

**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): August 10, 2023**

**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.)

**1700 Montgomery Street, Suite 210**  
**San Francisco, California**  
(Address of Principal Executive Offices)

**94111**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: (209) 727-2457**

N/A

(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:**

| Title of each class                        | Trading<br>Symbol(s) | Name of each exchange on which registered |
|--|----------------------|---|
| 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 August 10, 2023, Third Harmonic Bio, Inc. (the “**Company**”) issued a press release reporting the Company’s financial results for the second quarter ended June 30, 2023. 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 August 10, 2023</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: August 10, 2023

By: /s/ Robert Ho

---

Robert Ho  
Chief Financial Officer

---



## Third Harmonic Bio Announces Second Quarter 2023 Financial Results

*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, CA, August 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 physiochemical 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](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 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.

---

**Investor Contact:**

Bob Ho

rho@thirdharmonicbio.com

---



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

|   | December 31,<br>2022 | June 30,<br>2023  |
|---|----------------------|-------------------|
| <b>Assets</b>                                     |                      |                   |
| Cash and cash equivalents                         | \$ 288,877           | \$ 278,132        |
| Other current assets                              | 3,958                | 2,233             |
| Non-current assets                                | 5,840                | 5,457             |
| <b>Total assets</b>                               | <b>\$ 298,675</b>    | <b>\$ 285,822</b> |
| <b>Liabilities</b>                                |                      |                   |
| 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           |
| <b>Total liabilities and stockholders' equity</b> | <b>\$ 298,675</b>    | <b>\$ 285,822</b> |

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

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

|  | Six Months Ended June 30, |            |
|--|---------------------------|------------|
|  | 2022                      | 2023       |
| <b>Operating expenses:</b>                                   |                           |            |
| Research and development                                     | \$ 10,393                 | \$ 12,077  |
| General and administrative                                   | 5,177                     | 10,625     |
| Total operating expenses                                     | 15,570                    | 22,702     |
| <b>Loss from operations</b>                                  | 15,570                    | 22,702     |
| Other (income) expense, net                                  | (110)                     | (6,057)    |
| Net loss   | \$ 15,460                 | \$ 16,645  |
| 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 |

