
**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): March 20, 2023

Graphite Bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40532
(Commission File Number)

84-4867570
(IRS Employer
Identification No.)

**201 HASKINS WAY
SUITE 210
SOUTH SAN FRANCISCO, California**
(Address of Principal Executive Offices)

94080
(Zip Code)

Registrant's Telephone Number, Including Area Code: 650 484-0886

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 | GRPH | The Nasdaq Global 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 March 20, 2023, Graphite Bio, Inc. issued a press release announcing its financial results for the year ended December 31, 2022. A copy of the press release issued in connection with the announcement is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

The information in this report, including the exhibit hereto, 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. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Graphite Bio, Inc. under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

| Exhibit Number | Description |
|-----------------------|---|
| 99.1 | Press Release dated March 20, 2023 titled “ Graphite Bio Reports Recent Business Progress and Fourth Quarter and Fiscal Year 2022 Financial Results ” |
| 104 | Cover Page Interactive Data (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 thereunto duly authorized.

Graphite Bio, Inc.

Date: March 20, 2023

By: /s/ Alethia Young
Alethia Young
Chief Financial Officer

Graphite Bio Reports Recent Business Progress and Fourth Quarter and Fiscal Year 2022 Financial Results

SOUTH SAN FRANCISCO, Calif., March 20, 2023 – Graphite Bio, Inc. (Nasdaq: GRPH) today reported recent business progress and fourth quarter and fiscal year 2022 financial results.

“As announced last month, Graphite Bio has initiated a process to evaluate strategic alternatives that may result in changes to our business strategy,” said CEO Josh Lehrer, M.D., M.Phil. “We are working expeditiously to complete this strategic review and look forward to providing an update in the future when appropriate.”

Recent Business Updates

- In February 2023, Graphite Bio announced its decision to discontinue development of nulabeglogene autogedtemcel (nula-cel) for sickle cell disease and initiate a process to explore strategic alternatives. As a result of this decision, the company announced a corporate restructuring to preserve capital while it conducts the strategic review. The company also disclosed its intention to continue research activities associated with its early-stage non-genotoxic conditioning program, with the goal of advancing toward one or more potential development candidates.
- In January 2023, the company announced a voluntary pause of the Phase 1/2 CEDAR study of nula-cel. The company made this decision due to a serious adverse event of prolonged low blood cell counts (pancytopenia) in the first patient dosed with nula-cel, and the company’s conclusion that the event is likely related to study treatment.

Fourth Quarter 2022 Financial Highlights

- Cash Position:** As of December 31, 2022, cash, cash equivalents and investments in marketable securities totaled \$283.6 million.
- R&D Expenses:** Research and development expenses were \$18.5 million for the fourth quarter of 2022, which includes \$1.4 million in stock-based compensation expense.
- G&A Expenses:** General and administrative expenses were \$8.3 million for the fourth quarter of 2022, which includes \$2.2 million in stock-based compensation expense.
- Net Loss:** Net loss was \$24.6 million, or \$0.44 per basic and diluted share, for the fourth quarter of 2022.

Fiscal Year 2022 Financial Highlights

- R&D Expenses:** Research and development expenses were \$72.8 million for fiscal year 2022, which includes \$5.3 million in stock-based compensation expense.
- G&A Expenses:** General and administrative expenses were \$32.9 million for fiscal year 2022, which includes \$8.2 million in stock-based compensation expense.
- Net Loss:** Net loss was \$101.1 million, or \$1.84 per basic and diluted share, for fiscal year 2022.

About nulabeglogene autogedtemcel (nula-cel)

Nula-cel, formerly GPH101, is an investigational next-generation gene editing autologous hematopoietic stem cell (HSC) therapy designed to directly correct the genetic mutation that causes sickle cell disease (SCD). A serious, life-threatening inherited blood disorder, SCD affects approximately 100,000 people in the United States and millions of people around the world, making it the most prevalent monogenic blood disease worldwide. Nula-cel is the first investigational therapy to use a highly differentiated gene correction approach that seeks to efficiently and precisely correct the mutation in the beta-globin gene to decrease sickle hemoglobin (HbS) production and restore adult hemoglobin (HbA) expression, thereby potentially curing SCD. The U.S. Food and Drug Administration (FDA) granted Fast Track and Orphan Drug designations to nula-cel for the treatment of SCD.

About Graphite Bio

Graphite Bio is a clinical-stage, next-generation gene editing company harnessing high efficiency targeted gene integration to develop a new class of therapies to potentially cure a wide range of serious and life-threatening diseases. The company's precision gene editing approach aims to enable a variety of applications to transform human health through its potential to achieve one of medicine's most elusive goals: to precisely "find & replace" any gene in the genome. Graphite Bio's platform is designed to precisely correct mutations, replace entire disease-causing genes with normal genes or insert new genes into predetermined, safe locations. Additionally, the company is advancing the development of novel conditioning regimens to help bring curative therapies to more patients.

Graphite Bio was founded by academic pioneers in the fields of gene editing and gene therapy, including Maria Grazia Roncarolo, M.D., and Matthew Porteus, M.D., Ph.D. Learn more by visiting www.graphitebio.com and following the company on LinkedIn and Twitter.

Forward-Looking Statements (Legal to update)

Statements we make in this press release may include statements that are not historical facts and are considered forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact, including statements regarding our plans to explore strategic alternatives, our ability to complete a transaction on acceptable terms, or at all, in connection with our pursuit of strategic alternatives, our plans to continue research activities associated with our early-stage non-genotoxic conditioning program, our ability to advance this program toward potential candidate(s), our implementation of our corporate restructuring and workforce reduction and the timing and scope of these events, and our anticipated cash runway, may be deemed to be forward-looking statements. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and are making this statement for purposes of complying with those safe harbor provisions.

Any forward-looking statements in this press release are based on Graphite Bio's current views about our plans, intentions, expectations, strategies and prospects only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, including risks associated with volatility and uncertainty in the capital markets for biotechnology companies; availability of suitable third parties with which to conduct contemplated strategic transactions; whether we will be able to pursue a strategic transaction, or whether any transaction, if pursued, will be completed on attractive terms; whether our efforts to advance our non-genotoxic conditioning program will be successful; and whether our cash resources will be sufficient to fund our foreseeable and unforeseeable operating expenses and capital expenditure requirements. These risks concerning Graphite Bio's programs and operations are described in additional detail in our periodic filings with the SEC, including our most recently filed periodic report, and subsequent filings thereafter. Graphite Bio explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

GRAPHITE BIO, INC.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|------------------------------------|--------------------|-------------------------------------|--------------------|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses*: | | | | |
| Research and development | \$ 18,462 | \$ 11,205 | \$ 72,787 | \$ 37,932 |
| General and administrative | 8,289 | 7,736 | 32,852 | 22,511 |
| Total operating expenses | 26,751 | 18,941 | 105,639 | 60,443 |
| Loss from operations | (26,751) | (18,941) | (105,639) | (60,443) |
| Other income (expense), net: | | | | |
| Interest income, net | 2,152 | 10 | 4,587 | 24 |
| Change in fair value of the Series A redeemable convertible preferred stock tranche liability | — | — | — | (10,341) |
| Total other income (expense), net | 2,152 | 10 | 4,587 | (10,317) |
| Net loss | <u>\$ (24,599)</u> | <u>\$ (18,931)</u> | <u>\$ (101,052)</u> | <u>\$ (70,760)</u> |
| Unrealized gain (loss) on investments | 548 | — | (1,048) | — |
| Comprehensive loss | <u>\$ (24,051)</u> | <u>\$ (18,931)</u> | <u>\$ (102,100)</u> | <u>\$ (70,760)</u> |
| Net loss per share attributable to common stockholders—basic and diluted | <u>\$ (0.44)</u> | <u>\$ (0.35)</u> | <u>\$ (1.84)</u> | <u>\$ (2.45)</u> |
| Weighted-average shares used in computing net loss per share—basic and diluted | <u>55,721,704</u> | <u>53,429,766</u> | <u>54,873,675</u> | <u>28,919,255</u> |

*** Includes stock-based compensation as follows:**

| | | | | |
|----------------------------|-----------------|-----------------|------------------|-----------------|
| Research and development | \$ 1,436 | \$ 1,051 | \$ 5,317 | \$ 2,685 |
| General and administrative | 2,186 | 1,396 | 8,217 | 5,186 |
| | <u>\$ 3,622</u> | <u>\$ 2,447</u> | <u>\$ 13,534</u> | <u>\$ 7,871</u> |

GRAPHITE BIO, INC.
Condensed Balance Sheets
(in thousands)

| | December 31, | |
|---|---------------------|-------------|
| | 2022 | 2021 |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 47,730 | \$ 376,976 |
| Investments in marketable securities, current | 220,499 | — |
| Prepaid expenses and other current assets | 7,136 | 4,760 |
| Total current assets | 275,365 | 381,736 |
| Restricted cash | 1,716 | 1,716 |
| Investments in marketable securities, non-current | 15,322 | — |
| Property and equipment, net | 22,630 | 6,507 |
| Operating lease right-of-use assets | 5,580 | 11,574 |
| Other assets | 1,289 | 454 |
| Total assets | \$ 321,902 | \$ 401,987 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,608 | \$ 2,453 |
| Accrued compensation | 3,799 | 2,689 |
| Accrued research costs | 720 | 633 |
| Accrued expenses and other current liabilities | 1,871 | 886 |
| Operating lease liabilities, current | 4,045 | 5,482 |
| Total current liabilities | 13,043 | 12,143 |
| Operating lease liabilities, non-current | 1,749 | 5,794 |
| Other long- term liabilities | 10,819 | — |
| Total liabilities | 25,611 | 17,937 |
| Stockholders' equity: | | |
| Common stock | 1 | 1 |
| Additional paid-in-capital | 539,741 | 525,400 |
| Accumulated other comprehensive loss | (1,048) | — |
| Accumulated deficit | (242,403) | (141,351) |
| Total stockholders' equity | 296,291 | 384,050 |
| Total liabilities and stockholders' equity | \$ 321,902 | \$ 401,987 |

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Investors and Media:

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