

**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): May 11, 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 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 May 11, 2023, Third Harmonic Bio, Inc. (the “**Company**”) issued a press release reporting the Company’s financial results for the first quarter ended March 31, 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 | Press Release issued by Third Harmonic Bio, Inc. dated May 11, 2023 |
| 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: May 11, 2023

By: /s/ Robert Ho

Robert Ho
Chief Financial Officer

Third Harmonic Bio Announces First Quarter 2023 Financial Results

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

SAN FRANCISCO, CA, May 11, 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 first quarter ended March 31, 2023.

“We are pleased with our progress on our next generation oral KIT inhibitor program, and plan to announce our new development candidate this year,” said Natalie Holles, Chief Executive Officer of Third Harmonic Bio. “In addition, our preclinical mechanistic studies to elucidate the cause of the observed transaminitis with our previous development candidate, THB001, have yielded important insights that we are applying to our next-generation program. We continue to believe that an oral small molecule KIT inhibitor holds the potential for meaningful impact on the treatment landscape for mast-cell mediated inflammatory diseases such as chronic urticaria.”

In addition to the announcement of a development candidate in 2023, the company intends to present the full data set from the discontinued Phase 1b chronic inducible urticaria study for THB001 at an upcoming scientific conference. As stated previously, a preliminary analysis of the five subjects dosed showed evidence of pharmacodynamic and clinical activity with THB001 in that study.

Summary of Financial Results

Cash Position: Cash and cash equivalents totaled \$282.2 million as of March 31, 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 the next twelve months.

R&D Expenses: Research and development (R&D) expenses for the three months ended March 31, 2023 increased to \$6.7 million from \$6.2 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 next generation molecules and other discovery programs.

G&A Expenses: General and administrative (G&A) expenses for the three months ended March 31, 2023 increased to \$5.3 million from \$1.6 million for the same period in 2022. The increases were primarily attributable to increased costs associated with public company costs and personnel-related expenses.

Net Loss: Net loss for the three months ended March 31, 2023 increased to \$9.1 million compared to a net loss of \$7.8 million for the same period in 2022, primarily due to increases in loss from operations 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, oral 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. 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 announcing 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 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.

Investor Contact:

Bob Ho
rho@thirdharmonicbio.com

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

| | <u>December 31,</u> <u>2022</u> | <u>March 31,</u> <u>2023</u> |
|---|------------------------------------|---------------------------------|
| Assets | | |
| Cash and cash equivalents | \$ 288,877 | \$ 282,202 |
| Other current assets | 3,958 | 3,544 |
| Non-current assets | 5,840 | 5,641 |
| Total assets | <u>\$ 298,675</u> | <u>\$ 291,387</u> |
| Liabilities | | |
| Current liabilities | \$ 5,653 | \$ 4,947 |
| Non-current liabilities | 3,954 | 3,775 |
| Total liabilities | 9,607 | 8,722 |
| Stockholders' equity | 289,068 | 282,665 |
| Total liabilities and stockholders' equity | <u>\$ 298,675</u> | <u>\$ 291,387</u> |

THIRD HARMONIC BIO, INC.
Condensed consolidated statements of operations
(Unaudited)
(In thousands, except per share and share amounts)

| | <u>Three Months Ended March 31,</u> | |
|--|-------------------------------------|-----------------|
| | <u>2022</u> | <u>2023</u> |
| Operating expenses: | | |
| Research and development | \$ 6,212 | \$ 6,737 |
| General and administrative | 1,575 | 5,251 |
| Total operating expenses | <u>7,787</u> | <u>11,988</u> |
| Loss from operations | 7,787 | 11,988 |
| Other (income) expense, net | (3) | (2,903) |
| Net loss | <u>\$ 7,784</u> | <u>\$ 9,085</u> |
| Net loss per share of common stock, basic and diluted | \$ 0.81 | \$ 0.40 |
| Weighted-average common stock outstanding, basic and diluted | 9,643,963 | 22,792,781 |

