

Third Harmonic Bio Announces Third Quarter 2022 Financial Results and Provides Corporate Update

November 9, 2022 9:15 PM EST

Successfully Completed Upsized Initial Public Offering Providing Funding Through 2025

Patient Dosing Underway in Phase 1b Chronic Inducible Urticaria Clinical Trial

CAMBRIDGE, Mass., Nov. 09, 2022 (GLOBE NEWSWIRE) -- Third Harmonic Bio, Inc. (Nasdaq: THRD), a clinical-stage biopharmaceutical company focused on advancing the next wave of medicine for allergy and inflammation, today announced financial results for the quarter ended September 30, 2022 and provided a corporate update.

"With the recent close of our successful initial public offering, we believe we have the capital resources and experienced team in place to advance the continued development of THB001 for the treatment of urticaria, or chronic hives, and asthma - two inflammatory diseases where, despite current treatment options, a significant unmet medical need remains," said Natalie Holles, chief executive officer of Third Harmonic Bio. "We expect to initiate a Phase 1b clinical trial in asthma during the first half of 2023 and report results from our Phase 1b clinical trial in chronic inducible urticaria during the second half of 2023."

Recent Business Highlights

Completed Upsized \$213.1 Million Initial Public Offering

Third Harmonic Bio closed its initial public offering of 12,535,000 shares of its common stock, including the full exercise of the underwriters' option to purchase up to 1,635,000 additional shares of common stock. The gross proceeds from the offering, before deducting underwriting discounts and commissions and other offering expenses payable by Third Harmonic Bio, were approximately \$213.1 million.

Patient Dosing Underway in Phase 1b trial in Chronic Inducible Urticaria

Third Harmonic Bio completed its Phase 1a clinical trial of THB001 and expects to present full results of the trial at an upcoming medical meeting during the first half of 2023. Third Harmonic also began dosing patients in its Phase 1b clinical trial in chronic inducible urticaria. The trial is evaluating three dose levels of THB001 over 12 weeks of treatment. The objectives of the clinical trial are to evaluate safety and tolerability, efficacy and pharmacokinetics. Additional details about the study can be found under clinicaltrials.gov identifier NCT05510843.

Recent Leadership Updates

Third Harmonic Bio continued to strengthen its leadership team and board of directors by appointing Adrian S. Ray, Ph.D., as Chief Scientific Officer, Edward R. Conner, M.D., as Chief Medical Officer and Julie Person, as Chief Administrative Officer, and Thomas M. Soloway to its Board of Directors.

Upcoming Milestones

Third Harmonic Bio expects to deliver on the following milestones:

- Submit a clinical trial application (CTA) in Canada for THB001 to support the initiation of a Phase 1b trial in asthma during the first half of 2023.
- Report initial clinical data from its Phase 1b proof-of-concept clinical trial in chronic inducible urticaria during the second half of 2023.
- Submit both a CTA in Europe and an investigational new drug application in the United States
 to support the initiation of a Phase 2 trial in chronic spontaneous urticaria in the first half of
 2024.
- Report initial data from the Phase 1b asthma trial in the second half of 2024.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled \$299.5 million as of September 30, 2022. Based upon current internal infrastructure and pipeline initiatives, Third Harmonic Bio believes it has sufficient cash to fund operations through 2025.

R&D Expenses: Research and development (R&D) expenses decreased to \$4.8 million for the three months ended September 30, 2022 from \$4.9 million for the same period in 2021 due to the timing of non-clinical and clinical activities. R&D expenses for the nine months ended September 30, 2022 increased to \$15.2 million from \$11.5 million for the same period in 2021, primarily due to higher clinical trial expenses related to THB001.

G&A Expenses: General and administrative (G&A) expenses increased to \$3.8 million for the three months ended September 30, 2022 from \$0.8 million for the same period in 2021. G&A expenses for the nine months ended September 30, 2022 increased to \$9.0 million from \$1.8 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 September 30, 2022 was \$8.2 million compared to a net loss of \$7.4 million for the same period in 2021. Net loss for the nine months ended September 30, 2022 was \$23.7 million compared to a net loss of \$13.8 million for the same period in 2021.

About Third Harmonic Bio, Inc.

Third Harmonic Bio is a clinical-stage biopharmaceutical company focused on advancing the next wave of medicine for allergy and inflammation. Third Harmonic's lead product candidate, THB001, is a highly selective, oral small-molecule inhibitor of KIT, a cell surface receptor that serves as the master regulator of mast cell function and survival. THB001 is currently being evaluated in a Phase 1b proof-of-concept study in chronic inducible urticaria. With promising drug-like properties and an encouraging early clinical profile, THB001 has the potential to revolutionize the treatment of a broad range of dermatologic, respiratory and gastrointestinal allergic and mast-cell-mediated inflammatory diseases. 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 results and timing of clinical trials and regulatory submissions for THB001, 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'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 prospectus dated September 14, 2022 filed with the U.S. Securities and Exchange Commission (SEC) on September 15, 2022, and Third Harmonic Bio's annual and quarterly reports and 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.

Media Contact:

Lori Murray lori.murray@captivate-comms.com

Investor Contact:

Bob Ho rho@thirdharmonicbio.com

THIRD HARMONIC BIO, INC. Condensed consolidated balance sheet data (Unaddited)

(In thousands)

	De	December 31, 2021		September 30, 2022	
Assets					
Cash and cash equivalents	\$	128,280	\$	299,516	
Other current assets		884		4,053	
Non-current assets		<u> </u>		1,193	
Total assets	\$	129,164	\$	304,762	
Liabilities					
Current liabilities	\$	5,686	\$	6,340	
Non-current liabilities		<u> </u>			
Total liabilities		5,686		6,340	
Redeemable convertible preferred stock		170,184		_	
Stockholders' equity		(46,706)		298,422	
Total liabilities and stockholders' equity	\$	129,164	\$	304,762	

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

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

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2021		2022		2021		2022
Operating expenses:								
Research and development	\$	4,917	\$	4,757	\$	11,463	\$	15,150
General and administrative		780		3,831		1,790		9,008
Total operating expenses		5,697		8,588		13,253		24,158
Loss from operations		5,697		8,588		13,253		24,158
Other (income) expense, net		1,684		(383)		574		(493)
Net loss	\$	7,381	\$	8,205	\$	13,827	\$	23,665
Net loss per share of common stock, basic and diluted	\$	0.90	\$	0.69	\$	3.46	\$	2.26
Weighted-average common stock outstanding, basic and diluted		8,159,044		11,827,663		3,994,784		10,451,300