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 17, 2021

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.)**

Graphite Bio, Inc.
201 Haskins Way, Suite 210
South San Francisco, CA 94080
(Address of principal executive offices, including zip code)

(650) 484-0886
(Telephone number, including area code, of agent for service)

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 November 17, 2021, Graphite Bio, Inc. (the "Company") announced the enrollment of the first patient in the Company's Phase 1/2 clinical trial of GPH101, an investigational gene-edited autologous hematopoietic stem cell therapy designed to directly correct the genetic mutation that causes sickle cell disease. The Company expects to treat the first patient with GPH101 in the first half of 2022, with initial proof-of-concept data anticipated by the end of 2022.

Item 7.01. Regulation FD.

On November 17, 2021, the Company issued a press release announcing the enrollment of the first patient in the Company's Phase 1/2 clinical trial of GPH101. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information set forth in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is being furnished and 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 in this Item 7.01 and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the timing for treating the first patient in the Company's Phase 1/2 clinical trial of GPH101 and the availability of initial proof-of-concept data from the trial. The Company intends 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 is making this statement for purposes of complying with those safe harbor provisions. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the risks and uncertainties detailed in the Company's periodic filings with the Securities and Exchange Commission, including but not limited to the Company's most recently filed periodic report, and from time to time in the Company's press releases and other investor communications. The Company is providing the information in this release as of this date and does not undertake any obligation to update any forward-looking statements contained in this release as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated November 17, 2021 entitled "Graphite Bio Enrolls First Patient in Phase 1/2 Clinical Trial of 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: November 17, 2021

By: /s/ Philip P. Gutry

Philip P. Gutry
Chief Business Officer

Graphite Bio Enrolls First Patient in Phase 1/2 Clinical Trial of GPH101 for Sickle Cell Disease

GPH101 designed to directly correct the genetic mutation responsible for sickle cell disease

First patient expected to be treated in first half of 2022, with initial proof-of-concept data anticipated by end of 2022

SOUTH SAN FRANCISCO, Calif., November 17, 2021 – Graphite Bio, Inc. (Nasdaq: GRPH), a clinical-stage, next-generation gene editing company focused on therapies that harness targeted gene integration to treat or cure serious diseases, today announced that the first patient has been enrolled in the company's Phase 1/2 clinical trial of GPH101, an investigational gene-edited autologous hematopoietic stem cell therapy designed to directly correct the genetic mutation that causes sickle cell disease (SCD). The company expects to treat the first patient with GPH101 in the first half of 2022, with initial proof-of-concept data anticipated by the end of 2022.

"GPH101 is the first investigational therapy to enter clinical development that uses our next-generation gene editing platform technology to directly correct the mutation in the beta-globin gene that causes sickle cell disease," said Josh Lehrer, M.Phil., M.D., chief executive officer at Graphite Bio. "Using our gene correction approach, we have demonstrated in preclinical studies an ability to decrease the production of harmful sickle hemoglobin and restore the expression of normal adult hemoglobin. This approach has the potential to restore normal physiology and is viewed as the gold standard for curing sickle cell disease. We are thrilled that our first patient is now enrolled in our CEDAR clinical trial, and we look forward to evaluating GPH101's potential as we continue to advance its development with urgency in hopes of delivering a curative therapy to the sickle cell community."

The CEDAR trial is an open-label, multi-center Phase 1/2 clinical trial of GPH101 designed to evaluate the safety, engraftment success, gene correction rates, total hemoglobin, as well as other clinical and exploratory endpoints and pharmacodynamics of GPH101 in patients with severe SCD. The trial will enroll approximately 15 adult and adolescent participants at up to five clinical trial sites in the United States.

Graphite Bio will present information about the CEDAR trial at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition, being held virtually and in Atlanta December 11-14. The company's poster presentation will take place on Saturday, Dec. 11 at 5:30-7:30 p.m. ET.

About Sickle Cell Disease (SCD)
SCD is a serious, life-threatening inherited blood disorder that affects approximately 100,000 people in the United States and millions of people around the world, making it the most prevalent monogenic disease worldwide. SCD is caused by a single mutation in the beta-globin gene that leads red blood cells to become misshapen, resulting in anemia, blood flow blockages, intense pain, increased risk of stroke and organ damage, and reduced life span of approximately 20-30 years. Despite advancements in treatment and care, progressive organ damage continues to cause early mortality and severe morbidity, highlighting the need for curative therapies.

About GPH101
GPH101 is an investigational next-generation gene-edited autologous hematopoietic stem cell (HSC) therapy designed to directly correct the genetic mutation that causes sickle cell disease (SCD). GPH101 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 normal adult hemoglobin (HbA) expression, thereby potentially curing SCD.

Graphite Bio is evaluating GPH101 in the CEDAR trial, an open-label, multi-center Phase 1/2 clinical trial designed to assess the 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 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. Graphite Bio is pioneering a precision gene editing approach that could 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 allows it to precisely correct mutations, replace entire disease-causing genes with normal 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.

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 the clinical and therapeutic potential of our gene editing platform and our product candidates, and the timing for treating the first patient in the Phase 1/2 CEDAR trial of GPH101 and the availability of initial proof-of-concept data, 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 expectations, estimates and projections 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 delays in patient enrollment and in the initiation, conduct and completion of our planned clinical trials. These risks concerning Graphite Bio's programs and operations are described in additional detail in its periodic filings with the U.S. Securities and Exchange Commission, including but not limited to the Company's most recently filed periodic report. Graphite Bio is providing the information in this press release as of this date and explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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