



Third Harmonic Bio Announces Second Quarter 2023 Financial Results

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Introduced next-generation oral KIT inhibitor product candidate THB335, which retains the potency and selectivity of first-generation oral KIT inhibitor, THB001, with differentiated metabolic, distribution, and physicochemical profile

U.S. Investigational New Drug (IND) application filing and initiation of clinical trials of THB335 planned for the first half of 2024

Strong financial position with cash and cash equivalents totaling \$278.1 million as of June 30, 2023

SAN FRANCISCO, Aug. 10, 2023 (GLOBE NEWSWIRE) -- Third Harmonic Bio, Inc. (Nasdaq: THRD), a biopharmaceutical company focused on advancing the next wave of medicine for inflammatory diseases, today announced financial results for the second quarter ended June 30, 2023.

"We are pleased with the speed, rigor and capital efficiency of our team's efforts this year to advance our new development candidate, THB335, toward clinical trials in the first half of 2024," said Natalie Holles, Chief Executive Officer of Third Harmonic Bio. "As the development landscape for chronic urticaria evolves, we continue to believe that an orally available KIT inhibitor has the potential to be a transformative treatment for this large yet underserved patient population."

Recent Corporate Highlights

On July 25, 2023, the company announced its next-generation product candidate, THB335, and disclosed topline results of the Phase 1b clinical trial of THB001 for the treatment of chronic inducible urticaria, which was discontinued in December 2022 due to observed liver transaminitis in two of five patients enrolled. The results demonstrated evidence of clinical benefit in four of the five patients, achieving partial or complete responses despite early termination of the trial.

In addition, the company shared preliminary results from extensive studies of THB001 that were conducted to identify the mechanism for the observed liver toxicity, which was not predicted by nonclinical toxicology studies. These in-depth studies identified a metabolic pathway resulting in the formation of an intermediate reactive metabolite. Reactive metabolite formation has been previously implicated as a mechanistic basis for drug-induced liver injury. Structural modifications introduced into THB335 are believed to address this risk and studies conducted to-date support its differentiated metabolic profile.

THB335

THB335, the company's next-generation oral small molecule wild-type KIT inhibitor product candidate, maintains a similar potency and selectivity profile of THB001, with structural modifications which are expected to mitigate the hepatotoxicity risk as well as provide a differentiated metabolic, distribution and physicochemical profile.

The company plans to file a U.S. IND and initiate clinical trials of THB335 in the first half of 2024. Phase 2 development is expected to initially focus on chronic spontaneous urticaria, with planned expansion into other mast-cell mediated inflammatory disorders in later phases.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled \$278.1 million as of June 30, 2023. 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 2025.

R&D Expenses: Research and development (R&D) expenses increased to \$5.3 million for the three months ended June 30, 2023, from \$4.2 million for the same period in 2022. R&D expenses for the six months ended June 30, 2023 increased to \$12.1 million, from \$10.4 million for the same period in 2022. The increases were primarily due to increases in discovery and development costs relating to the research and nonclinical development of THB335 and other next-generation discovery efforts.

G&A Expenses: General and administrative (G&A) expenses increased to \$5.4 million for the three months ended June 30, 2023, from \$3.6 million for the same period in 2022. G&A expenses for the six months ended June 30, 2023 increased to \$10.6 million, from \$5.2 million for the same period in 2022. The increases were primarily attributable to increased costs associated with being a public company and personnel-related expenses.

Net Loss: Net loss for the three months ended June 30, 2023 decreased to \$7.6 million from a net loss of \$7.7 million for the same period in 2022. Net loss for the six months ended June 30, 2023 increased to \$16.6 million, compared to a net loss of \$15.5 million for the same period in 2022, primarily due to increases in research and development expenses and public company costs that were partially offset by increases in interest income.

About Third Harmonic Bio, Inc.

Third Harmonic Bio is a biopharmaceutical company focused on advancing the next wave of medicine for 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, intracellular small molecule inhibitor may provide the optimal therapeutic profile against this target. Third Harmonic's lead product candidate, THB335, is a titratable, oral, intracellular small molecule inhibitor expected to enter clinical trials during the first half of 2024. For more information, please visit the Third Harmonic Bio website: www.thirdharmonicbio.com.

Forward-Looking Statements

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 product profile of THB335 as compared to THB001, the timing of filing a U.S. IND application for THB335, the expected timing for clinical activities. 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, 2023, filed with the U.S. Securities and Exchange Commission (SEC) on August 10, 2023, 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)

	<u>December 31, 2022</u>	<u>June 30, 2023</u>
Assets		
Cash and cash equivalents	\$ 288,877	\$ 278,132
Other current assets	3,958	2,233
Non-current assets	5,840	5,457
Total assets	<u>\$ 298,675</u>	<u>\$ 285,822</u>
Liabilities		
Current liabilities	\$ 5,653	\$ 4,223
Non-current liabilities	3,954	3,591
Total liabilities	9,607	7,814
Stockholders' equity	289,068	278,008
Total liabilities and stockholders' equity	<u>\$ 298,675</u>	<u>\$ 285,822</u>

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

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

	<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2023</u>
Operating expenses:		
Research and development	\$ 10,393	\$ 12,077
General and administrative	5,177	10,625
Total operating expenses	15,570	22,702
Loss from operations	15,570	22,702
Other (income) expense, net	(110)	(6,057)
Net loss	<u>\$ 15,460</u>	<u>\$ 16,645</u>
Net loss per share of common stock, basic and diluted	\$ 3.58	\$ 0.42
Weighted-average common stock outstanding, basic and diluted	4,321,267	39,504,882