



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

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THB335 Phase 1 SAD/MAD clinical trial progressing; study now on track to report clinical results in 1Q'25

Strong financial position with cash and cash equivalents totaling \$255.3 million as of June 30, 2024

SAN FRANCISCO, Aug. 08, 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 second quarter June 30, 2024, along with business updates.

"We are making excellent progress in our Phase 1 SAD/MAD clinical trial of THB335 and now expect to report clinical results during the first quarter of 2025," said Natalie Hollis, Chief Executive Officer at Third Harmonic Bio. "In parallel with conduct of this ongoing clinical trial, we are already preparing to move THB335 rapidly into a Phase 2 clinical trial in chronic spontaneous urticaria with subsequent expansion into additional mast cell-mediated diseases."

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 quarter of 2025.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled \$255.3 million as of June 30, 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 increased to \$8.4 million for the three months ended June 30, 2024, from \$5.3 million for the same period in 2023. R&D expenses for the six months ended June 30, 2024, increased to \$14.6 million, from \$12.1 million for the same period in 2023. The increases were primarily due to increased spend related to the THB335 clinical program and next-generation discovery efforts, partially offset by decreases in development costs relating to the termination of the THB001 program.

G&A Expenses: General and administrative (G&A) expenses increased to \$5.7 million for the three months ended June 30, 2024, from \$5.4 million for the same period in 2023. G&A expenses for the six months ended June 30, 2024, increased to \$10.7 million, from \$10.6 million for the same period in 2023. The increases were primarily attributable to increased personnel-related expenses due to executive recruiting during 2024.

Net Loss: Net loss for the three months ended June 30, 2024, increased to \$10.7 million from a net loss of \$7.6 million for the same period in 2023. Net loss for the six months ended June 30, 2024, increased to \$18.6 million from a net loss of \$16.6 million for the same period in 2023, primarily due to increases in research and development expenses that were partially offset by increases in interest income.

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, progress of the clinical trials and the availability of clinical data from such 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 six months ended June 30, 2024, filed with the U.S. Securities and Exchange Commission (SEC) on August 8, 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	June 30, 2024
Assets		
Cash and cash equivalents	\$ 269,070	\$ 255,331
Other current assets	3,376	5,898
Non-current assets	5,265	4,628
Total assets	\$ 277,711	\$ 265,857
Liabilities		
Current liabilities	\$ 5,418	\$ 6,352
Non-current liabilities	3,208	2,791
Total liabilities	8,626	9,143
Stockholders' equity	269,085	256,714
Total liabilities and stockholders' equity	\$ 277,711	\$ 265,857

THIRD HARMONIC BIO, INC.
Condensed consolidated statements of operations
(Unaudited)

(In thousands of, except per share and share amounts)

	Six Months Ended June 30,	
	2023	2024
Operating expenses:		
Research and development	\$ 12,077	\$ 14,620
General and administrative	10,625	10,740
Total operating expenses	22,702	25,360
Loss from operations	22,702	25,360
Other (income) expense, net	(6,057)	(6,797)
Net loss	\$ 16,645	\$ 18,563
Net loss per share of common stock, basic and diluted	\$ 0.42	\$ 0.46
Weighted-average common stock outstanding, basic and diluted	39,504,882	40,384,338