I-Mab Reports Third Quarter 2024 Results

November 14, 2024

- Givastomig data presented at ESMO 2024 and SITC 2024 highlights encouraging monotherapy data
- On track to dose first patient in randomized Phase 2 study of ulilediimab in first-line mNSCLC in 1H 2025
- Appointed Dr. Sean Fu as permanent CEO effective November 1, 2024
- Estimated cash runway into 2027, based on $184.4 million in cash and cash equivalents, and short-term investments as of September 30, 2024

ROCKVILLE, Md., Nov. 14, 2024 /PRNewswire/ -- I-Mab (NASDAQ: IMAB) (the "Company"), a U.S.-based, global biotech company, exclusively focused on the development of highly differentiated immunotherapies for the treatment of cancer, today announced financial results for the three and nine months ended September 30, 2024, and highlighted recent pipeline progress and business updates.

"I-Mab is making excellent progress in advancing the development of our pipeline projects, supported by our strong cash balance, streamlined operating model, and a focused in-licensing strategy," said **Dr. Sean Fu, CEO and Board Member** of I-Mab. "In addition, Phase 1 data presented this year for ulilediimab, givastomig, and ragistomig at four international medical conferences highlight the strength of our early data sets for each program. These results have provided us with a strong foundation for advancing each molecule into expanded clinical trials, including Phase 2 studies, in the next year."

Pipeline Overview and Potential Upcoming Milestones:

Ulilediimab (CD73 antibody): Initiating a randomized Phase 2 combination study in first-line metastatic non-small cell lung cancer ("mNSCLC")

Ulilediimab (TJ004309) is an antibody designed to target CD73, the rate-limiting enzyme critical for adenosine-driven immunosuppression in the tumor microenvironment. I-Mab owns worldwide rights to ulilediimab outside of Greater China.

Pharmacokinetic/pharmacodynamic ("PK/PD") Phase 1 data presented at the 2024 World Conference on Lung Cancer ("WCLC 2024") in September showed that ulilediimab achieved full target engagement with a positive correlation between the overall response rate ("ORR") in patients with mNSCLC and ulilediimab exposure.

The Company is on track to dose the first patient in the randomized Phase 2 study in patients with first-line mNSCLC testing multiple doses of ulilediimab in combination with pembrolizumab plus chemotherapy versus standard of care in 1H 2025.

Givastomig (Claudin 18.2 x 4-1BB bispecific antibody): Ongoing Phase 1b escalation and expansion study in combination with nivolumab plus chemotherapy in first-line metastatic gastric cancer

Givastomig (TJ033721 / ABL111) is a bispecific antibody targeting Claudin 18.2 ("CLDN 18.2")-positive tumor cells that conditionally activates T cells via 4-1BB in the tumor microenvironment, with potential CLDN 18.2 specificity even in tumors with low levels of CLDN 18.2 expression. The program is being jointly developed with ABL Bio.

Topline Phase 1 monotherapy dose escalation and dose expansion data presented at the European Society for Medical Oncology ("ESMO 2024") in September 2024 showed promising objective responses in patients with gastric cancers expressing CLDN 18.2 across low and high levels and defined the optimal monotherapy dose range (8-12 mg/kg). The study showed an ORR of 16.3% (7/43), including seven partial responses ("PR") at doses between 5 mg/kg and 18 mg/kg, with five of the seven patients (71%) having received prior checkpoint inhibitor therapy. Stable disease ("SD") was reported in 14 patients, with a disease control rate ("DCR") of 48.8% (21/43 patients). The safety profile was favorable, with mainly grade 1 or 2 treatment-related adverse events ("TRAEs") and no observations of dose-limiting toxicities ("DLTs") or identification of a maximum tolerated dose ("MTD").

I-Mab presented a poster highlighting Phase 1 pharmacokinetic modeling data for optimizing dose estimation of givastomig at the Society for Immunotherapy of Cancer ("SITC 2024") on November 9, 2024, based on three clinical studies and additional nonclinical data. The studies demonstrated a dose-response relationship for givastomig and supported 8-12 mg/kg administered every two weeks ("Q2W") as the optimal monotherapy dose range for gastric cancer patients.

Topline data from the on-going Phase 1b study evaluating givastomig in combination with nivolumab plus chemotherapy are expected in 2H 2025 in patients with treatment-naïve CLDN 18.2-positive metastatic gastric cancer. The primary endpoint is safety, with secondary endpoints including tumor response, PK/PD, and survival.

Ragistomig (PD-L1 x 4-1BB bispecific antibody): Ongoing Phase 1 dose escalation and dose expansion in advanced and/or PD-L1 positive, solid tumors

Ragistomig (TJ-L14B / ABL503) is a bispecific, Fc-silent antibody designed to provide anti-PD-L1 activity and conditional 4-1BB-driven T-cell activation in one molecule. The program is being jointly developed with ABL Bio.

In October, the United States Patent and Trademark Office ("USPTO") issued a composition of matter patent for ragistomig, providing coverage through February 2039 before consideration of any potential patent term extensions.

Additional dose schedules are being explored to maximize the therapeutic index in advanced and/or PD-L1-positive solid tumors.

Significant Strategic Progress and Corporate Development

- **Appointment of Dr. Sean (Xi-Yong) Fu, PhD, MBA, as Chief Executive Officer:** Dr. Fu was appointed as the Company's permanent Chief Executive Officer ("CEO") effective November 1, 2024. Dr. Fu has served as the Company's Interim CEO since July 15, 2024. Dr. Fu will continue to serve as a member of the I-Mab Board of Directors. Dr. Fu has over 20 years of experience in the life sciences industry, leading and developing clinical-stage assets.
- **Sanofi S.A. ("Sanofi") / TJ Biopharma ("TJ Bio") agreement for uliledlimab:** On September 25, 2024, Sanofi and TJ Bio entered into a collaboration agreement to develop and commercialize uliledlimab in Greater China. The agreement includes an initial payment and near-term milestone payments totaling approximately €32 million, with the potential to receive up to €213 million in success-based milestone payments plus tiered royalties based on sales, with upside from potential expanded indications. I-Mab holds worldwide rights, excluding Greater China.
- **Settlement of remaining repurchase obligations**: I-Mab settled the remaining RMB equivalent of approximately $15 million in redemption obligations related to the divestiture of its China operations in mid-September 2024. As previously disclosed, in connection with the divestiture of I-Mab's China operations, certain non-participating shareholders of TJ Bio commenced arbitration against I-Mab Biopharma Hong Kong Limited. As reported in the Company's 1H 2024 business update, the RMB equivalent of $17.3 million related to the ongoing arbitration with certain non-participating shareholders was settled from funds previously placed into escrow, which was accounted for in prepayments and other current assets. I-Mab's ownership in TJ Bio post-settlement of the repurchase obligations is approximately 15%. As a result of the settlement of the redemption obligations, the corresponding put right liability was fully extinguished.

Third Quarter 2024 Financial Results

Cash Position

As of September 30, 2024, the Company had cash and cash equivalents, and short-term investments of $184.4 million, compared to $311.0 million as of December 31, 2023. There was $10.8 million of cash classified as discontinued operations as of December 31, 2023. The Company expects its existing cash and cash related balances to be sufficient to fund its current operating plan into 2027.

Shares Outstanding

As of September 30, 2024, the Company had 187,452,500 ordinary shares issued and outstanding, representing the equivalent of 81,501,087 ADSs, assuming the conversion of all ordinary shares into ADSs.

Research & Development Expenses

Research and development ("R&D") expenses were $4.5 million and $15.7 million for the three and nine months ended September 30, 2024, respectively, compared to $5.1 million and $13.3 million for the three and nine months ended September 30, 2023, respectively. R&D costs for the three months ended September 30, 2024, were $0.6 million lower than the comparable period in 2023, primarily due to streamlined clinical pipeline activities. R&D costs for the nine months ended September 30, 2024, were $2.4 million higher than the comparable period in 2023, driven by higher clinical trial costs associated with the preparation of enrollment for the uliledlimab Phase 2 combination study and increased spend on the givastomig Phase 1b dose expansion study. These higher costs were partially offset by decreased share-based compensation expense.

Administrative Expenses

Administrative expenses were $7.9 million and $22.3 million for the three and nine months ended September 30, 2024, respectively, compared to $5.9 million and $19.9 million for the three and nine months ended September 30, 2023, respectively. The increase of $2.0 million and $2.4 million for the three and nine months ended September 30, 2024, respectively, were primarily driven by legal costs associated with the litigation against Inhibrx, Inc., partially offset by lower share-based compensation expense.

Other Income (Expenses), Net

Other income (expenses), net were $(10.5) million and $(5.0) million for the three and nine months ended September 30, 2024, respectively, compared to $2.4 million and $(9.1) million for the three and nine months ended September 30, 2023, respectively. The $12.9 million increase in other expenses for the three months ended September 30, 2024, was primarily driven by the settlement of the TJ Bio repurchase obligations. The $4.1 million decrease in other expenses for the nine months ended September 30, 2024, was primarily driven by a smaller impact from foreign exchange losses for the current period, partially offset by the settlement of the TJ Bio repurchase obligations.

Net Loss from Continuing Operations

Net loss from continuing operations was $(20.5) million and $(38.9) million for the three and nine months ended September 30, 2024, respectively, compared to $(8.2) million and $(45.3) million for the three and nine months ended September 30, 2023, respectively.

About I-Mab

I-Mab (NASDAQ: IMAB) is a U.S.-based, global biotech company, exclusively focused on the development of highly differentiated immunotherapies for the treatment of cancer. I-Mab has established operations in the U.S. in Rockville, Maryland, and Short Hills, New Jersey. For more information, please visit https://www.i-mabbiopharma.com and follow us on LinkedIn and X.

Exchange Rate Information

As part of I-Mab's strategic transition to a US-based biotech, effective April 2, 2024, the Company changed its reporting currency from RMB to USD. As indicated in its interim financial results, reported on August 28, 2024, the Company applied this change retrospectively to its historical results of operations and financial statements, as if the Company had always used the U.S. dollar as its reporting currency.

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 Company's pipeline and capital strategy; the projected advancement of the Company's portfolio and anticipated milestones and related timing; the market opportunity and I-Mab's potential next steps (including the potential expansion, differentiation, or commercialization) for ulilediimab, givastomig and ragistomig; the Company's expectations regarding the impact of data from ongoing and future clinical trials; the Company's financial condition and results of operations; the Company's expectations regarding its cash runway; timing and progress of studies and trials (including with respect to patient enrollment); the availability of data and information from ongoing studies and trials; and the patent protection available for the Company's product candidates. 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.

I-Mab Investor & Media Contacts

Tyler Ehler
Senior Director, Investor Relations
IR@imabbio.com

I-Mab
Consolidated Balance Sheets
(All amounts in thousands, except for share data)

	As of September 30, 2024	As of December 31, 2023
	(Unaudited)	*(Unaudited)*
Assets		
Current assets		
Cash and cash equivalents	$ 79,327	$ 290,799
Short-term investments	105,064	20,172
Prepayments and other current assets	3,820	714
Current assets of discontinued operations	—	17,428
Total current assets	**188,211**	**329,113**
Property, equipment and software	186	1,772
Operating lease right-of-use assets	3,505	3,768
Investments at fair value - available for sale securities	39,343	—
Other non-current assets	1,437	248
Non-current assets of discontinued operations	—	33,127
Total assets	**$ 232,682**	**$ 368,028**

Liabilities and shareholders' equity		
Current liabilities		
Accruals and other payables	$ 11,018	$ 7,895
Operating lease liabilities, current	753	624
Current liabilities of discontinued operations	—	49,484
Total current liabilities	**11,771**	**58,003**
Put right liabilities, non-current	—	13,819
Operating lease liabilities, non-current	3,028	3,253
Other non-current liabilities	—	105
Non-current liabilities of discontinued operations	—	50,851
Total liabilities	**$ 14,799**	**$ 126,031**
Shareholders' equity		
Ordinary shares (US$0.0001 par value, 800,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 187,452,500 and 185,613,662 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively)	19	19
Treasury stock	(6,225)	(8,001)
Additional paid-in capital	1,459,196	1,380,918
Accumulated other comprehensive income	41,869	42,013
Accumulated deficit	(1,276,976)	(1,172,952)
Total shareholders' equity	**217,883**	**241,997**
Total liabilities and shareholders' equity	**$ 232,682**	**$ 368,028**

I-Mab
Consolidated Statements of Comprehensive Loss
(All amounts in thousands, except for share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
	(Unaudited)		***(Unaudited)***	
Revenues				
Licensing and collaboration revenue	$ —	$ 315	$ —	$ 627
Total revenues	**—**	**315**	**—**	**627**
Expenses				
Research and development expenses (Note 1)	(4,475)	(5,088)	(15,740)	(13,286)
Administrative expenses (Note 2)	(7,937)	(5,861)	(22,315)	(19,895)
Loss from operations	**(12,412)**	**(10,634)**	**(38,055)**	**(32,554)**
Interest income	2,449	2,483	5,289	6,989
Other income (expenses), net	(10,528)	2,379	(5,048)	(9,102)
Equity in loss of affiliates (Note 3)	—	(2,449)	(1,038)	(10,640)
Loss from continuing operations before income tax expense	**(20,491)**	**(8,221)**	**(38,852)**	**(45,307)**
Income tax expense	—	—	—	—
Loss from continuing operations	**$ (20,491)**	**$ (8,221)**	**$ (38,852)**	**$ (45,307)**
Discontinued operations:				
Loss from operations of discontinued operations (Note 4)	$ —	$ (25,035)	$ (6,898)	$ (94,522)
Income tax expense	—	—	—	—
Gain on sale of discontinued operations	—	—	32,582	—
Income (loss) from discontinued operations	**$ —**	**$ (25,035)**	**$ 25,684**	**$ (94,522)**
Net loss attributable to I-Mab	**$ (20,491)**	**$ (33,256)**	**$ (13,168)**	**$ (139,829)**
Net loss attributable to ordinary shareholders	**$ (20,491)**	**$ (33,256)**	**$ (13,168)**	**$ (139,829)**
Net loss attributable to I-Mab	**$ (20,491)**	**$ (33,256)**	**$ (13,168)**	**$ (139,829)**
Foreign currency translation adjustments net of tax	1,071	(13,547)	(494)	8,887

Total comprehensive loss attributable to I-Mab	**$ (19,420)**	**$ (46,803)**	**$ (13,662)**	**$ (130,942)**
Net loss from continuing operations per share attributable to ordinary shareholders —Basic and diluted	$ (0.11)	$ (0.04)	$ (0.21)	$ (0.24)
Net loss from continuing operations per ADS attributable to ordinary shareholders (Note 5) —Basic and diluted	$ (0.25)	$ (0.09)	$ (0.48)	$ (0.55)
Net income (loss) from discontinued operations per share attributable to ordinary shareholders —Basic and diluted	$ -	$ (0.13)	$ 0.14	$ (0.49)
Net income (loss) from discontinued operations per ADS attributable to ordinary shareholders (Note 5) —Basic and diluted	$ -	$ (0.30)	$ 0.32	$ (1.13)
Net loss attributable to ordinary shareholders —Basic and diluted	$ (0.11)	$ (0.17)	$ (0.07)	$ (0.73)
Net loss per ADS attributable to ordinary shareholders (Note 5) —Basic and diluted	$ (0.25)	$ (0.39)	$ (0.16)	$ (1.68)
Weighted-average number of ordinary shares outstanding —Basic and diluted	187,440,440	192,922,665	186,485,241	191,306,670

Notes:

(1) Includes share-based compensation expense of $0.6 million and $0.9 million for the three and nine months ended September 30, 2024, respectively, compared to $0.6 million and $2.3 million for the three and nine months ended September 30, 2023, respectively.

(2) Includes share-based compensation expense of $(0.3) million and ($3.7) million for the three and nine months ended September 30, 2024, respectively, compared to $1.5 million and $6.2 million for the three and nine months ended September 30, 2023, respectively. The period ended September 30, 2024 includes forfeitures as a result of the divestiture of China operations and organizational changes.

(3) Includes share-based compensation expense of $0.0 million and ($0.7) million for the three and nine months ended September 30, 2024, respectively, compared to $0.1 million and $0.7 million for the three and nine months ended September 30, 2023, respectively. The period ended September 30, 2024 includes forfeitures as a result of the divestiture of China operations.

(4) Includes share-based compensation expense of $0.0 million and ($11.5) million for the three and nine months ended September 30, 2024, respectively, compared to $2.7 million and $14.8 million for the three and nine months ended September 30, 2023, respectively. The period ended September 30, 2024 includes forfeitures as a result of the divestiture of China operations.

(5) Each 10 ADSs represents 23 ordinary shares.

View original content to download multimedia:https://www.prnewswire.com/news-releases/i-mab-reports-third-quarter-2024-results-302305143.html

SOURCE I-Mab Biopharma