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 11, 2022

Graphite Bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40532**	**84-4867570**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

201 HASKINS WAY SUITE 210 SOUTH SAN FRANCISCO, California	**94080**
(Address of Principal Executive Offices)	**(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 8.01 Other Events.

On August 11, 2022, Graphite Bio, Inc. (the "Company") issued a press release titled, "Graphite Bio Doses First Patient with Investigational Gene Editing Therapy GPH101 for Sickle Cell Disease." A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit Number	Description
99.1	Press Release dated August 11, 2022 titled "Graphite Bio Doses First Patient with Investigational Gene Editing Therapy GPH101 for Sickle Cell Disease"
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: August 11, 2022

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

Exhibit 99.1

Graphite Bio Doses First Patient with Investigational Gene Editing Therapy GPH101 for Sickle Cell Disease

GPH101, now called nulabeglogene autogedtemcel (nula-cel), designed to directly correct the genetic mutation that causes sickle cell disease

Initial proof-of-concept data from Phase 1/2 CEDAR trial anticipated in mid-2023

SOUTH SAN FRANCISCO, Calif., August 11, 2022 – Graphite Bio, Inc. (Nasdaq: GRPH), a clinical-stage, next-generation gene editing company harnessing the power of high-efficiency precision gene repair to develop therapies with the potential to cure serious diseases, today announced that the first patient has been dosed with GPH101, now called nulabeglogene autogedtemcel (nula-cel), in the company's Phase 1/2 CEDAR trial in people with sickle cell disease (SCD). Nula-cel is an investigational gene editing therapy designed to directly correct the genetic mutation that causes SCD and definitively cure the disease.

"For decades, the goal of gene editing has been to precisely correct genetic mutations that cause disease. Today, we took an important step toward achieving that goal by dosing our first patient with nula-cel, the first investigational therapy designed to correct a mutated gene to normal. This first use of high-efficiency precision DNA repair to correct a genetic mutation is an important milestone not only for our company but also for the gene editing field and, hopefully, for the sickle cell community," said Josh Lehrer, M.D., M.Phil., chief executive officer of Graphite Bio.

"We continue to make tremendous progress with the development of nula-cel, which in preclinical studies successfully corrected the sickle cell disease mutation, directly reducing sickle hemoglobin and restoring healthy adult hemoglobin to potentially curative levels," Lehrer continued. "We believe nula-cel could be a definitive cure for sickle cell disease, with the potential to address all complications associated with this life-threatening disease. We look forward to reporting initial proof-of-concept data from the CEDAR trial in mid-2023."

The CEDAR trial is a Phase 1/2 open-label, single-dose clinical trial evaluating the safety, preliminary efficacy and pharmacodynamics of nula-cel in approximately 15 patients with severe SCD. The trial is currently enrolling patients at multiple sites in the United States.

About nula-cel

Nula-cel, formerly known as 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 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.

Graphite Bio is evaluating nula-cel in the CEDAR trial, an open-label, multi-center Phase 1/2 clinical trial designed to assess safety, engraftment success, gene correction rates, total hemoglobin, as well as other clinical and exploratory endpoints and pharmacodynamics in patients with severe SCD.

About Graphite Bio

Graphite Bio is a clinical-stage, next-generation gene editing company driven to discover and develop cures for a wide range of serious and life-threatening diseases. The company is pioneering a precision gene editing approach that has the potential to transform human health by achieving one of medicine's most elusive goals: to precisely "find & replace" any gene in the genome. Graphite Bio's UltraHDR™ gene editing platform takes CRISPR beyond cutting and harnesses the power of high-efficiency precision DNA repair, also known as homology directed repair (HDR), to precisely correct genetic mutations, replace entire disease-causing genes with functional genes or insert new genes into predetermined, safe locations. The company was co-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 about Graphite Bio by visiting www.graphitebio.com and following the company on LinkedIn and Twitter.

Forward-Looking Statements

Statements we make in this press release may include statements which 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 nula-cel (formerly GPH101) product candidate, its clinical and therapeutic potential, our plans to advance nula-cel in our Phase 1/2 CEDAR trial and to report initial proof-of-concept data, and the timing of these events, 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 the risk that we may encounter regulatory hurdles or delays, for example, in patient enrollment and dosing, and in the progress, conduct and completion of our Phase 1/2 CEDAR trial and our other planned clinical trials. These risks concerning Graphite Bio's programs and operations are described in additional detail in its periodic filings with the SEC, including its 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.

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