

Third Harmonic Bio Announces Fourth Quarter and Year-End 2022 Financial Results

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Company Progresses Preclinical Next-Generation oral KIT Inhibitor for Mast Cell-Mediated Inflammatory Diseases

SAN FRANCISCO, March 29, 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 fourth quarter and full year ended December 31, 2022.

"Given the promising preliminary clinical activity observed in our discontinued Phase 1b clinical trial of THB001, we believe 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," said Natalie Holles, Chief Executive Officer of Third Harmonic Bio. "We are making meaningful progress toward selecting a next-generation KIT inhibitor development candidate in 2023 and look forward to providing a more substantive update in the near term."

Recent Business Highlights

In December 2022, the Company announced the discontinuation of its Phase 1b clinical trial of THB001 in chronic inducible urticaria following observation of asymptomatic liver transaminitis in two subjects enrolled in the first dose cohort of 200 mg BID. As a result, Third Harmonic Bio initiated nonclinical studies to elucidate the mechanism for the observed transaminitis, which was not predicted by extensive GLP toxicology studies of THB001 nor observed in the Phase 1a clinical trial. Preliminary analyses showed evidence of pharmacodynamic and clinical activity at the 200 mg BID dose. The Company plans to present the full data set from the five enrolled subjects at an upcoming scientific conference.

In parallel with the early clinical development of THB001, the company has conducted an extensive medicinal chemistry effort to identify chemically distinct next-generation oral wild-type KIT inhibitors and has advanced multiple candidate molecules into exploratory toxicology studies. Third Harmonic Bio intends to nominate a development candidate from this program in early 2023.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled \$288.9 million as of December 31, 2022. 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 the next twelve months.

R&D Expenses: Research and development (R&D) expenses increased to \$9.3 million for the three months ended December 31, 2022, from \$4.3 million for the same period in 2021. R&D expenses for the year ended December 31, 2022, increased to \$24.4 million from \$15.7 million for the same period in 2021. The increases were primarily due to increases in discovery and development costs relating to the research and nonclinical development of next generation molecules and other discovery programs, as well as increases in personnel related costs.

G&A Expenses: General and administrative (G&A) expenses increased to \$4.3 million for the three months ended December 31, 2022, from \$1.5 million for the same period in 2021. G&A expenses for the year ended December 31, 2022, increased to \$13.3 million from \$3.3 million for the same period in 2021. The increases were primarily attributable to increases in costs associated with personnel-related expenses and the initial public offering.

Net Loss: Net loss for the three months ended December 31, 2022, decreased to \$11.5 million from a net loss of \$15.8 million for the same period in 2021, primarily due to the change in fair value of the preferred stock tranche liability partially offset by increases in loss from operations. Net loss for the year ended December 31, 2022, was \$35.2 million compared to a net loss of \$29.6 million for the same period in 2021.

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 a novel highly selective, oral small-molecule inhibitor 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. 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 timing of selecting a next-generation KIT inhibitor development candidate and additional corporate announcements and presentations, the results and timing of preclinical studies and clinical trials for future development candidates, expectations regarding cash forecasts, and planned clinical and development activities and timelines. 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 the ongoing COVID-19 pandemic, 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 Annual Report on Form 10-K for the year ended December 31, 2022, filed with the U.S. Securities and Exchange Commission (SEC) on March 29, 2023, and in Third Harmonic Bio's other filings with the SEC 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, 2021		December 31, 2022	
Assets				
Cash and cash equivalents	\$	128,280	\$	288,877
Other current assets		884		3,959
Non-current assets				5,840
Total assets	\$	129,164	\$	298,676
Liabilities				
Current liabilities	\$	5,686	\$	5,653
Non-current liabilities				3,954
Total liabilities		5,686		9,607
Redeemable convertible preferred stock		170,184		_
Stockholders' equity		(46,706)		289,068
Total liabilities and stockholders' equity	\$	129,164	\$	298,675

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

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

		Year Ended December 31,			
	2021		2022		
Operating expenses:					
Research and development	\$	15,748	\$	24,407	
General and administrative		3,256		13,301	
Total operating expenses		19,004		37,708	
Loss from operations		19,004		37,708	
Other (income) expense, net		10,605		(2,553)	
Net loss	\$	29,609	\$	35,155	
Net loss per share of common stock, basic and diluted Weighted-average common stock outstanding, basic and diluted	\$	7.32 4,043,416	\$	2.62 13,426,066	