Third Harmonic Bio Announces First Quarter 2024 Financial Results and Provides Business Update

May 15, 2024 12:05 PM EDT

U.S. FDA clears Investigational New Drug application for THB335

Phase 1 SAD/MAD clinical trial initiated and subject screening underway, with results expected during 1H'25

Strengthened leadership team with the appointment of Christopher J. Dinsmore, Ph.D., to Chief Scientific Officer, Dennis Dean, Ph.D., to Chief Non-Clinical Development Officer, and the promotion of Jennifer Dittman to Chief Development Operations Officer

Strong financial position with cash and cash equivalents totaling $262.8 million as of March 31, 2024

SAN FRANCISCO, May 15, 2024 (GLOBE NEWSWIRE) -- Third Harmonic Bio, Inc. (Nasdaq: THRD), a clinical stage biopharmaceutical company focused on advancing the next wave of medicine for dermal, respiratory, and gastrointestinal inflammatory diseases, today announced financial results for the first quarter March 31, 2024, recent business updates, and anticipated milestones.

As part of its business update, the Company announced U.S. FDA clearance of its Investigational New Drug (IND) application to initiate a first-in-human clinical trial of THB335, a potent, highly selective, oral, small molecule KIT inhibitor that is in development for the treatment of mast cell-mediated diseases, with an initial focus in chronic spontaneous urticaria (CSU). The Company has initiated a Phase 1 single and multiple ascending doses (SAD/MAD) clinical trial of THB335 to evaluate safety, pharmacokinetics, and pharmacodynamics in healthy volunteers, and expects to report clinical results from the trial during the first half of 2025. The Phase 1 trial is expected to be followed by a Phase 2 trial in CSU, with planned rapid expansion into additional mast cell-mediated disorders.

"With the initiation of THB335 clinical trials, we are advancing the development of our potentially best-in-class oral KIT inhibitor toward becoming an important treatment for patients living with chronic spontaneous urticaria and other mast-cell mediated inflammatory diseases," said Natalie Holles, Chief Executive Officer at Third Harmonic Bio. "We are continuing to conduct our development efforts with urgency given the significant unmet need in CSU and the potentially transformative benefit that TBH335 may deliver to patients."

The Phase 1 SAD/MAD clinical trial of THB335 is being conducted in healthy volunteers to assess safety and tolerability, characterize pharmacokinetics, and to measure the pharmacodynamic effect by reductions in serum tryptase, a biomarker associated with mast cell activation and correlated with clinical response in urticaria studies. Results are expected in the first half of 2025.

Leadership Team Updates

The Company also announced the appointment and promotion of key executive leaders to the organization. Christopher J. Dinsmore, Ph.D., was appointed to Chief Scientific Officer, Dennis Dean, Ph.D., was appointed to Chief Non-Clinical Development Officer, and Jennifer Dittman was promoted to Chief Development Operations Officer.

"We are excited to expand the executive team with the appointments of Chris, Dennis and Jennifer to their respective leadership roles in these critical discovery, research and development functions," continued Natalie Holles. "In addition to their outstanding collective track record in our industry, all three embody our core operating principles of open collaboration, enterprise-level thinking and drive. I look forward to our future achievements under this outstanding leadership team."

Chris is a seasoned leader with a strong track record of advancing early targets to drug candidate identification and through clinical development. In his role as Chief Scientific Officer, he will oversee the Company's scientific research strategy from discovery through preclinical proof-of-concept, IND filing, and also support early clinical development. Chris joins Third Harmonic Bio from Kronos Bio, where he was Chief Scientific Officer, responsible for the discovery functions, and played a key role in the company's initial public offering and partnership with Genentech. Prior to Kronos, he served as an Entrepreneur-in-Residence at Third Rock Ventures, focusing on the launch of new biomedical companies. Earlier in his career, he served as Vice President, Head of Chemistry, of Forma Therapeutics, where he oversaw chemistry functions in support of discovery and early development. He began his career at Merck Research Laboratories where he held positions of increasing responsibility in discovery chemistry. He received his Ph.D. in organic chemistry from University of Minnesota, Minneapolis, and was a NIH Postdoctoral Fellow in organic chemistry at Harvard University.

Dennis brings extensive experience across multiple therapeutic areas of drug discovery and development, with a particular focus in DMPK, preclinical safety assessment, clinical pharmacology, biomarkers, and modeling and simulation. In his role as Chief Non-Clinical Development Officer, he will be responsible for leading the selection of high-quality development candidates, including toxicology, DMPK and translation functions. Prior to joining Third Harmonic Bio, Dennis has served as Chief Development Officer of IFM Therapeutics, where he oversaw preclinical and clinical development, advancing multiple programs into early clinical development leading to three acquisitions by global pharmaceutical companies. Before IFM Therapeutics, he was Senior Vice President, Head of Preclinical Development at Vertex Pharmaceuticals, where he linked key preclinical translational groups, effectively progressed the pipeline, and bridged transition for discovery into development. Earlier in his career, he held positions of increasing responsibility in DMPK at Merck Research Laboratories. He received his Ph.D. in medicinal chemistry at State University of New York, Buffalo, and was a Postdoctoral Fellow at Emory University.

Jennifer joined Third Harmonic Bio in November 2022 as Vice President of Regulatory Affairs. In her expanded role as Chief Development Operations Officer, she is now responsible for regulatory affairs, program management, quality, and CMC. Prior to joining Third Harmonic Bio, Jennifer was Vice President of Regulatory Affairs and Medical Writing at Generation Bio, where she was responsible for platform and pipeline regulatory activities. Before Generation Bio, she held roles of increasing responsibility at Vertex Pharmaceuticals, most recently serving as Executive Director, Therapeutic Area Head, in Regulatory Affairs, where she helped set the global regulatory strategy for multiple pipeline products in development, including small molecule and gene therapy/editing programs. Earlier in her career, Jennifer served in roles of increasing responsibility in Regulatory Affairs at bluebird bio and was Adjunct Faculty in the Regulatory Affairs program at Northeastern University. She holds a M.S. in regulatory affairs for drugs, biologics,

and medical devices from Northeastern University.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled $262.8 million as of March 31, 2024. Based on the company's current operating plan, Third Harmonic Bio believes that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements through at least 2026.

R&D Expenses: Research and development (R&D) expenses decreased to $6.2 million for the three months ended March 31, 2024, from $6.7 million for the same period in 2023. The decreases were primarily due to decreases in development costs relating to the termination of the THB001 program, partially offset by increases in research costs relating to the nonclinical development of THB335 and other next-generation discovery efforts.

G&A Expenses: General and administrative (G&A) expenses decreased to $5.1 million for the three months ended March 31, 2024, from $5.3 million for the same period in 2023. The decreases were primarily attributable to decreases in non-cash stock-based compensation.

Net Loss: Net loss for the three months ended March 31, 2024, decreased to $7.9 million from a net loss of $9.1 million for the same period in 2023. The decreases were primarily due to increases in interest income and decreases in operating expenses.

About Third Harmonic Bio, Inc.

Third Harmonic Bio is a clinical stage biopharmaceutical company focused on advancing the next wave of medicine for dermal, respiratory, and gastrointestinal inflammatory diseases through the development of novel, highly selective, small-molecule inhibitors of KIT, a cell surface receptor that serves as the master regulator of mast cell function and survival. Early clinical studies demonstrate that KIT inhibition has the potential to revolutionize the treatment of a broad range of mast-cell-mediated inflammatory diseases, and that a titratable, oral small molecule inhibitor may provide the optimal therapeutic profile against this target. Third Harmonic Bio's lead product candidate, THB335, is a titratable, oral, small molecule inhibitor that is currently in a Phase 1 clinical trial. For more information, please visit the Third Harmonic Bio website: www.thirdharmonicbio.com.

Forward-Looking Statement

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the expected timing for clinical trials and regulatory submissions for THB335, planned clinical and development activities and timelines, and the sufficiency of Third Harmonic Bio's cash and cash equivalents to fund its operating expenses and capital expenditure requirements through at least 2026. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties, including risks and uncertainties related to Third Harmonic Bio's cash forecasts, ability to advance its product candidates, the receipt and timing of potential regulatory submissions, designations, approvals and commercialization of product candidates, our ability to protect our intellectual property, the timing and results of preclinical and clinical trials, changes to laws or regulations, market conditions, geopolitical events, and further impacts of pandemics or health epidemics, that could cause actual results to differ materially from what Third Harmonic Bio expects. Further information on potential risk factors that could affect Third Harmonic Bio's business and its financial results are detailed under the heading "Risk Factors" included in Third Harmonic Bio's Quarterly Report on Form 10-Q for the three months ended March 31, 2024, filed with the U.S. Securities and Exchange Commission (SEC) on May 15, 2024, and in Third Harmonic Bio's other filings filed from time to time with the SEC. Third Harmonic Bio undertakes no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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THIRD HARMONIC BIO, INC.
Condensed consolidated balance sheet data
(Unaudited)
(In thousands)

	December 31, 2023	March 31, 2024
Assets		
Cash and cash equivalents	$ 269,070	$ 262,826
Other current assets	3,376	2,771
Non-current assets	5,265	4,924
Total assets	$ 277,711	$ 270,521
Liabilities		
Current liabilities	$ 5,418	$ 4,018
Non-current liabilities	3,208	3,002
Total liabilities	8,626	7,020
Stockholders' equity	269,085	263,501
Total liabilities and stockholders' equity	$ 277,711	$ 270,521

THIRD HARMONIC BIO, INC.
Condensed consolidated statements of operations
(Unaudited)
(In thousands of, except per share and share amounts)

	Three Months Ended March 31,	
	2023	2024
Operating expenses:		
Research and development	$ 6,737	$ 6,226

General and administrative	5,251	5,064
Total operating expenses	11,988	11,290
Loss from operations	11,988	11,290
Other (income) expense, net	(2,903)	(3,434)
Net loss	$ 9,085	$ 7,856
Net loss per share of common stock, basic and diluted	$ 0.23	$ 0.20
Weighted-average common stock outstanding, basic and diluted	39,438,572	40,213,158