

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): November 09, 2022**

**THIRD HARMONIC BIO, INC.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-41498**  
(Commission File Number)

**83-4553503**  
(IRS Employer  
Identification No.)

**300 Technology Square, 8th Floor**  
**Cambridge, Massachusetts**  
(Address of Principal Executive Offices)

**02139**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: 617 915-6680**

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Securities registered pursuant to Section 12(b) of the Act:**

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
Common Stock, par value \$0.0001 per share	THRD	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

## Item 2.02 Results of Operations and Financial Condition.

On November 9, 2022, Third Harmonic Bio, Inc. (the “*Company*”) issued a press release reporting the Company’s financial results for the quarter ended September 30, 2022. A copy of the Company’s press release is attached as Exhibit 99.1 to this report.

The information in this Item 2.02, including Exhibit 99.1 attached to this report, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “*Securities Act*”). The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any other filing under the Exchange Act or under the Securities Act, except as shall be expressly set forth by specific reference in such filing.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	<a href="#">Press Release issued by Third Harmonic Bio, Inc. dated November 9, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**THIRD HARMONIC BIO, INC.**

Date: November 9, 2022

By: /s/ Robert Ho  
Robert Ho  
Chief Financial Officer

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

Successfully Completed Upsized Initial Public Offering Providing Funding Through 2025  
Patient Dosing Underway in Phase 1b Chronic Inducible Urticaria Clinical Trial

**CAMBRIDGE, Mass., November 9, 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](https://clinicaltrials.gov/ct2/show/study/NCT05510843) identifier NCT05510843.

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## 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.

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**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](http://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.

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

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

**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
<b>Operating expenses:</b>				
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
<b>Loss from operations</b>	<b>5,697</b>	<b>8,588</b>	<b>13,253</b>	<b>24,158</b>
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

