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

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 UNDER
THE SECURITIES EXCHANGE ACT OF 1934**

For the month of March 2023

Commission File Number: 001-39173

I-MAB

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

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F

Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

I-MAB

By : /s/ Richard Yeh
Name : Richard Yeh
Title : Chief Operating Officer and Interim Chief Financial Officer

Date: March 31, 2023



I-Mab Provides Business and Corporate Updates and Reports Financial Results for the Year Ended December 31, 2022

- Strategic reprioritization of the Company’s pipeline to focus on key clinical assets and overall streamlining of corporate structure and workforce, resulting in a significant reduction in the cash burn rate and in significant pipeline achievements by focus
- Thirteen key clinical milestones achieved in 2022, including positive data readout for lemozoparlimab, uliledlimab, and givastomig and significant progress on eftansomatropin alfa and felzartamab. Phase 3 data readout of eftansomatropin alfa and potential biologics license applications (“BLA”) submission expected by the end of 2023 or early 2024
- I-Mab and AbbVie continue to collaborate on the global development of anti-CD47 antibody therapy under an amendment to the original agreement
- A strong cash position of RMB3.5 billion (US\$514.2 million) by the end of 2022, sufficient to fund key business operations for the next three years
- I-Mab will host conference calls and webcasts on March 31, 2023. A Mandarin session will be held at 7:00 am E.T., and an English session at 8:15 am E.T.

GAITHERSBURG, MD. and SHANGHAI, China, March 31, 2023 – I-Mab (the “Company”) (Nasdaq: IMAB), a clinical-stage biopharmaceutical company committed to the discovery, development, and commercialization of novel biologics, today announced its financial results for the 12 months ended December 31, 2022, and provided key business updates.

In 2022, the Company faced a series of risks, including macroeconomic and geopolitical headwinds, which prompted the Company to re-position its 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 laser-focused R&D activity on five key clinical assets, significantly reducing the cash burn rate in 2022 and beyond. Today, the risks imposed by the Holding Foreign Companies Accountable Act (the “HFCAA”) and the COVID-19 pandemic are largely mitigated. Collectively, the Company is 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 its key business operations for the next three years.

More specifically, the Company made significant progress in its pipeline development by focusing on five key clinical assets: eftansomatropin alfa, felzartamab, lemozoparlimab, uliledlimab, and givastomig. The major achievements in 2022 included (1) positive Phase 2 data readout for lemozoparlimab and regulatory approval to initiate a Phase 3 clinical trial in China; (2) positive Phase 2 data readout for uliledlimab – a very 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 2H 2023 in advanced NSCLC. In addition, the Company expects that the recent Phase 2 data could contribute to the ongoing discussions for a potential global partnership; (3) encouraging Phase 1 data for givastomig (TJ-CD4B), which will potentially enable the initiation of a Phase 2 trial in 2H 2023, and a potential global partnership, and (4) significant progress on eftansomatropin alfa and felzartamab, leading to Phase 3 data readout expected in 2H 2023 and potential BLA submission in China by the end of 2023 or early 2024 for eftansomatropin alfa, and at a later time for felzartamab.

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“In 2022, while facing unprecedented challenges, we strived to achieve two overarching business goals. One is the re-positioning of our core business and the optimization of our organization and resources to reduce our cash burn rate and extend our cash runway. The other is the achievement of thirteen key milestones, including positive data readouts for lemozoparlimab, uliledlimab, and givastomig and significant progress made for two pre-BLA assets, felzartamab and eftansomatropin alfa, towards BLA submission,” said Dr. Andrew Zhu, Acting CEO of I-Mab.

“Going into 2023, we are now in a strong position to deliver on our innovative pipeline and corporate milestones, as well as to make expected progress in global partnerships and commercial partnerships given that business development remains a key strategic priority of the Company. We will stay laser-focused on creating value for our shareholders while extending the cash runway to support key business operations in the coming years,” Dr. Zhu concluded.

Updated Pipeline Development Highlights and Upcoming Milestones

The five prioritized clinical assets include the Company’s three Phase 3 assets (eftansomatropin alfa, felzartamab, and lemozoparlimab), one End-of-Phase 2 (EOP2) asset (uliledlimab), and one Phase 1 asset (givastomig). As the studies progress, the Company expects to have two potential near-term BLA submissions in China (potentially 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.

(1) Progress on the five prioritized clinical assets:

Eftansomatropin alfa (Phase 3 data readout expected in 2H 2023 followed by BLA submission):

Phase 3 trial for pediatric growth hormone deficiency (PGHD): This Phase 3 registrational trial (TALLER) of eftansomatropin alfa as a weekly treatment for PGHD is ongoing in China. On May 31, 2022, the Company announced the completion of patient enrollment in the TALLER study for the treatment of PGHD. TALLER is a multi-center, randomized, open-label, active-controlled Phase 3 clinical study (NCT04633057) of 168 patients in China. The study aims to evaluate the efficacy, safety, and pharmacokinetics (PK) of eftansomatropin alfa in PGHD, as compared to Norditropin®, a daily rhGH marketed in China. The study is on track, and the final dataset is anticipated in the second half of 2023, which is expected to be followed by a BLA submission by the end of 2023 or early 2024.

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Commercialization plan for eftansomatropin alfa: In November 2021, the Company announced a strategic commercial partnership with Jumpcan, a leading domestic pharmaceutical company specializing in pediatric medicines, to accelerate the commercialization of eftansomatropin alfa. I-Mab will be the marketing authorization holder (MAH) of the product and supply the product at an agreed cost rate to Jumpcan. Jumpcan will be responsible for commercializing the product and developing new indications in collaboration with I-Mab in mainland China. Jumpcan has made an upfront payment of RMB224 million (US\$32.5 million) to I-Mab. Moreover, upon the achievement of certain development, registration, and sales milestones, I-Mab will be eligible to receive milestone payments in aggregate of up to RMB 1.792 billion (US\$259.8 million). 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 I-Mab 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.

Jumpcan and I-Mab have been working together to prepare for the future product launch of eftansomatropin alfa in China.

Felzartamab (Phase 3 ongoing):

Third-line multiple myeloma (MM): The pivotal trial has been completed, and the topline data met the preset primary and secondary endpoints. The clinical data confirmed the clinical advantages of felzartamab in terms of lower infusion-related reaction rate and shorter infusion time, which has made it feasible and practical for its use in an outpatient clinic setting.

China phase 3 trial as a second-line treatment for MM: Patient enrollment for a randomized, open-label, parallel-controlled Phase 3 registrational trial of felzartamab in combination with lenalidomide and dexamethasone as a second-line treatment for MM was completed in September 2021. The study is on track.

BLA submission, local manufacturing and commercialization: The Company is focusing on a local manufacturing plan to support felzartamab's BLA submission in positioning felzartamab as the first locally manufactured CD38 antibody for the Chinese market, which could lead to increased affordability and commercial competitiveness. In parallel, the Company is exploring a potential commercial partnership for felzartamab, with the goal of enabling the Company to quickly gain and scale up market share for felzartamab without investing significant resources in its own commercialization capabilities.

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Lemzoparlimab (Phase 3, potential first-in-class in China):

Lemzoparlimab in combination with azacitidine (AZA) for MDS: In September 2022, the Company announced encouraging data from its Phase 2 trial (NCT04202003) of Lemzoparlimab in combination with AZA in patients with newly diagnosed higher-risk myelodysplastic syndrome (HR-MDS), presented in a selected oral presentation at the 2022 European Society for Medical Oncology (ESMO). Topline data of 53 patients enrolled as of March 31, 2022, showed that for patients who began treatments six months or longer prior to the analysis, the overall response rate (ORR) and complete response rate (CRR) were 86.7% and 40.0%, respectively. It should be noted that this study enrolled more patients with worse baseline conditions than the comparable clinical trials conducted in western countries due to the underlying disease that is heavily influenced by clinical practice in China. In this group, 74% of patients had grade ≥ 3 anemia, and 51% of patients had grade ≥ 3 thrombocytopenia at baseline. The overall 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 on the study have demonstrated consistent clinical efficacy including ORR and CRR with no new safety signals identified. The Company plans to present the updated data at a major scientific meeting in 2H 2023.

Phase 3 clinical trial of lemzoparlimab in combination with AZA as a 1L treatment for HR-MDS: In September 2022, the Company obtained approval from the Center for Drug Evaluation (CDE) to initiate a Phase 3 registrational trial evaluating lemzoparlimab in combination with AZA as a first-line treatment for patients with newly diagnosed HR-MDS. This is the first approved Phase 3 trial for anti-CD47 therapies in China. With this, the Company aims to develop lemzoparlimab as a potential first-in-class product in China.

Other ongoing clinical trials: the Company continues to evaluate lemzoparlimab in combination with rituximab for non-Hodgkin's lymphoma and lemzoparlimab in combination with PD-1 therapy for selected advanced solid tumors.

Update on AbbVie partnership: In August 2022, I-Mab and AbbVie entered into an amendment to the original license and collaboration agreement dated September 3, 2020 (as amended, the "Agreement"). The parties are collaborating on the global development of anti-CD47 antibody therapy under the Agreement. According to the Agreement, the Company will be eligible to receive certain milestone payments and tiered royalties upon the accomplishments of the conditions set forth therein (Form [6-K](#) filed on August 16, 2022¹). The Company 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. This discontinuation was not related to any specific or unexpected safety concerns.

Details of the financial implication of this amendment are discussed below in the section titled "Full-Year 2022 Financial Results".

¹ https://www.sec.gov/Archives/edgar/data/1778016/000110465922091739/tm2223576d1_6k.htm

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Uliledlimab (Currently end of Phase 2, a biomarker-guided pivotal study planned in 2H 2023):

Phase 2 study of uliledlimab in combination with toripalimab (PD-1 inhibitor) in Stage 4 NSCLC: The Company presented the preliminary results of a Phase 2 study of uliledlimab in combination with toripalimab (TUYOYI[®]) in patients with Stage 4 NSCLC who were previously ineligible for standard-of-care treatment at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting. The results were largely consistent with those observed in the Phase 1 clinical trial with regard to the favorable safety, pharmacokinetics (PK), and pharmacodynamic (PD) profile of uliledlimab. Uliledlimab 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). In addition, uliledlimab exhibited a linear PK profile at doses \geq 5mg/kg and a dose-dependent receptor occupancy with no “hook effect” whereby the antibody loses its effectiveness at high concentrations.

As of December 2022, 70 patients had been enrolled in the same Phase 2 study of uliledlimab and PD-1 combination therapy in Stage 4 NSCLC patients. In summary, at the time of the first data cutoff in March 2022, ORR was 26%, and the DCR was 74% for the 19 evaluable patients. Approximately 80% of the 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 anti-PD-1 monotherapy as demonstrated in KEYNOTE-042 (ORR=16.9% for patients with PD-L1 TPS 1-49%). Remarkably, in patients with high CD73 expression (\geq 35% expression level in tumor cells or immune cells), a much higher ORR was observed with 57% ORR and 100% DCR. Similar efficacy data in relation to CD73 expression were obtained in August 2022 with 32 evaluable patients and December 2022 with 45 evaluable patients, showing a consistent trend of efficacy signals with an overall ORR $>$ 30% in all patients and an ORR \sim 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 uliledlimab and PD-1 combination therapy correlates with high tumor CD73 expression in patients with advanced NSCLC.

The current status of the Phase 2 clinical trial and clinical development plans: (1) The enrollment of 70 patients with advanced NSCLC was completed in December 2022. Data readout for ORR is expected in 1H 2023 and for PFS in 2H 2023. The Company plans to present the data at a major scientific venue in 2023. (2) With the new data, the Company has been discussing with potential global partners and aims to accelerate the ongoing business discussion for a potential global partnership in sync with the planned global study. (3) Further clinical development plan is being finalized to include (a) a biomarker-guided pivotal trial of uliledlimab in combination with a PD-1 therapy in Stage IV NSCLC in 2H 2023 in China, and (b) a global study of uliledlimab in combination with a PD-1 therapy and chemo regimen in advanced NSCLC. (4) A companion diagnostic kit is being developed with Wuxi Diagnostics and is on track for the planned studies.

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Givastomig (Phase 1, FDA Orphan Drug Designation for the treatment of gastric cancer):

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 models. This feature makes givastomig unique among the CLDN18.2-targeted agents, including ADC and zolbetuximab (a CLDN18.2 monoclonal antibody), 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. The preliminary clinical data described below are consistent with the differentiation of givastomig.

Phase 1 trial of givastomig in patients with advanced or metastatic solid tumors: The dose escalation part of the study reached 15 mg/kg without encountering DLT. By the end of 2022, 8 dose cohorts had been studied, with 38 subjects dosed. Givastomig was well tolerated and most of the TRAEs were grade 1 or 2. No severe hepatic and gastrointestinal toxicities or signs of systemic cytokine release. No DLTs were reported. There is a dose-dependent increase of drug exposure and soluble 4-1BB in serum, indicating a favorable PK/PD profile and potentially a longer dosing interval given its ability to induce durable T cell activation. Partial response (PR) and stable disease (SD) signals of givastomig monotherapy were observed across different dose levels in gastric cancer patients who failed multiple lines of prior therapies, including PD-1 therapy. Of note, efficacy signals were also observed in patients with low CLDN18.2 expression, suggestive of 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 2H 2023.

Clinical development plans: (1) The clinical development plan (including the next Phase 2 study) is being finalized to initiate in 2H 2023. (2) The Company is developing a CLDN18.2 IHC assay for patient selection to be used in future clinical studies. (3) The Company continues to explore potential global partnership opportunities for this asset.

(2) Other active clinical assets

TJ-L14B (Phase 1):

TJ-L14B, also known as ABL503, is another 4-1BB-based bi-specific antibody targeting both PD-L1 and 4-1BB and is being developed in collaboration with ABL Bio. Similar to givastomig, TJ-L14B is designed to induce conditional activation of 4-1BB when it binds to its target PD-L1 expressed on tumor cells, leading to the localized T cell activation at the tumor site and minimized systemic side effects such as liver toxicity and cytokine release. Additionally, with the advantage of maximizing T cell activation by simultaneously turning off the PD-1/PD-L1 co-inhibitory pathway and turning on the 4-1BB co-stimulatory pathway, TJ-L14B has the potential to overcome resistance to PD-(L)1 therapy as demonstrated in pre-clinical models, which may bring additional clinical benefits to patients who are resistant or refractory to standard PD-(L)1 therapy.

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Phase 1 dose-escalation and dose-expansion trial: The trial is ongoing in cancer 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. Early clinical efficacy signals were observed. The dose expansion part of TJ-L14B will be initiated in 2H 2023, both in the U.S. and South Korea.

Efineptakin alfa (Phase 2):

Phase 2 Clinical Trial of efineptakin alfa (also known as TJ107) 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).

Clinical data published by Genexine/NeoImmuneTech: (1) Data from phase 1b/2 Keynote-899 study, presented at ASCO 2022, showed that the combination of efineptakin alfa with pembrolizumab (Keytruda®) induced an ORR of 15.7% (8/51) in phase 1b and 21.2% (7/33) in phase 2 study in patients with metastatic TNBC. Notably, 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 investigation of a combination regimen for patients with PD-L1 CPS ≥ 10 . (2) Recent data from an ongoing phase 1b study presented at 2022 American Society of Hematology Annual Meeting (ASH) evaluating the safety, preliminary anti-tumor activity, and T cell reconstitution with efineptakin alfa administered following Tisagenlecleucel (Kymriah), a CD19-directed CAR-T therapy in subjects with relapsed/refractory large B-cell lymphoma showed that efineptakin alfa treatment following tisagenlecleucel was safe and well-tolerated with no induction of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS). In addition, a single dose of efineptakin alfa was shown to increase the absolute numbers of lymphocytes and CD19 CAR-T cells in the peripheral blood of treated patients.

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(3) Preclinical programs

Several discovery and pre-clinical programs of bi-specific antibodies are under early development, including a Claudin6 x 4-1BB bi-specific antibody and a PD-L1 x interferon-alpha bi-specific antibody. (1) TJ-C64B is specifically designed to simultaneously target Claudin6 (CLDN6), uniquely expressed in specific cancer types, and 4-1BB expressed by T cells to mediate the T cell killing of CLDN6+ tumor cells. CLDN6 is hardly detectable in normal adult tissues offering treatment specificity for solid tumors, including ovarian cancer and NSCLC. TJ-C64B activates T cells through 4-1BB stimulation only upon CLDN6 engagement, providing a localized immune activation in tumors with expected efficacy and reduced systemic toxicity. (2) TJ-L11F is engineered as a novel PD-L1/IFN- α antibody-cytokine fusion protein and is specifically designed for the treatment of PD-1/PD-L1 resistant tumors that can potentially convert “cold” tumors to “hot” tumors to achieve superior responses to PD-(L)1 antibody monotherapy. Novel drug molecules with such a design address the current clinical challenges of a majority of cancer patients who do not respond or respond poorly to PD-1/PDL-1 therapies. TJ-L11F is an antibody prodrug in that the IFN- α 2b moiety is masked by a PEG group through a protease-cleavable linker rendering the drug inactive in the systemic circulation, thus strongly reducing systemic toxicity. Once the drug accumulates at the tumor site through PD-L1 antibody targeting, the linker is cleaved by proteases that are uniquely expressed in the tumor environment to achieve localized activation. Other discovery and clinical programs are ongoing at an early development stage.

The Company’s Responses to Recent Challenges and Risks

Reduction of Costs and Cash Burn Rate: In 2022, the Company faced volatile market conditions and macroeconomic headwinds globally, including China, prompting the Company to re-position its overall business and preserve cash. The Company took a series of coordinated measures to respond to the challenges through (a) pipeline prioritization to focus only on five key clinical assets; (b) streamlining of the workforce and corporate structure; and (c) reduction in operating costs, capital expenditures and other expenses. As a result, the Company significantly reduced its headcount as compared to that as of December 2021 and reduced its yearly gross cash burn rate by 20% (constant rate) at the end of 2022. The Company now maintains a lean and efficient global R&D organization with an extended cash runway for at least three years.

Mitigating Potential Challenges from the Holding Foreign Companies Accountable Act (HFCAA): I-Mab was listed as a “Commission-Identified Issuer” by the SEC in May 2022 under the HFCAA following the filing of the Company’s annual report on Form 20-F for the fiscal year 2021. On December 15, 2022, the U.S. Public Company Accounting Oversight Board (PCAOB) issued a report that vacated its previous determination and secured complete access to inspect or investigate registered public accounting firms headquartered in mainland China and Hong Kong. For this reason, the Company does not expect to be identified as a Commission-Identified Issuer under the HFCAA after it files its annual report on Form 20-F for the fiscal year 2022. Each year, the PCAOB will determine whether it can fully inspect and investigate auditing firms in mainland China and Hong Kong, among other jurisdictions. Nevertheless, the Company has put in place a contingency plan for an expedient change of its auditor to a U.S.-based public accounting firm as the Company sees fit.

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I-Mab’s Strong Commitment to Environmental, Social, and Governance (ESG)

As an integral part of the Company’s business and as a core value, I-Mab strives to make a positive impact around the world through the transformational medicines that it develops, manufactures, and delivers. I-Mab is committed to reflecting ethical, social, and environmental responsibilities in its business decisions, ensuring that the Company’s products improve people’s lives and maintaining the sustainability of its business.

In August 2021, I-Mab established an ESG committee to supervise its ESG strategies, policies, long-term sustainability objectives, and risks of the Company. In February 2023, I-Mab was granted an “A” rating by MSCI (Morgan Stanley Capital International) ESG following MSCI ESG’s most recent annual review. I-Mab’s commitment to ESG can be summarized into three “P”s: patients, philanthropy, and people.

Patients: Since its inception, I-Mab has 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. I-Mab has built an innovative and advanced pipeline of over ten highly differentiated, novel biologics with the potential to address the significant unmet medical needs in cancer.

According to GLOBOCAN 2020, there were approximately 19.29 million new cancer cases worldwide in 2020, in which China had the highest number of new cases (4.57 million), exceeding all other countries. In fact, one out of every three patients who die from cancer in the world is from China. I-Mab is committed to addressing this significant global disease burden and addressing the unmet needs of patients through innovative treatment paradigms.

As soon as COVID-19 broke out in 2020, I-Mab set up an emergency response plan by coordinating with local warehouses, logistics vendors, and CROs and designing a direct-to-patient plan to ensure that our medicines were delivered to patients on time amid lockdowns. In order to allow patients to continue to receive medication without interruption, the clinical operation team actively communicated with pharmacies, cold chain logistics companies, and local research centers in Shanghai and took precautions with its rich operation experience and assessment of clinical drug inventory. At the same time, the Company coordinated and arranged 14 emergency shipments. In addition, on the premise of fully protecting patients’ privacy, the Company also developed an emergency process to send drugs directly to patients from the pharmacies to ensure smooth delivery.

Philanthropy: At the peak of the COVID-19 outbreak, the Company donated personal protective equipment and funds worth a total of RMB800 thousand to support medical personnel and hospitals in Wuhan. I-Mab also donated US\$50 thousand to BayHelix, a non-profit organization focused on global life sciences and the healthcare community, to support the relief of COVID-19 in the United States.

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

People: People are the most valuable asset of I-Mab, and I-Mab is committed to creating a healthy, engaging, diversified, and inclusive environment for all staff. I-Mab is at the forefront of promoting diversity and inclusiveness in the workplace. Women account for about 71% of our employees; 59% of them hold a master’s degree or above. In 2020, I-Mab launched the Women’s Leadership Council (“WLC”) globally to support the Company’s future female leaders to accelerate their career and personal development. In 2021 and 2022, I-Mab was selected for inclusion in the Asia Pacific Diversity, Equity, and Inclusivity Best Practice Guide for two consecutive years. In 2022, in response to the COVID-19 pandemic, I-Mab set up an emergency task force to deliver food supplies to employees in areas experiencing prolonged home quarantine. These packages included daily necessities and anti-pandemic gift packs to support employees and their families affected by the pandemic in Shanghai. I-Mab also organized a series of virtual town halls, virtual birthday parties, and mental well-being lectures to connect employees and help relieve their stress during the lockdown.

Corporate Development

- The Company and its senior management demonstrated full confidence in the Company’s fundamentals by implementing share purchase plans:

The Company announced on August 23, 2022, that it plans to implement share repurchases pursuant to the share repurchase program previously authorized by its board of directors. On the same day, the Company was informed by Dr. Jingwu Zang, Founder and Chairman of the Company, and other members of senior management of their intention to use personal funds to purchase the Company’s American Depositary Shares (the “ADSs”) on the open market. 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 718,496 of our ADSs in an aggregate amount of approximately US\$3 million under the authorized share purchase program.

- The Company invested in I-Mab Hangzhou in 2020 as a part of the Company’s overall and long-term strategic plan for the current and future manufacturing demand at both clinical trial material and commercial production scales. In July 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 the occurrence of certain triggering events, as specified in the shareholders’ agreement among I-Mab Hangzhou, I-Mab (through its wholly-owned subsidiary), and other domestic investors, including but not limited to I-Mab Hangzhou’s failure to accomplish certain public offering conditions, I-Mab may be obligated to repurchase the equity held by other domestic investors in cash or in I-Mab’s stocks within a certain time period.

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As previously disclosed, the Company is involved in an arbitration proceeding with Tracon Pharmaceuticals. The Company currently expects that the outcome of the arbitration may be available in 2Q 2023.

Full-Year 2022 Financial Results

Cash Position

As of December 31, 2022, the Company 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. I-Mab's strong cash balance is estimated to provide the Company with adequate funding to support its key business operations for over three years.

Net Revenues

Total net revenue for the full year of 2022 were RMB-221.6 million (US\$-32.1 million), compared with RMB88.0 million for the full year of 2021. The decrease in 2022 net revenue was primarily due to a one-off non-cash accounting treatment of US\$-48.0 million (equivalent to RMB-314.2 million) recorded in 2H 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 consideration of revenue recognition in prior years. As of December 31, 2020 and 2021, the Company noted that the achievement of the key milestone was probable based on the clinical progress. The decrease was partially offset by revenue of RMB92.6 million from license and collaboration arrangements and the supply of investigational products.

Research & Development Expenses

Research and development expenses for the full year of 2022 were RMB904.9 million (US\$131.2 million), compared with RMB1,213.0 million for the full year of 2021. The decrease was primarily due to the reduced demand for investigational products as the Company procured sufficient stock in 2021 and lower share-based compensation expenses. Share-based compensation expense was RMB117.9 million (US\$17.1 million) for the full year of 2022, compared with RMB201.9 million for the full year of 2021.

Administrative Expenses

Administrative expenses for the full year of 2022 were RMB720.3 million (US\$104.4 million), compared with RMB899.9 million for the full year of 2021. The decrease was primarily due to lower share-based compensation expenses in relation to the management personnel and optimized control of operating and administrative expenses. Share-based compensation expense was RMB239.3 million (US\$34.7 million) for the full year of 2022, compared with RMB406.7 million for the full year of 2021.

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Other Income (Expenses), Net

Net other expenses for the full year of 2022 were RMB126.6 million (US\$18.4 million), compared with net other income of RMB83.2 million for the full year of 2021. The change was primarily caused by unrealized exchange losses due to the significant fluctuation in the exchange rate of the Renminbi against the U.S. dollars in 2022.

Equity in Loss of Affiliates

Equity in loss of affiliates for the full year of 2022 was RMB437.5 million (US\$63.4 million), compared with RMB367.9 million for the full year of 2021. The change was primarily due to the increased expenditure of the Company's investee, I-Mab Hangzhou.

Net Loss

Net loss for the full year of 2022 was RMB2,411.8 million (US\$349.7 million), compared with RMB2,331.5 million for the year 2021. Net loss per share attributable to ordinary shareholders for the full year of 2022 was RMB12.71 (US\$1.84), compared with RMB13.35 for the full year of 2021. Net loss per ADS attributable to ordinary shareholders for the full year of 2022 was RMB29.23 (US\$4.24), compared with RMB30.71 for the full year of 2021.

Non-GAAP Net Loss

Non-GAAP adjusted net loss, which excludes share-based compensation expenses, for the full year of 2022, was RMB2,040.8 million (US\$295.9 million), compared with RMB1,709.7 million for the full year of 2021. Non-GAAP adjusted net loss per share attributable to ordinary shareholders for the full year of 2022 was RMB10.75 (US\$1.56), compared with RMB9.79 for the full year of 2021. Non-GAAP adjusted net loss per ADS attributable to ordinary shareholders for the full year of 2022 was RMB24.73 (US\$3.58), compared with RMB22.52 for the full year of 2021.

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About I-Mab

I-Mab (Nasdaq: IMAB) is a dynamic, global biotech company exclusively focused on discovery, development and soon, commercialization of novel or highly differentiated biologics in the therapeutic areas of immuno-oncology and autoimmune diseases. The Company's mission is to bring transformational medicines to patients around the world through innovation. I-Mab's innovative pipeline of more than 10 clinical and pre-clinical stage drug candidates is driven by the Company's Fast-to-Proof-of-Concept and Fast-to-Market development strategies through internal R&D and global partnerships and commercial partnerships. I-Mab has established its global footprint in Shanghai, Beijing, Hangzhou, Guangzhou, Lishui and Hong Kong in China, and Maryland and San Diego in the United States. For more information, please visit <http://www.i-mabbiopharma.com> and follow I-Mab on LinkedIn, Twitter, and WeChat.

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I-Mab Forward Looking Statements

This announcement contains forward-looking statements. These statements are made under the “safe harbor” provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements can be identified by terminology such as “will,” “expects,” “anticipates,” “future,” “intends,” “plans,” “believes,” “estimates,” “confident” and similar statements. I-Mab may also make written or oral forward-looking statements in its periodic reports to the U.S. Securities and Exchange Commission (the “SEC”), in its annual report to shareholders, in press releases and other written materials and in oral statements made by its officers, directors or employees to third parties. Statements that are not historical facts, including statements about I-Mab’s beliefs and expectations, are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties. A number of factors could cause actual results to differ materially from those contained in any forward-looking statement, including but not limited to the following: I-Mab’s ability to demonstrate the safety and efficacy of its drug candidates; the clinical results for its drug candidates, which may not support further development or NDA/BLA approval; the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approval of I-Mab’s drug candidates; I-Mab’s ability to achieve commercial success for its drug candidates, if approved; I-Mab’s ability to obtain and maintain protection of intellectual property for its technology and drugs; I-Mab’s reliance on third parties to conduct drug development, manufacturing and other services; I-Mab’s limited operating history and I-Mab’s ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; and the impact of the COVID-19 pandemic on the Company’s clinical developments, commercial and other operations, as well as those risks more fully discussed in the “Risk Factors” section in I-Mab’s most recent annual report on Form 20-F, as well as discussions of potential risks, uncertainties, and other important factors in I-Mab’s subsequent filings with the SEC. All forward-looking statements are based on information currently available to I-Mab, and I-Mab undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

Use of Non-GAAP Financial Measures

To supplement its consolidated financial statements which are presented in accordance with U.S. GAAP, the Company uses adjusted net income (loss) as a non-GAAP financial measure. Adjusted net income (loss) represents net income (loss) before share-based compensation. The Company’s management believes that adjusted net income (loss) facilitates understanding of operating results and provide management with a better capability to plan and forecast future periods. For more information on the non-GAAP financial measures, please see the table captioned “Reconciliation of GAAP and Non-GAAP Results” set forth at the end of this press release.

Non-GAAP information is not prepared in accordance with GAAP and may be different from non-GAAP methods of accounting and reporting used by other companies. The presentation of this additional information should not be considered a substitute for GAAP results. A limitation of using adjusted net income (loss) is that adjusted net income (loss) excludes share-based compensation expense that has been and may continue to be incurred in the future.

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Exchange Rate Information

This announcement contains translations of certain RMB amounts into U.S. dollars at a specified rate solely for the convenience of the reader. Unless otherwise noted, all translations from Renminbi to U.S. dollars are made at a rate of RMB6.8972 to US\$1.00, the rate in effect as of December 30, 2022 published by the Federal Reserve Board.

For more information, please contact:

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I-MAB
Consolidated Balance Sheets
(All amounts in thousands, except for share and per share data, unless otherwise noted)

	As of December 31,		
	2021	2022	
	RMB	RMB	US\$
Assets			
Current assets			
Cash and cash equivalents	3,523,632	3,214,005	465,987
Restricted cash	-	96,764	14,029
Accounts receivable	33,081	-	-
Contract assets	253,780	-	-
Short-term investments	753,164	235,429	34,134
Inventories	27,237	-	-
Prepayments and other receivables	190,824	80,278	11,639
Total current assets	4,781,718	3,626,476	525,789
Property, equipment and software	45,716	60,841	8,821
Operating lease right-of-use assets	112,781	63,125	9,152
Intangible assets	119,666	118,888	17,237
Goodwill	162,574	162,574	23,571
Investments accounted for using the equity method	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	-	18,956	2,748
Accruals and other payables	593,335	608,148	88,173
Operating lease liabilities, current	30,669	23,961	3,474
Contract liabilities	-	8,677	1,258
Total current liabilities	624,004	659,742	95,653
Put right liabilities	96,911	88,687	12,858
Contract liabilities	224,000	267,878	38,839
Operating lease liabilities, non-current	81,786	32,069	4,650
Other non-current liabilities	14,934	16,963	2,459
Total liabilities	1,041,635	1,065,339	154,459
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)	126	132	19
Treasury stock	-	(21,249)	(3,081)
Additional paid-in capital	9,100,777	9,579,375	1,388,879
Accumulated other comprehensive income (loss)	(186,510)	216,723	31,422
Accumulated deficit	(4,354,833)	(6,766,655)	(981,073)
Total shareholders' equity	4,559,560	3,008,326	436,166
Total liabilities and shareholders' equity	5,601,195	4,073,665	590,625

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I-MAB
Consolidated Statements of Comprehensive Income (Loss)
(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\$
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 (Note 1)	(984,689)	(1,212,958)	(904,901)	(131,198)
Administrative expenses (Note 2)	(402,409)	(899,943)	(720,271)	(104,429)
Income (loss) from operations	155,570	(2,071,307)	(1,873,972)	(271,700)
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 (Note 3)	(108,587)	(367,883)	(437,465)	(63,426)
Income (loss) before income tax expense	483,146	(2,334,695)	(2,411,125)	(349,579)
Income tax benefit (expense)	(12,231)	3,154	(697)	(101)
Net income (loss) attributable to I-MAB	470,915	(2,331,541)	(2,411,822)	(349,680)
Net income (loss) attributable to ordinary shareholders	470,915	(2,331,541)	(2,411,822)	(349,680)
Net income (loss) attributable to I-MAB	470,915	(2,331,541)	(2,411,822)	(349,680)
Other comprehensive income (loss):				
Foreign currency translation adjustments, net of nil tax	(120,920)	(135,717)	403,233	58,463
Total comprehensive income (loss) attributable to I-MAB	349,995	(2,467,258)	(2,008,589)	(291,217)

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I-MAB
Consolidated Statements of Comprehensive Income (Loss) (Continued)
 (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\$
Net income (loss) attributable to ordinary shareholders	470,915	(2,331,541)	(2,411,822)	(349,680)
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
Weighted-average number of ordinary shares used in calculating net income (loss) per share - diluted	157,231,652	174,707,055	189,787,292	189,787,292
Net income (loss) per share attributable to ordinary shareholders				
—Basic	3.51	(13.35)	(12.71)	(1.84)
—Diluted	3.00	(13.35)	(12.71)	(1.84)
Net income (loss) per ADS attributable to ordinary shareholders (Note 4)				
—Basic	8.07	(30.71)	(29.23)	(4.24)
—Diluted	6.90	(30.71)	(29.23)	(4.24)

Note:

(1) Includes share-based compensation expense of RMB201,926 thousand and RMB117,876 thousand (US\$17,090 thousand) for the years ended December 31, 2021 and 2022, respectively.

(2) Includes share-based compensation expense of RMB406,683 thousand and RMB239,272 thousand (US\$34,691 thousand) for the years ended December 31, 2021 and 2022, respectively.

(3) Includes share-based compensation expense of RMB13,267 thousand and RMB13,852 thousand (US\$2,008 thousand) for the years ended December 31, 2021 and 2022, respectively.

(4) Each ten ADSs represents twenty-three ordinary shares.

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I-MAB
Reconciliation of GAAP and Non-GAAP Results

	Year ended December 31,			
	2020	2021	2022	
	RMB	RMB	RMB	US\$
GAAP net income (loss) attributable to I-MAB	470,915	(2,331,541)	(2,411,822)	(349,680)
Add back:				
Share-based compensation expense	526,171	621,876	371,000	53,789
Non-GAAP adjusted net income (loss) attributable to I-MAB	997,086	(1,709,665)	(2,040,822)	(295,891)
Non-GAAP adjusted income (loss) attributable to ordinary shareholders	997,086	(1,709,665)	(2,040,822)	(295,891)
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
Weighted-average number of ordinary shares used in calculating net income (loss) per share - diluted	157,231,652	174,707,055	189,787,292	189,787,292
Non-GAAP adjusted income (loss) per share attributable to ordinary shareholders				
—Basic	7.43	(9.79)	(10.75)	(1.56)
—Diluted	6.34	(9.79)	(10.75)	(1.56)
Non-GAAP adjusted income (loss) per ADS attributable to ordinary shareholders				
—Basic	17.09	(22.52)	(24.73)	(3.58)
—Diluted	14.58	(22.52)	(24.73)	(3.58)

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