

**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 03, 2022

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

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 3, 2022, Graphite Bio, Inc. issued a press release titled “Graphite Bio Announces Abstracts Accepted for Upcoming 64th ASH Annual Meeting and Exposition.” 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 November 3, 2022 titled “ Graphite Bio Announces Abstracts Accepted for Upcoming 64th ASH Annual Meeting and Exposition ”
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 hereunto duly authorized.

Graphite Bio, Inc.

Date: November 3, 2022

By:

/s/ Alethia Young
Alethia Young
Chief Financial Officer

Graphite Bio Announces Abstracts Accepted for Upcoming 64th ASH Annual Meeting and Exposition

SOUTH SAN FRANCISCO, Calif., November 3, 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 announced that two abstracts have been accepted as part of the 64th American Society of Hematology (ASH) Annual Meeting and Exposition, which will be held December 10-13 in New Orleans and broadcast virtually from the Ernest N. Morial Convention Center.

“Our ASH abstracts demonstrate the potential of our UltraHDR™ gene editing platform to provide highly differentiated and potentially curative outcomes for patients living with serious genetic diseases. In beta-thalassemia, using our unique gene replacement approach, we have demonstrated an ability to replace the entire non-functional beta-globin gene to restore the expression of healthy adult hemoglobin, thereby potentially curing the disease,” said Josh Lehrer, M.D., M. Phil., chief executive officer of Graphite Bio. “Additionally, we developed a single-cell RNA sequencing method to help us assess potential gene-editing outcomes in the immature red blood cells of people treated with nula-cel, our investigational therapy for sickle cell disease. Nula-cel is currently being evaluated in an early-stage clinical trial, and we look forward to sharing initial proof-of-concept data for nula-cel in the middle of next year.”

The ASH abstracts are now available at www.hematology.org. Details of the Graphite Bio publications are as follows:

Publication #5965: Development of a Beta-Globin Gene Replacement Strategy As a Beta-Thalassemia Therapy

Author: Kirby Wallace, Ph.D., scientist II

Location: Online publication

This abstract describes how Graphite Bio researchers developed a precise beta-globin gene replacement approach using the company’s UltraHDR™ gene editing platform to potentially treat beta-thalassemia, a genetic disorder caused by more than 300 mutations in the beta-globin gene. The researchers devised a novel knock-in strategy that uses heterologous introns and diverged coding sequences to overcome the challenges of being able to replace the diversity of mutations in the beta-globin gene that cause beta-thalassemia while restoring physiological adult hemoglobin (HbA) expression. By adding heterologous introns to the coding sequence, the researchers were able to successfully replace the entire nonfunctional beta-globin gene and restore physiologic HbA expression, offering a potential differentiated approach for treating beta-thalassemia.

Poster Session 801: Gene Therapies: Poster II

Abstract #3468: Single-Cell RNA Sequencing of Sickle Cell Reticulocytes to Identify Beta-Globin Genotypes and Associated Gene Expression Differences

Presenting Author: Sebastian Treusch, Ph.D., director, genomics

Date and Time: Sunday, December 11, 6-8 p.m. CT

Location: Hall D

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.

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 GPH102

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 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 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 the clinical and therapeutic potential of our gene editing platform and our product candidates, our expectations with respect to the clinical development of nula-cel, including availability of initial proof-of-concept data from our Phase 1/2 CEDAR trial, and the potential of our GPH102 research program for the treatment of beta-thalassemia, 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 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.

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