UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K/A
(Amendment No. 1)

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 16, 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.)

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)

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. ☐

Explanatory Note

This Amendment No. 1 on Form 8-K/A is an amendment to the Current Report on Form 8-K of Graphite Bio, Inc. filed on May 16, 2022 (the "Original Form 8-K"). Following the initial filing of the Original Form 8-K, the registrant discovered that Item 8.01 was inadvertently tagged in the submission as Item 2.02. The Registrant is amending the Original Form 8-K solely to correct the item tag from Item 2.02 to Item 8.01. No disclosure has changed from the Original Form 8-K.

Item 8.01. Other Events.

On May 16, 2022, Graphite Bio, Inc. (the "Company") issued a press release titled "Graphite Bio Presents Preclinical Gene Replacement Data for GPH102 for Beta-Thalassemia at the ASGCT 25th Annual Meeting." 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.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated May 16, 2022 entitled "Graphite Bio Presents Preclinical Gene Replacement Data for GPH102 for Beta-Thalassemia at the ASGCT 25th Annual Meeting."
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: July 13, 2022

By: /s/ Alethia Young

Alethia Young
Chief Financial Officer

Exhibit 99.1

Graphite Bio Presents Preclinical Gene Replacement Data for GPH102 for Beta-thalassemia at the ASGCT 25th Annual Meeting

Trial-in-progress poster of Phase 1/2 CEDAR trial evaluating GPH101 for sickle cell disease to be presented as an encore

SOUTH SAN FRANCISCO, Calif., May 16, 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 treat or cure serious diseases, today presented preclinical data for GPH102, the company's differentiated gene replacement program for beta-thalassemia, in an oral presentation at the American Society of Gene and Cell Therapy (ASGCT) 25th Annual Meeting. The hybrid meeting is taking place virtually and at the Walter E. Washington Convention Center in Washington, D.C., from May 16-19.

"Our gene replacement program for beta-thalassemia is a natural application of our powerful gene editing platform and the result of our own internal discovery efforts. With GPH102, we aim to replace the mutated beta-globin gene with a functional gene. This is the first approach that has the potential to normalize the hundreds of mutations in the beta-globin gene that cause beta-thalassemia and restore adult hemoglobin expression to healthy levels, thereby directly addressing the underlying cause of the disease," said Josh Lehrer, M.D., M.Phil., chief executive officer of Graphite Bio. "We believe our gene replacement approach could be the optimal way to treat beta-thalassemia and potentially provide a definitive cure to patients. We look forward to continuing to build the body of preclinical evidence supporting this program and plan to submit an Investigational New Drug Application by mid-2024, pending feedback from regulatory authorities."

GPH102: An optimal approach to treat beta-thalassemia by replacing the mutated beta-globin gene with a functional gene

The oral presentation (Abstract #66) provides an overview of the development of a precise beta-globin gene replacement strategy that could be the optimal approach to treat beta-thalassemia, a genetic disorder caused by more than 300 mutations in the beta-globin gene. By replacing the mutated beta-globin gene with a functional gene, GPH102 aims to restore expression of adult hemoglobin to levels similar to those who do not have the disease.

Graphite Bio researchers sought to develop a gene replacement approach using the company's UltraHDR™ gene editing platform to overcome the challenge of achieving high levels of gene replacement that result in high adult hemoglobin (HbA) expression. In particular, where the donor gene shares high nucleotide sequence identity with the targeted mutant allele, undesired partial recombination events can lead to incomplete or unsuccessful integration of the entirety of the intended donor sequence.

To address this challenge, researchers devised a novel knock-in strategy that uses heterologous introns and diverged coding sequences. These were screened using a T2A-EGFP reporter system, which served as a predictive screening tool for protein expression. After screening 39 versions of T2A-EGFP-tagged beta-globin coding sequences containing various heterologous introns and polyadenylation signals, two top DNA donor candidates for beta-globin gene replacement were identified. The selected DNA donors were then further optimized by truncating the introns to create a smaller donor cassette.

The optimized DNA donors were tested in hematopoietic stem and progenitor cells (HSPCs) from sickle cell disease (SCD) patients, which served as a therapeutically relevant model to determine if the DNA donors can effectively replace a dysfunctional beta-globin gene. Use of the optimized DNA donors resulted in homology directed repair (HDR) rates of up to 40% in the sickle cell HSPCs and restoration of HbA expression. These results support further advancement of GPH102 for beta-thalassemia.

An encore of this abstract detailing the preclinical gene replacement data for GPH102 was accepted as a poster presentation at the European Hematology Association (EHA) 2022 Hybrid Congress, which will take place virtually and at the Messe Wien Exhibition & Congress Center in Vienna from June 9-12. The encore abstract is now available online at https://ehaweb.org with additional details following:

Abstract P1436: Development of a Beta-Globin Gene Replacement Strategy as a Therapeutic Approach for Beta-Thalassemia
Presenting Author: Beeke Wienert, Ph.D., associate director, gene engineering, Graphite Bio
Date and Time: Friday, June 10, 16:30-17:45 CEST

GPH101: Gene correction for sickle cell disease Phase 1/2 CEDAR trial encore poster presentation

At the ASGCT Annual Meeting, Graphite Bio will present an encore of the trial-in-progress poster (Abstract #806) for the company's Phase 1/2 CEDAR trial for GPH101, an investigational therapy designed to directly correct the genetic mutation responsible for SCD. The CEDAR trial is an open-label, single-dose, multi-site clinical trial evaluating GPH101 in approximately 15 participants with severe SCD. The trial-in-progress poster is being presented by John DiPersio, M.D., Ph.D., professor of medicine at Washington University School of Medicine and an investigator in the CEDAR trial. Information about this trial was previously presented at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition in December 2021.

About GPH102 for Beta-Thalassemia

GPH102 is Graphite Bio's research program for the treatment of beta-thalassemia, one of the most common autosomal recessive disorders with approximately 68,000 people worldwide born with the disease each year. Beta-thalassemia is a genetic blood disorder characterized by reduced production of beta-globin, a protein that forms oxygen-carrying hemoglobin with alpha-globin. Individuals with the most severe form of beta-thalassemia fail to produce functional beta-globin, which results in severe anemia and transfusion dependency. Using Graphite Bio's gene replacement approach, GPH102 is designed to replace the mutated beta-globin gene with a functional gene and restore adult hemoglobin (HbA) expression to levels similar to individuals who do not have the disease.

About GPH101 for Sickle Cell Disease

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). 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. 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 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 the power of high-efficiency precision gene repair 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 UltraHDR™ gene editing platform is designed 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.

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 UltraHDR™ gene editing platform and our GPH101 and GPH102 product candidates, including our plans to submit an Investigational New Drug Application for GPH102, and the timing thereof, 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.

###

Company Contact:

Stephanie Yao
VP, Communications and Investor Relations
443-739-1423
syao@graphitebio.com

Investors:

Stephanie Ascher
Stern IR, Inc.
212-362-1200
ir@graphitebio.com

Media:

Julia Stern
Real Chemistry
763-350-5223
media@graphitebio.com