



I-Mab Reports Full Year 2023 Financial Results and Business Update

3月 14, 2024

- Recently announced agreement to divest assets and business operations in China marks an important milestone for the Company; the transaction is expected to close by the end of March 2024
- Uliledlimab (CD73 antibody) on track to file an IND in combination with chemotherapy and checkpoint inhibitors for patients with newly diagnosed NSCLC in 1H 2024
- First patient dosed in an ongoing, triplet combination, dose escalation study of givastomig (CLDN18.2x4-1BB bispecific antibody) in 1Q 2024
- RMB2.3 billion (US\$321.8 million) in cash and cash equivalents, and short-term investments as of December 31, 2023

ROCKVILLE, Md., March 14, 2024 /PRNewswire/ -- I-Mab (the "Company") (NASDAQ: IMAB), a U.S.-based, global biotech company, exclusively focused on the development and potential commercialization of highly differentiated immunotherapies for the treatment of cancer, today announced financial results for the full year ended December 31, 2023, and highlighted recent business updates.

"2023 was a transitional year for I-Mab and we were pleased to report encouraging clinical results in our two lead global assets in oncology, uliledlimab and givastomig. As we prepare for the closing of the strategic divestiture, we look forward to providing investors with a road map to value creation and believe that our differentiated clinical assets, uliledlimab, givastomig, and ragistomig will achieve critical milestones and trial initiations this year," said Raj Kannan, Director and Chief Executive Officer of I-Mab.

Pipeline Overview and Upcoming Milestones:

Uliledlimab: Phase 2, with a focus on non-small cell lung cancer (NSCLC)

Uliledlimab is designed to target CD73 and promote stronger activation of the patient's immune system against cancer cells. Uliledlimab is potentially differentiated from other products in development due to its non-competitive binding with adenosine monophosphate and the potential for complete inhibition of CD73's immune dampening function. Encouraging results from a Phase 2 study of uliledlimab in combination with toripalimab, presented at the American Society for Clinical Oncology (ASCO 2023) in patients with advanced NSCLC, provided compelling support for further development of uliledlimab. In particular, the subset of patients with both high CD73 expression and PD-L1 TPS \geq 1% showed an impressive 63% overall response rate. Additionally, enrollment of patients with treatment resistant ovarian cancer has been completed, and ongoing efforts will be streamlined to focus on expediting NSCLC development.

- Upon the receipt of the investigational new drug (IND) approval, the Company plans to initiate the triplet study for uliledlimab in combination with chemotherapy and checkpoint inhibitors in newly diagnosed patients with advanced NSCLC in the second half of 2024.

Givastomig (Claudin 18.2 x 4-1BB bispecific antibody): Phase 1b, with a focus on gastric cancer and esophageal adenocarcinoma

Givastomig was designed as a bispecific antibody to target Claudin 18.2-positive tumor cells, with conditional activation of pro-immune 4-1BB in the tumor microenvironment. Phase 1 monotherapy data presented at the European Society of Medical Oncology (ESMO 2023) showed encouraging objective responses in patients with gastric cancer and esophageal adenocarcinoma whose tumors progressed or recurred after prior standard treatments, including those with low levels of Claudin 18.2 expression. This program is being jointly developed with ABL Bio. I-Mab owns 50% of the global rights of givastomig.

- The enrollment of patients from the U.S. and China with newly diagnosed (frontline treatment) gastric and esophageal cancer in combination with chemotherapy and a checkpoint inhibitor began in the first quarter of 2024.

Ragistomig (PD-L1 x 4-1BB bispecific antibody): Phase 1 dose escalation, with a focus on solid tumors

Ragistomig was designed as a bispecific antibody to address PD-L1 resistant tumors, differentiated by the conditional activation of 4-1BB's pro-immune stimulation when it binds to its PD-L1 target. Early observations reported by our development partner, ABL Bio, showed promising objective responses in patients with various solid tumors whose tumors progressed or recurred after prior standard treatments, including in patients with relapsed or refractory cancer after prior PD-L1 inhibitors. These early signs of efficacy are encouraging, and enrollment in the Phase 1 study continues. This program is being jointly developed with ABL Bio. I-Mab owns 50% of the global rights of ragistomig (TJ-L14B/ABL503).

- Top-line Phase 1 dose escalation and dose expansion results are expected to be presented at a major medical conference in the first half of 2024.

Impact of Strategic Transaction on Pipeline

The agreement to divest assets and business operations in China, previously announced in a press release on February 7, 2024, is expected to be completed by the end of March 2024. Upon the closing of the transaction, the Greater China rights for assets including eftansomatropin alfa, felzartamab, uliledlimab, and givastomig will be transferred to I-Mab Biopharma (Hangzhou) Co., Ltd., an unconsolidated affiliate (the "**Hangzhou Company**"). I-Mab will no longer bear future development costs of these divested assets in China and may receive an aggregate consideration of the RMB equivalent of up to US\$80 million, contingent on the Hangzhou Company group's achievement of certain future regulatory and sales-based milestone events relating to these divested assets in China. The transaction, if closed, will also extinguish existing repurchase obligations owed by a wholly-owned subsidiary of the Company in the amount of approximately US\$183 million.

As a result of the closing of the transaction, the Company will cease consolidation of the divested entities, assets, and businesses as well as their corresponding financial results. The Company's financial condition and results of operations will be materially affected and the Company's historical results will not be indicative of future financial condition or results of operations.

Full-Year 2023 Financial Results

Cash Position

As of December 31, 2023, the Company had cash, cash equivalents, and short-term investments of RMB2.3 billion (US\$321.8 million), compared with RMB3.5 billion as of December 31, 2022.

Share Buyback

In August 2023, the Board of Directors of the Company authorized a new share repurchase program under which the Company may repurchase up to US\$40 million of American Depositary Shares ("ADSs"), each ten ADSs representing 23 ordinary shares of the Company, or ordinary shares in aggregate over a 12-month period. During the period ended December 31, 2023, the Company repurchased US\$8.6 million of its ADSs, equating to 4,633,386 ADSs or 10,656,794 ordinary shares. As of December 31, 2023, the Company had issued and outstanding ordinary shares of 185,613,662, representing the equivalent of 80,701,592 ADSs assuming the conversion of all ordinary shares into ADSs.

Net Revenues

Total net revenues for the full year of 2023 were RMB27.6 million (US\$3.9 million), compared with RMB221.6 million (US\$32.1 million) for the full year of 2022. Total net revenues in 2023 consisted of revenues recognized in connection with the strategic collaboration with AbbVie Inc. (AbbVie) and revenues generated from the supply of investigational products to AbbVie and Human Immunology Biosciences, Inc. The negative figure for net revenue in 2022 was primarily due to a one-time, non-cash accounting treatment of US\$48.0 million (equivalent to RMB314.2 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 reduced probability of achieving a key milestone that was included in the consideration of revenue recognition in prior years.

Research & Development Expenses

Research and development expenses for the full year of 2023 were RMB810.6 million (US\$114.2 million), compared with RMB904.9 million (US\$131.2 million) for the full year of 2022. The decrease was primarily due to reduced payroll expenses related to headcount optimization as a result of asset prioritization and reduced share-based compensation expenses. Share-based compensation expense was RMB66.8 million (US\$9.4 million) for the full year of 2023, compared with RMB117.9 million (US\$17.1 million) for the full year of 2022.

Administrative Expenses

Administrative expenses for the full year of 2023 were RMB453.0 million (US\$63.8 million), compared with RMB815.8 million (US\$118.3 million) for the full year of 2022. The decrease was primarily due to reduced payroll expenses related to decreased headcount as a result of resource optimization and reduced share-based compensation expenses for management personnel, reduced expenses for professional services, and reduced legal expenses in relation to the disputes with Tracoon Pharmaceuticals, Inc. of RMB95.5 million (US\$13.5 million). Share-based compensation expense was RMB126.2 million (US\$17.8 million) for the full year of 2023, compared with RMB239.3 million (US\$34.7 million) for the full year of 2022.

Other Expenses, Net

Net other expenses for the full year of 2023 were RMB38.1 million (US\$5.4 million), compared with RMB126.6 million (US\$18.4 million) for the full year of 2022. The change was primarily driven by unrealized exchange rate losses due to the significant fluctuation in the exchange rate of the Renminbi against the U.S. dollar in 2022.

Equity in Loss of Affiliates

Equity in loss of affiliates for the full year of 2023 was RMB80.0 million (US\$11.3 million), compared with RMB437.5 million (US\$63.4 million) for the full year of 2022. The loss was mainly recognized in relation to the operating loss of the Company's investee, I-Mab Biopharma (Hangzhou) Co., Ltd.

Impairment of Goodwill

For the full year of 2023, the Company recognized an impairment of goodwill of RMB162.6 million (US\$22.9 million). The goodwill impairment resulted from the Company's annual impairment analysis, and reflects the continued disconnect between I-Mab's anticipated future performance and present uncertainty reflected in its market valuation.

Net Loss

Net loss for the full year of 2023 was RMB1,465.7 million (US\$206.4 million), compared with RMB2,507.3 million (US\$363.5 million) for the year 2022.

Net loss per share attributable to ordinary shareholders for the full year of 2023 was RMB7.19 (US\$1.01), compared with RMB13.21 (US\$1.92) for the full year of 2022. Net loss per ADS attributable to ordinary shareholders for the full year of 2023 was RMB16.54 (US\$2.33), compared with RMB30.38 (US\$4.41) for the full year of 2022.

Non-GAAP Net Loss

Non-GAAP adjusted net loss, which excludes share-based compensation expenses and impairment of goodwill, for the full year of 2023 was RMB1,105.3 million (US\$155.7 million), compared with RMB2,136.3 million (US\$309.7 million) for the full year of 2022. Non-GAAP adjusted net loss per share attributable to ordinary shareholders for the full year of 2023 was RMB5.42 (US\$0.76), compared with RMB11.26 (US\$1.63) for the full year of 2022. Non-GAAP adjusted net loss per ADS attributable to ordinary shareholders for the full year of 2023 was RMB12.47 (US\$1.76), compared with RMB25.90 (US\$3.75) for the full year of 2022.

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 and impairment of goodwill. The Company's management believes that adjusted net income (loss) facilitates understanding of operating results and provides 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 and impairment of goodwill that has been and may continue to be incurred in the future.

Exchange Rate Information

This announcement contains translations of certain Renminbi 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 of the financial results for the year of 2023 are made at a rate of RMB7.0999 to US\$1.00, the rate in effect as of December 29, 2023, published by the Federal Reserve Board. All translations from Renminbi to U.S. dollars of the financial results for the year of 2022 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.

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Consolidated Balance Sheets

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

	As of December 31, 2022		As of December 31, 2023	
	RMB	US\$	RMB	US\$
	(Unaudited)		(Unaudited)	
Assets				
Current assets				
Cash and cash equivalents	3,214,005	465,987	2,141,445	301,616
Short-term restricted cash	96,764	14,029	-	-
Short-term investments	235,429	34,134	143,221	20,172
Prepayments and other receivables	80,278	11,639	52,003	7,325
Total current assets	3,626,476	525,789	2,336,669	329,113
Long-term restricted cash	-	-	58,913	8,298
Property, equipment and software	60,841	8,821	36,511	5,142
Operating lease right-of-use assets	63,125	9,152	46,400	6,535
Intangible assets	118,888	17,237	118,110	16,635
Goodwill	162,574	23,571	-	-
Investments accounted for using the equity method	30,850	4,473	12,082	1,702
Other non-current assets	10,911	1,582	4,282	603
Total assets	4,073,665	590,625	2,612,967	368,028
Liabilities and shareholders' equity				
Current liabilities				
Short-term bank borrowings	18,956	2,748	29,970	4,221
Accruals and other payables	706,572	102,443	357,754	50,389
Operating lease liabilities, current	23,961	3,474	21,890	3,083
Contract liabilities, current	8,677	1,258	2,200	310
Total current liabilities	758,166	109,923	411,814	58,003

Put right liabilities	88,687	12,858	98,110	13,819
Contract liabilities, non-current	267,878	38,839	292,124	41,145
Operating lease liabilities, non-current	32,069	4,650	23,099	3,253
Other non-current liabilities	16,963	2,459	69,664	9,811
Total liabilities	1,163,763	168,729	894,811	126,031

Shareholders' equity

Ordinary shares (US\$0.0001 par value, 800,000,000 shares authorized as of December 31, 2022 and 2023; 190,879,919 and 185,613,662 shares issued and outstanding as of December 31, 2022 and 2023, respectively)	132	19	136	19
Treasury stock	(21,249)	(3,081)	(82,509)	(11,621)
Additional paid-in capital	9,579,375	1,388,879	9,830,082	1,384,538
Accumulated other comprehensive income	213,794	30,997	298,291	42,013
Accumulated deficit	(6,862,150)	(994,918)	(8,327,844)	(1,172,952)
Total shareholders' equity	2,909,902	421,896	1,718,156	241,997
Total liabilities and shareholders' equity	4,073,665	590,625	2,612,967	368,028

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Consolidated Statements of Comprehensive Loss

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

	Year Ended December 31,			
	2022		2023	
	RMB (Unaudited)	US\$	RMB (Unaudited)	US\$
Revenues				
Licensing and collaboration revenue	(249,665)	(36,198)	16,814	2,368
Supply of investigational products	28,102	4,074	10,830	1,525
Total revenues	(221,563)	(32,124)	27,644	3,893
Cost of revenues	(27,237)	(3,949)	-	-
Expenses				
Research and development expenses (Note 1)	(904,901)	(131,198)	(810,646)	(114,177)
Administrative expenses (Note 2)	(815,766)	(118,275)	(453,017)	(63,806)
Loss from operations	(1,969,467)	(285,546)	(1,236,019)	(174,090)
Interest income	26,908	3,901	51,749	7,289
Interest expense	(9)	(1)	(722)	(102)
Other expenses, net	(126,587)	(18,353)	(38,109)	(5,368)
Equity in loss of affiliates (Note 3)	(437,465)	(63,426)	(80,019)	(11,270)
Impairment of goodwill	-	-	(162,574)	(22,898)
Loss before income tax expense	(2,506,620)	(363,425)	(1,465,694)	(206,439)
Income tax expense	(697)	(101)	-	-
Net loss attributable to I-Mab	(2,507,317)	(363,526)	(1,465,694)	(206,439)
Net loss attributable to ordinary shareholders	(2,507,317)	(363,526)	(1,465,694)	(206,439)
Net loss attributable to I-Mab	(2,507,317)	(363,526)	(1,465,694)	(206,439)
Foreign currency translation adjustments, net of nil tax	400,304	58,039	84,497	11,901
Total comprehensive loss attributable to I-Mab	(2,107,013)	(305,487)	(1,381,197)	(194,538)
Net loss attributable to ordinary shareholders	(2,507,317)	(363,526)	(1,465,694)	(206,439)
Weighted-average number of ordinary shares used in calculating net loss per share – basic and diluted	189,787,292	189,787,292	203,904,346	203,904,346

Net loss per share attributable to ordinary shareholders

—Basic and diluted	(13.21)	(1.92)	(7.19)	(1.01)
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Net loss per ADS attributable to ordinary shareholders (Note 4)

—Basic and diluted	(30.38)	(4.41)	(16.54)	(2.33)
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Notes:

(1) Includes share-based compensation expense of RMB117,876 thousand (US\$17,090 thousand) and RMB66,758 thousand (US\$9,403 thousand) for the years ended December 31, 2022 and 2023, respectively.

(2) Includes share-based compensation expense of RMB239,272 thousand (US\$34,691 thousand) and RMB126,244 thousand (US\$17,781 thousand) for the years ended December 31, 2022 and 2023, respectively.

(3) Includes share-based compensation expense of RMB13,852 (US\$2,008 thousand) and RMB4,815 thousand (US\$678 thousand) for the years ended December 31, 2022 and 2023, respectively.

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

I-Mab**Reconciliation of GAAP and Non-GAAP Results**

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

	Year ended December 31,			
	2022		2023	
	RMB (Unaudited)	US\$	RMB (Unaudited)	US\$
GAAP net loss attributable to I-MAB	(2,507,317)	(363,526)	(1,465,694)	(206,439)
Add back:				
Share-based compensation expense	371,000	53,789	197,817	27,862
Impairment of goodwill	-	-	162,574	22,898
Non-GAAP adjusted net loss attributable to I-Mab	(2,136,317)	(309,737)	(1,105,303)	(155,679)
Non-GAAP adjusted loss attributable to ordinary shareholders	(2,136,317)	(309,737)	(1,105,303)	(155,679)
Weighted-average number of ordinary shares used in calculating net loss per share				
—Basic and diluted	189,787,292	189,787,292	203,904,346	203,904,346
Non-GAAP adjusted loss per share attributable to ordinary shareholders				
—Basic and diluted	(11.26)	(1.63)	(5.42)	(0.76)
Non-GAAP adjusted loss per ADS attributable to ordinary shareholders				
—Basic and diluted	(25.90)	(3.75)	(12.47)	(1.76)

About I-Mab

I-Mab (NASDAQ: IMAB) is a U.S.-based, global biotech company, exclusively focused on the development and potential commercialization of highly differentiated immunotherapies for the treatment of cancer. I-Mab has established operations in the U.S. in Rockville, Maryland, and in San Diego, California. For more information, please visit <https://www.i-mabbiopharma.com> and follow us on [LinkedIn](#), [X](#), and [WeChat](#).

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", "believes", "designed to", "anticipates", "future", "intends", "plans", "potential", "estimates", "confident", and similar terms or the negative thereof. 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 in this press release include, without limitation, statements regarding: the timing of the completion of the expected divestiture of the Company's assets and business operations in China and its anticipated impact on the Company (including the transfer of Greater China rights for assets, including eftansomatropin alfa, felzartamab, uliledlimab, and givastomig to the Hangzhou Company, the expected consideration to be received by I-Mab and the expected extinguishment of an existing repurchase obligation of US\$183 million); the Company's expectations regarding providing a road map to value creation and its belief that its clinical oncology programs will achieve critical milestones and trial initiations this year; the Company's pipeline overview and upcoming anticipated milestones, including with respect to uliledlimab, givastomig, and ragistomig, and the intended impact and the Company's plans with respect thereto. Forward-looking statements involve inherent risks and uncertainties that may cause actual results to differ materially from those contained in these forward-looking statements, 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 or may not support further development or New Drug Application/Biologics License Application (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; and 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, 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. 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.

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