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 10, 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)

279 East Grand Avenue, Suite 430
South San Francisco, CA 94080
(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 November 10, 2021, Graphite Bio, Inc. issued a press release announcing its financial results for the third quarter ended September 30, 2021. 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.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated November 10, 2021 titled "Graphite Bio Reports Recent Business Progress and Third Quarter 2021 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: November 10, 2021

By: /s/ Philip P. Gutry

Philip P. Gutry
Chief Business Officer

Exhibit 99.1

Graphite Bio Reports Recent Business Progress and Third Quarter 2021 Financial Results

Recruitment for Phase 1/2 CEDAR clinical trial of GPH101 for sickle cell disease underway at multiple sites

Details about CEDAR trial to be presented at 63rd ASH Annual Meeting and Exposition in December

$395.0 million in cash, cash equivalents and restricted cash as of September 30, 2021

SOUTH SAN FRANCISCO, Calif., Nov. 10, 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 reported recent business progress and third quarter 2021 financial results.

"We continue to remain focused on execution as we work to carry out our vision to develop potential one-time cures for patients with a wide range of serious and life-threatening diseases, starting with sickle cell disease," said Josh Lehrer, M.Phil., M.D., chief executive officer of Graphite Bio. "We were pleased to present preclinical data that are foundational to our sickle cell disease program at the Sickle Cell Disease Association of America's National Convention last month, and we are excited to share details about our Phase 1/2 CEDAR trial of GPH101 during a poster presentation at the ASH Annual Meeting next month. Importantly, recruitment for our CEDAR trial is underway at multiple clinical trial sites, keeping us on track to enroll our first patient before the end of the year."

Recent Highlights and Upcoming Milestones

- Activated multiple clinical trial sites for Graphite Bio's Phase 1/2CEDAR trial of GPH101, an investigational therapy designed to directly correct the genetic mutation responsible for sickle cell disease (SCD). With patient recruitment and activation of additional clinical trial sites underway, the company remains on track to enroll the first patient in the trial before the end of the year and expects to report initial proof-of-concept data by the end of 2022.
- Received acceptance of an abstract at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition, which will take place December 11-14 virtually and in Atlanta. Graphite Bio will present details about the company's Phase 1/2 CEDAR trial of GPH101.
- Presented preclinical data for GPH101 at the 49th Annual SCDAA National Convention. The data presented support the ability of Graphite Bio's gene editing platform to precisely and efficiently correct the underlying SCD-causing mutation to reduce sickle hemoglobin production and restore adult hemoglobin expression to levels that are considered potentially curative. These data are foundational to the company's SCD program and support the evaluation of GPH101 in the Phase 1/2 CEDAR trial.

Third Quarter Financial Highlights

- **Cash, Cash Equivalents and Restricted Cash:** As of September 30, 2021, cash, cash equivalents and restricted cash totaled $395.0 million, which includes approximately $33.2 million in net proceeds received on July 2 from the full exercise of the underwriters' option to purchase additional shares from the company's upsized IPO.
- **R&D Expenses:** Research and development expenses were $8.7 million for the third quarter of 2021, which includes $0.8 million in stock-based compensation expense.
- **G&A Expenses:** General and administrative expenses were $5.9 million for the third quarter of 2021, which includes $1.6 million in stock-based compensation expense.
- **Net Loss:** Net loss was $14.6 million, or $0.28 per basic and diluted share, for the three months ended September 30, 2021.

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 by

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 enrollment of 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.

GRAPHITE BIO, INC.
Condensed Statements of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine months ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses*:				
Research and development	$ 8,683	$ 2,310	$ 26,727	$ 2,733
General and administrative	5,919	1,454	14,776	2,444
Total operating expenses	14,602	3,764	41,503	5,177
Loss from operations	(14,602)	(3,764)	(41,503)	(5,177)
Other income (expense), net:				
Other income (expense), net:	10	—	14	—
Change in fair value of the Series A redeemable convertible preferred stock tranche liability	—	380	(10,341)	380
Related party convertible note interest expense	—	—	—	(40)
Total other income (expense), net	10	380	(10,327)	340
Net loss and comprehensive loss	$ (14,592)	$ (3,384)	$ (51,830)	$ (4,837)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.28)	$ (1.00)	$ (2.51)	$ (2.53)
Weighted-average shares used in computing net loss per share attributable to common stockholders - basic and diluted	52,769,916	3,382,118	20,668,560	1,908,759
*** Includes stock-based compensation as follows:**				
Research and development	$ 824	$ 6	$ 1,635	$ 6
General and administrative	1,550	30	3,790	30
Total stock-based compensation expense	$ 2,374	$ 36	$ 5,425	$ 36

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

	September 30, 2021	December 31, 2020
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 394,804	$ 19,782
Restricted cash	149	35
Prepaid expenses and other current assets	6,276	1,286
Total current assets	401,229	21,103
Property, plant, and equipment, net	5,834	1,461
Operating lease right-of-use assets	9,077	—
Other assets	12	—
Total assets	$ 416,152	$ 22,564
Liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,763	$ 630
Accrued compensation	1,659	466
Accrued research costs	1,730	1,764
Accrued expenses and other current liabilities	1,314	126
Current portion of operating lease liabilities	4,806	—
Series A redeemable convertible preferred stock tranche liability	—	29,062
Total current liabilities	11,272	32,048
Non-current operating lease liabilities	4,684	—
Other liabilities	64	316
Total liabilities	16,020	32,364
Series A redeemable convertible preferred stock	—	55,608
Stockholders' equity (deficit):		
Common stock	1	—
Additional paid-in capital	522,552	5,183
Accumulated deficit	(122,421)	(70,591)
Total stockholders' equity (deficit)	400,132	(65,408)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 416,152	$ 22,564

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