao Haiyang Innovation Investment Co., Ltd.	
	Attention:	***
	Phone:	***
	E-mail:	***
	Address:	***

Ningbo Yijing Management Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Ningbo Hangjing Management Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

Ningbo Zhengjing Management Partnership (Limited Partnership)

Attention: ***

Phone: ***

E-mail: ***

Address: ***

(2) Each notice, request or other communication delivered or served in accordance with the provisions of Article 8.2 (1) shall be deemed as delivered or served as follows: (a) if sent by a courier company or personally delivered, it shall be deemed as delivered when the relevant notice, request or communication is sent to the above-mentioned address; (b) if sent by fax, then the relevant notice, request or communication shall be deemed as delivered when it is transmitted to the above fax number and the report of successful fax transmission is obtained; (c) if sent by e-mail, it shall be deemed as delivered twenty-four hours after the date on which the e-mail containing the relevant notice, request or communication as recorded by the sender's computer is sent, provide, however, if the sender does not receive the recipient's confirmation of receipt of the above e-mail within twenty-four hours (except for automatic email confirmation of receipt), the above notice, request or other communication shall be sent by courier or fax by the end of the same day. The addresses and e-mails provided by the Parties be used as the address for service of dispute resolution under this Agreement. The confirmed address for service applies to all stages of dispute resolution, including arbitration, first instance, second instance, retrial, and execution, etc.

8.4 **Governing law**. This Agreement shall be governed by and be construed in accordance with the PRC laws.

8.5 **Dispute Resolution**. In the event of is a dispute over the interpretation or performance of this Agreement, the Parties shall firstly attempt to resolve the dispute through friendly consultation. If the dispute cannot be resolved through consultation within thirty (30) days after one Party delivers written notice to the Other Parties requesting the commencement of consultation, then any Party may submit the dispute to the China International Economic and Trade Arbitration Commission for arbitration, and the arbitration shall be conducted in Hangzhou according to the said commission's arbitration rules then in force. The arbitration award shall be final and binding on all Parties and cannot be appealed. The arbitration costs shall be borne by the losing party unless the arbitration award provides otherwise. When any dispute occurs and when any dispute is under arbitration, except the matter under disputes, the Parties shall continue to exercise their other rights and perform their other obligations under this Agreement.

8.6 **Confidentiality**. Each of the Parties shall not, and shall cause its respective Affiliates, shareholders, directors, senior officers, employees, representatives or agents not to, directly or indirectly disclose the existence of this Agreement or any information related to the Transactions (including any information obtained by the Party during the course of the negotiation and execution of this Agreement), unless (a) it has obtained the prior written consent of the non-disclosing Parties, or (b) such information is required to be disclosed by the applicable laws and is only disclosed to the extent necessary to comply with the applicable laws or any regulations or policies of any stock exchange, provided, however that the disclosing Party shall, within a reasonable time before the disclosure or submission of the relevant information, seek opinions of the Other Parties on such disclosure and submission, and that if required by the Other Parties, the disclosing Party shall seek for confidential treatment of the disclosed or submitted information to the extent possible. Notwithstanding the foregoing covenants, I-Mab, as a company listed in the United States, is entitled to disclose information about the Company's financing as required by the U.S. securities laws or other securities regulatory authorities that may apply thereto, without the Parties' separate consent. Upon completion of the closing, each party shall have the right to disclose the existence of the Series B Round investor's investment in the Company to third parties or the public, provided that any party disclosing matters relating to the Series B Round Investor's investment in the Company shall consult with I-Mab HK in order to comply with the disclosure requirements under U.S. securities laws or other securities regulatory laws and regulations that may be applicable thereto.

8.7 **Severability**. The obligations under this Agreement shall be regarded as separate obligations and be independently enforceable. When one or more obligations of this Agreement are unenforceable, the enforceability of other obligations shall not be affected. If this Agreement is not enforceable against any Party, the enforceability of this Agreement among the Other Parties shall not be affected. If one or more of the provisions of this Agreement are found to be invalid, illegal or unenforceable in any respect according to any applicable law, or a government agency requests amendment of one or more provisions of this Agreement, the validity, legality and enforceability of the remaining provisions shall not be affected or damaged in any way. The Parties shall endeavor to replace these invalid, illegal or unenforceable provisions with valid provisions through sincere consultations, and the economic effects of such valid provisions shall be as similar as possible to those of the invalid, illegal or unenforceable provisions.

8.8 **Entire Agreement**. This Agreement (including the other Transaction Documents and any other documents referred to or contemplated hereunder or thereunder) constitutes the entire agreement among the Parties with regard to the subjects hereof, and supersedes any other agreements or intentions previously reached by the Parties on the same subjects. The Company and its Existing Shareholders (excluding the Series A Round Investors) hereby confirm that the Company, the Existing Shareholders (excluding the Series A Round Investors) have completed the Series A Round Investment Agreement and the conditions of delivery agreed in other Transaction Documents have all been satisfied, and there is no breach of the Series A Round Investment Agreement and other Transaction Documents. For the avoidance of doubt, notwithstanding the provisions of this Article, Article 8 Liability for Breach of Contract; Indemnification of the Series A Round Investment Agreement, shall remain in effect.

8.9 **Assignment**. Without prejudice to the provisions of the PRC laws and the other provisions of this Agreement, the Investors have the right to assign their rights and obligations under this Agreement to their respective Affiliates, and such assignment does not require prior consent of Other Parties or the Company. An Investor has the right to assign its rights and obligations under this Agreement to any third party along with the sale or transfer (if any) of its equity in the Company to such third party; provided, however, such equity transfer shall be subject to the other Investors' Right of First Refusal under Article 3.2 hereof. Notwithstanding anything to the contrary herein, after completion of its capital contribution obligation, any Investor may transfer its then effective rights and obligations under this Agreement to its Affiliates along with the sale or transfer (if any) of its equity in the Company, which transfer or assignment shall not be subject to any other shareholders' consent, the Right of First Refusal, the Co-Sale Rights or similar rights. Except the foregoing, without the prior written consent of each other Party, no Party shall assign its rights or obligations under this Agreement; any assignment without the Other Parties' consent shall be invalid.

8.10 **Counterparts**. This Agreement is written in Chinese. This Agreement shall be signed in 38 original copies. Each Party shall hold one (1) original copy, and the remaining original copies shall be held by the company. Each copy of this Agreement shall be equally effective.

8.11 **Priority**. If, in order to request any government agency to carry out any specific act, separate agreements in connection with the Transactions (including but not limited to, the Investment Agreement, the Company's articles of association or amendments to the articles of association, as may be amended from time to time) have to be signed in accordance with the standard templates or requirements of the government agency, this Agreement shall control over any such agreements, and such agreements shall only be used to request the government agency to implement the specific act, and shall not be used to establish or as an evidence of any rights or obligations of the relevant parties on matters that may be stipulated in such agreements. In the event of any conflict between the contents of this Agreement and the articles of association, the Parties agree that this Agreement shall prevail to the extent permitted by law.

(No text below)

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Company:

I-Mab Biopharma (Hangzhou) Co., Ltd.
(Seal)

/s/ Lili Qian
Name: Lili Qian
Position: General Manager

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

I-Mab Shanghai:

I-Mab Biopharma Co., Ltd.
(Seal)

/s/ Jingwu Zhang Zang
Name: JINGWU ZHANG ZANG
Position: CHAIRMAN

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

I-MAB BIOPHARMA HONGKONG LIMITED

/s/ Jingwu Zhang Zang
Name: JINGWU ZHANG ZANG
Position: DIRECTOR

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Hangzhou Fushi Investment Management Partnership (Limited Partnership)
(Seal)

/s/ Hongbo Lu
Name: Hongbo Lu
Position: Authorized signatory

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Shenzhen Tsingsong Shengrui Investment Partnership (Limited Partnership)
(Seal)

/s/ Song Zhang
Name: Song Zhang
Position: Authorized signatory

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Nanjing Tsingsong Healthcare Investment Partnership (Limited Partnership)
(Seal)

/s/ Song Zhang
Name: Song Zhang
Position: Authorized signatory

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Hangzhou Heda Biotech Investment Partnership (Limited Partnership)
(Seal)

/s/ Yufeng Jin
Name: Yufeng Jin
Position: Authorized signatory

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Xiamen Ronghui Derong Equity Investment Partnership (Limited Partnership)
(Seal)

/s/ Wenwen Zhang
Name: Wenwen Zhang
Position: Authorized signatory

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Zhuzhou Guochuang Junyao Investment Partnership (Limited Partnership)
(Seal)

/s/ Xiaohu Xin
Name: Xiaohu Xin
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Hangzhou Haibang Yigu Investment Partnership (Limited Partnership)
(Seal)

/s/ Li Xie
Name: Li Xie
Position: Authorized signatory

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

/s/ Jialiang Shan
Name: Jialiang Shan

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Zhejiang Silu Industry Investment Fund Partnership (Limited Partnership)
(Seal)

/s/ Guanxin Zhou
Name: Guanxin Zhou
Position: Authorized signatory

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Viva Biotech (Shanghai) Ltd.
(Seal)

/s/ Ying Wu
Name: Ying Wu
Position: COO

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Tianjin Huatian Enterprise Management Consultation Limited Partner (Limited Partner)
(Seal)

/s/ Zhanyue Yang
Name: Zhanyue Yang
Position: Authorized signatory

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Qingdao Xinneng Property Management Co., Ltd.
(Seal)

/s/ Ning Xu
Name: Ning Xu
Position: Legal Representative

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Hangzhou Yijing Biotech Partnership (Limited Partnership)
(Seal)

/s/ Lili Qian
Name: Lili Qian
Position: Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Existing Shareholder:

Hangzhou Lanjing Biotech Partnership (Limited Partnership)
(Seal)

/s/ Lili Qian
Name: Lili Qian
Position: Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Lili Qian
Lili Qian

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Zhengsong Zhang
Zhengsong Zhang

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Yunfei Zhang
Yunfei Zhang

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Lihong Lou
Lihong Lou

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Kai Zhou
Kai Zhou

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

The Management:

/s/ Fang Yin
Fang Yin

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Series B Round Investor:

Huzhou Jingyun Equity Investment Partnership (Limited Partnership)
(Seal)

/s/ Danjun Kong
Name: Danjun Kong
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Series B Round Investor:

Pingtan Wenzhou Ruihe Investment Partnership (Limited Partnership)
(Seal)

/s/ Shuguang Wang
Name: Shuguang Wang
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Series B Round Investor:

Pingtan Wenzhou Ruizhi Investment Partnership (Limited Partnership)
(Seal)

/s/ Shuguang Wang
Name: Shuguang Wang
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Series B Round Investor:

Jiaxing Hongtong Investment Partnership (Limited Partnership)
(Seal)

/s/ Haifang Wang
Name: Haifang Wang
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Series B Round Investor:

Qingdao Zhongou Industry Investment Partnership (Limited Partnership)
(Seal)

/s/ Yuanyi Ji
Name: Yuanyi Ji
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Series B Round Investor:

Qingdao Haiyang Innovation Investment Co., Ltd.
(Seal)

/s/ Bingbing Liu
Name: Bingbing Liu
Position: Delegated Representative of Legal Representative

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Series B Round Investor:

Ningbo Yijing Management Partnership (Limited Partnership)
(Seal)

/s/ Lili Qian
Name: Lili Qian
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Series B Round Investor:

Ningbo Hangjing Management Partnership (Limited Partnership)
(Seal)

/s/ Lei Wang
Name: Lei Wang
Position: Delegated Representative of Executive Affairs Partner

IN WITNESS WHEREOF, the Parties have been in person or caused their respective authorized representatives to execute this Agreement on the date first above written.

Series B Round Investor:

Ningbo Zhengjing Management Partnership (Limited Partnership)
(Seal)

/s/ Daling Zhang
Name: Daling Zhang
Position: Delegated Representative of Executive Affairs Partner

Schedule 1
Shareholding Structure Immediately After Completion of the Transactions

Schedule 1

Schedule 2
List of Competitors of the Company

Schedule 2

EXHIBIT 8.1

List of Principal Subsidiaries of I-MAB

Name of Subsidiary	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
Zhejiang Tianli Pharmaceutical Sales Co., Ltd.	People's Republic of China
I-Mab Pharmaceutical (Shanghai) Co., Ltd.	People's Republic of China
Thirdventure Beijing Bio-tech Co., Ltd.	People's Republic of China
Eftan Biotech (Shanghai) Co., Ltd.	People's Republic of China

EXHIBIT 12.1

Certification by the Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

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

5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: May 1, 2023

By: /s/ Andrew Zhu
Name: Andrew Zhu
Title: Director, President and Acting Chief Executive Officer

EXHIBIT 12.2

Certification by the Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Richard Yeh, 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: May 1, 2023

By: /s/ Richard Yeh
Name: Richard Yeh
Title: Interim 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 year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Andrew Zhu, Acting Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 1, 2023

By: /s/ Andrew Zhu
Name: Andrew Zhu
Title: Director, President and Acting 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 year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Richard Yeh, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 1, 2023

By: /s/ Richard Yeh
Name: Richard Yeh
Title: Interim Chief Financial Officer

Exhibit 15.1

君合律师事务所 JUNHE

26/F HKRI Centre One, HKRI Taikoo Hui,
288 Shimen Road (No. 1),
Shanghai 200041, P.R. China
T: (86-21) 5298-5488
F: (86-21) 5298-5492
junhesh@junhe.com

May 1, 2023

I-Mab
55th Floor, New Bund Center
555 West Haiyang Road
Pudong District, Shanghai
People's Republic of China

Dear Sir/Madam:

We hereby consent to the reference of our name under the headings "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China" and "Item 10. Additional Information—E. Taxation—PRC Taxation" in I-Mab's Annual Report on Form 20-F for the year ended December 31, 2022 (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, No. 333-256603 and No. 333-265684) and Form F-3 (No. 333-252793) of I-Mab of the summary of our opinions under the headings "Item 3. Key Information—D. Risk Factors—Risks Related to Doing Business in China" and "Item 10. Additional Information—E. Taxation—PRC Taxation" in 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
JunHe LLP

Exhibit 15.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-239871, No. 333-256603 and No. 333-265684) of I-Mab of our report dated May 1, 2023 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 20-F.

/s/PricewaterhouseCoopers Zhong Tian LLP
Shanghai, the People's Republic of China
May 1, 2023

Exhibit 15.3

HARNEYS

Harney Westwood & Riegels
3501 The Center
99 Queen's Road Central
Hong Kong
Tel: +852 5806 7800
Fax: +852 5806 7810

Date: 1 May 2023

057753.0003

I-Mab 天境生物
55th Floor, New Bund Center
555 West Haiyang Road
Pudong District, Shanghai
People's Republic of China

Dear Sir or Madam

I-Mab 天境生物 (the ***Company***)

We are attorneys-at-law qualified to practice in the Cayman Islands and have acted as Cayman Islands legal advisers to the Company in connection with the filing by the Company with the United States Securities and Exchange Commission (the ***SEC***) of an annual report on Form 20-F for the year ended 31 December 2022 (the ***Form 20-F***).

We hereby consent to the reference of our name under the headings "Item 5. Operating and Financial Review and Prospects –Taxation – Cayman Islands" and "Item 10. Additional Information—E. Taxation—Cayman Islands Taxation" in the Form 20-F and further consent to the incorporation by reference of the summary of our opinion under those headings into the Company's Registration Statements on Form S-8 (No. 333-239871, No. 333-256603 and No. 333-265684) and Form F-3 (No. 333-252793).

We consent to the filing with the SEC of this consent letter as an exhibit to the Form 20-F. 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.

[signature page to follow]

Yours faithfully

/s/ Harney Westwood & Riegels
Harney Westwood & Riegels