UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark one)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2023

OR

□ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission File Number: 001-40532

GRAPHITE BIO, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**2836**	**84-4867570**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

611 Gateway Blvd, Suite 120
South San Francisco, CA, 94080
(650) 484-0886
(Address, including zip code and telephone number, including area code, of Registrant's principal executive offices)

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, par value $0.00001 per share	GRPH	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes □ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes □ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No □

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No □

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	□	Accelerated filer	□
Non-accelerated filer	☒	Smaller reporting company	☒
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. □

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. □

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. □

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☒ No □

As of June 30, 2023, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $150.8 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market of $2.60 per share

As of February 23, 2024, the registrant had 58,236,926 shares of common stock, $0.00001 par value per share, outstanding.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Form 10-K"), including its section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Form 10-K may include, but are not limited to, statements about:

- the risk that the conditions to closing of the potential merger with LENZ Therapeutics, Inc. ("LENZ"), announced on November 15, 2023 (the "merger") are not satisfied, including failure to obtain stockholder approval for the transactions;
- the timing, receipt and terms and conditions of any required governmental or regulatory approvals of the merger that could cause us or LENZ to abandon the merger;
- our ability to meet expectations regarding the timing and completion of the merger;
- the risk that the agreement to issue certain institutional investors shares of our common stock immediately following the merger in a private placement transaction (the "Graphite private placement") is not completed in a timely manner or at all;
- uncertainties as to the timing and costs of the consummation of the transaction and the ability of each of us and LENZ to consummate the transaction, including the Graphite private placement;
- statements regarding the special cash dividend that we may pay to our stockholders in connection with the completion of the merger;
- risks related to our continued listing on the Nasdaq Global Stock Market until closing of the proposed merger;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the agreement with LENZ relating to the merger (the "Merger Agreement");
- the fact that under the terms of the Merger Agreement, we are restrained from soliciting other acquisition proposals during the pendency of the merger, except in certain circumstances;
- the effect of the announcement or pendency of the merger on our business relationships, operating results and business generally, including disruption of our management's attention from ongoing business operations due to the merger and potential adverse reactions or changes to business relationships resulting from the announcement or completion of the transaction;
- the risk that the Merger Agreement may be terminated in circumstances that require us to pay a termination fee;
- the outcome of any legal proceedings that may be instituted against us, LENZ or any of our respective directors or officers related to the Merger Agreement or the transactions contemplated thereby;
- our ability to protect our intellectual property rights;
- competitive responses to the merger;
- legislative, regulatory, political and economic developments beyond our control
- the initiation, timing and success of clinical trials for our product candidates;
- success in retaining, or changes required in, our officers, key employees or directors;
- the need to hire additional personnel and ability to attract and retain such personnel;
- our public securities' potential liquidity and trading;
- the timing, scope and likelihood of regulatory filings and regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- our plans and ability to manufacture our product candidates in conformity with the requirements of the U.S. Food and Drug Administration (the "FDA") and to scale up manufacturing of its product candidates to commercial scale, if approved;

- our reliance on third-party contract development and manufacturer organizations to manufacture and supply product candidates;
- the beneficial characteristics, and the potential safety, efficacy and therapeutic effects of our product candidates;
- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise;
- our plans and ability to successfully commercialize product candidates and, if approved, the rate and degree of market acceptance of such product candidates; and
- developments and projections relating to our competitors or industry.

In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled "Risk Factors" and elsewhere in this Form 10-K. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those expressed or implied by the forward-looking statements. No forward-looking statement is a promise or a guarantee of future performance.

The forward-looking statements in this Form 10-K represent our views as of the date of this Form 10-K. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Form 10-K.

This Form 10-K may include statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We have not independently verified the information contained in such sources.

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. All other trademarks or trade names referred to in this Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-K may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Summary of Risk Factors

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the "Risk Factors" section of this Form 10-K. These risks include, but are not limited to, the following:

- Failure to complete, or delays in completing, the potential merger with LENZ, announced on November 15, 2023 could materially and adversely affect our results of operations, business, financial results and/or common stock price.
- The exchange ratio will not change or otherwise be adjusted based on the market price of our common stock as the exchange ratio depends on our net cash at the closing and not the market price of our common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed. Failure to complete the merger may result in us paying a termination fee to LENZ, and could harm our common stock price and future business and operations.
- Some of our and LENZ directors and executive officers may have interests in the merger that are different from our stockholders and that may influence them to support or approve the merger without regard to our stockholders' interests.
- Our stockholders and LENZ stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger.
- If the merger is not completed, our stock price may decline significantly.
- We have incurred significant losses since our inception, we expect to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.
- Our limited operating history may make it difficult for you to evaluate the performance of our business to date and to assess our future viability.

- We have never generated revenue from product sales, may never generate any revenue from product sales and may never become profitable.
- We will need substantial additional funding. If we are unable to raise capital when needed on acceptable terms, or at all, we would be forced to delay, reduce, or terminate our research and product development programs, future commercialization efforts or other operations;
- We may not be successful in completing the merger or any strategic transactions we may consummate in the future could have negative consequences.
- If we are successful in completing the merger, we may be exposed to other operational and financial risks.
- If the merger is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- Our ability to consummate the merger depends on our ability to retain our employees required to consummate such transaction.
- Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected, and could disrupt our business. We may not be successful in our efforts to identify and develop potential product candidates. If these efforts are unsuccessful, it may never become a commercial stage company or generate any revenues.
- Even if we complete the necessary clinical trials, we cannot predict when, or if, it will obtain regulatory approval to commercialize a product candidate we may develop in the United States or any other jurisdiction, and any such approval may be for a more narrow indication than we seek.
- We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, less expensive or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize our product candidates.
- If we are unable to obtain and maintain patent and other intellectual property protection for any product candidates we develop and for our platform technology, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates, and our platform technology may be adversely affected.
- Our rights to develop and commercialize our gene editing platform technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.
- The intellectual property landscape around the technologies we use or plan to use, including gene editing technology, is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent, delay or otherwise interfere with our product discovery and development efforts.
- We expect to rely on third parties to conduct clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.
- We may enter into collaborations with third parties for the research, development, and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.
- With certain of our operating assets sold, written-off or disposed of, we are considered a “shell company” under federal securities laws and are subject to more stringent reporting requirements.

PART I

Item 1. Business.

Overview

We have historically been a clinical-stage, next-generation gene editing company. In January 2023, we announced a voluntary pause of our Phase 1/2 CEDAR study of nulabeglogene autogedtemcel ("nula-cel"), for sickle cell disease ("SCD") due to a serious adverse event in the first patient dosed, which we concluded is likely related to study treatment. Nula-cel was being developed as a highly differentiated approach to treating SCD, with the potential to directly correct the mutation that causes SCD and restore normal adult hemoglobin expression.

In February 2023, we announced our decision to discontinue the development of nula-cel and initiate a process to explore strategic alternatives. As a result of this decision, we announced a corporate restructuring that resulted in an approximately 78.1% reduction in our workforce. As part of the corporate restructuring, we also elected not to utilize the portion of our facilities space subject to our lease agreement with Bayside Area Development for purposes of our own operations.

In August 2023, we entered into a license and option agreement (the "LOA"), pursuant to which we granted Kamau Therapeutics, Inc. ("Kamau") an option to acquire certain of our technology and intellectual property related to our nula-cel program and related pre-clinical platform assets. We also entered into an asset purchase agreement pursuant to which we transferred to Maro Bio, Inc. ("Maro") our pre-clinical non-genotoxic conditioning program, including technology and intellectual property, while we continued to explore strategic alternatives. On September 12, 2023, we entered into an amendment to the LOA with Kamau, under which we agreed to assign certain contracts to Kamau prior to exercise of the option. Following these transactions, we have no remaining ongoing development programs. However, we continue to hold, maintain and preserve the technology, licenses and intellectual property related to our nula-cel program and related preclinical platform assets subject to Kamau's option using our remaining workforce.

In October 2023, we entered into a sublease for a portion of the facility leased to us by Bayside Area Development, as well as an amendment to the master lease, which provided for an accelerated termination of the lease. The amendment to the master lease also provided for a release of liabilities under the master lease, as well as a release of liabilities under the new sublease upon payment of a lump sum at the time of signing. Following this transaction, we are no longer obligated for any rent payments under our lease with Bayside Area Development.

After a comprehensive review of strategic alternatives, including identifying and reviewing potential candidates for a strategic transaction, on November 14, 2023, we entered into the merger agreement (the "Merger Agreement") with LENZ, pursuant to which our newly created subsidiary (the "Merger Sub") will merge with and into LENZ, with LENZ surviving as our wholly-owned subsidiary. The merger was unanimously approved by our board of directors, and our board resolved to recommend approval of the Merger Agreement to our stockholders. The closing of the merger is subject to approval by our and LENZ's stockholders, as well as other customary closing conditions, including the effectiveness of a registration statement filed with the SEC in connection with the transaction and Nasdaq's approval of the listing of the shares of our common stock to be issued in connection with the transaction. If the merger is completed, the business of LENZ will continue as the business of the combined company.

Our future operations are highly dependent on the success of the merger and there can be no assurances that the merger will be successfully consummated. There can be no assurance that the strategic review process or any transaction relating to a specific asset, including the merger or any asset sale, will result in us pursuing such a transaction(s), or that any transaction(s), if pursued, will be completed on terms favorable to us and our stockholders in our existing entity or any possible entity that results from a combination of entities. If the strategic review process is unsuccessful, our board of directors may decide to pursue a dissolution and liquidation of our business.

Our Historical Operations and Product Candidates

Our historical technology was built on first-generation proven CRISPR technology to achieve high rates of targeted gene integration. Our platform technology includes patent rights and proprietary technology exclusively licensed from The Board of Trustees of the Leland Stanford Junior University ("Stanford") and developed in the Stanford laboratories of two of our scientific founders, both pioneers in gene therapy and gene editing: Matthew Porteus, M.D., Ph.D., and Maria Grazia Roncarolo, M.D.

Our approach was designed to have broad therapeutic applications and enable high-efficiency targeted gene integration in a wide range of primary human cell types. In the initial programs, we applied our approach ex vivo in a patient's own hematopoietic stem cells ("HSCs") which are reinfused after gene integration ("autologous HSCT"). HSCs are multipotent stem and progenitor cells that can give rise to all cells of the blood and immune system and have proven their curative potential across dozens of diseases as demonstrated by allogenic HSC transplant ("allo-HSCT"). We considered that our technology could be applied in the following three key settings: Gene Correction, Gene Replacement, and Targeted Gene Insertion.

Gene Correction: nula-cel for the Treatment of SCD

Nula-cel was our lead product candidate, a next generation gene-edited autologous HSC product candidate that was designed to directly correct the mutation responsible for SCD. The mortality and morbidity associated with SCD, all caused by a single mutation, has made

curing SCD by direct gene correction a dream of many clinicians. Indeed, multiple genetic therapies are in development to address SCD, but due to technical limitations of other approaches, these therapies are primarily focused on expressing alternate hemoglobin genes such as fetal hemoglobin or a transgenic hemoglobin. Our approach was the first in industry to directly correct the SCD-causing mutation to restore normal adult hemoglobin expression. In January 2023, we announced a voluntary pause of our Phase 1/2 CEDAR study of our lead product candidate nula-cel due to a serious adverse event in the first patient dosed, which we concluded was likely related to study treatment. In February 2023, we announced our decision to discontinue the development of nula-cel. We continue to maintain and preserve the technology, licenses and intellectual property related to the program and related preclinical platform assets.

Gene Replacement: GPH102 for the Treatment of Beta-Thalassemia and GPH201 for the Treatment of XSCID

GPH102 was our research program for the treatment of beta-thalassemia, leveraging our gene replacement platform technology by replacing one or both copies of the mutated beta-globin ("HBB") gene through HDR to restore HgbA expression to levels similar to healthy individuals who do not have disease or to individuals who carry one copy of the mutated HBB gene ("beta-thalassemia trait"). Alternative genetic therapies are in clinical development to address beta-thalassemia, but in general due to technical limitations, these potential therapies are indirect and are focused on expressing alternate hemoglobin genes such as fetal hemoglobin ("HgbF") or a transgenic hemoglobin without correcting the underlying genetic lesions. Given this program leveraged the same gene editing platform technology as nula-cel, we do not currently intend to continue development of this program.

GPH201 was an investigational next generation gene-edited autologous HSC product candidate for the treatment of XSCID. XSCID is a rare, life-threatening disease where multiple mutations in a single gene prevent the formation of multiple interleukin receptors resulting in defects in immune cell formation. As a consequence, severe, persistent, or recurrent early-onset infections are the hallmark of XSCID. Without treatment, infants with XSCID usually do not live beyond one year of age. Allogeneic HSCT that results in functional reconstitution of the immune system is the only curative treatment for XSCID, but the procedure has limitations including identification of an HLA matched sibling donor as well as potential complications of GvHD and subsequent poor immune reconstitution. An effective targeted genetic therapy would need to replace a large portion of the IL2RG gene in order to be effective across XSCID patients with different IL2RG mutations. The goal of GPH201 was to replace a sufficient quantity of a patient's HSCs with gene edited cells to eliminate the symptoms of, and potentially cure, XSCID. Given this program leveraged the same gene editing platform technology as nula-cel, we have terminated the development of this program.

Targeted Gene Insertion with Therapeutic Protein Production ("CCR5 Safe Harbor Locus"): GPH301 for the Treatment of Gaucher Disease

Our GPH301 product candidate was a next generation gene-edited autologous HSC product candidate from its CCR5 locus technology for the treatment of Gaucher disease, an autosomal recessive genetic disorder caused by mutations in the GBA gene which encodes GCase. GCase is an enzyme responsible for degrading glucocerebroside, a cell membrane building block, into glucose and lipids within lysosomes of cells. In patients with Gaucher disease, lack of GCase leads to accumulation of glucocerebroside in macrophages resulting in inflammation that impacts the liver, spleen and bone marrow. Given this program leverages the same gene editing platform technology as nula-cel, we have terminated the development of this program.

Manufacturing

We have no commercial manufacturing capabilities. For our initial clinical programs, we used qualified third-party contract manufacturing organizations with relevant manufacturing experience in genetic medicines. We established manufacturing processes for nula-cel and established relationships with third-party manufacturers with capabilities to manufacture the necessary Drug Substance and Drug Product in accordance with current Good Manufacturing Practices ("cGMP"). Since we have no ongoing development programs, we are in the process of terminating our manufacturing-related relationships. However, we continue to hold, maintain and preserve the technology, licenses and intellectual property related to our nula-cel program and related preclinical platform assets subject to Kamau's option using our remaining workforce.

Competition

We have historically competed in the segments of the pharmaceutical, biotechnology, and other related markets that utilize technologies encompassing genomic medicines to create therapies, including gene editing and gene therapy. There are several other companies advancing gene editing and gene therapy product candidates in preclinical or clinical development in sickle cell disease, including Beam Therapeutics Inc., bluebird bio, Inc., Cellectis SA, CRISPR Therapeutics AG, and Editas Medicine, Inc. Companies advancing gene editing and gene therapy programs in beta-thalassemia include bluebird bio, Inc., CRISPR Therapeutics AG, and Edigene Inc. Companies advancing gene therapy programs in XSCID include Mustang Bio, Inc. Companies advancing gene therapy programs in Gaucher disease include AVROBio, Inc. and Freeline Therapeutics Holdings plc. Companies advancing gene editing and gene therapy programs in preclinical development for AAT deficiency include Beam Therapeutics Inc., Editas Medicine, Inc., Intellia Therapeutics, Inc., Krystal Biotech Inc., Apic Bio Inc., and LogicBio Therapeutics Inc. Companies combining CRISPR with HDR (homology directed repair) include CRISPR Therapeutics AG, which, for oncology applications, inserts a chimeric antigen receptor ("CAR") construct into the TCR alpha constant ("TRAC") locus in T-cells using HDR. Additionally, an academic collaboration between the University of California, San Francisco and the University of California, Los Angeles is seeking to correct the sickle cell mutation using CRISPR

followed by delivery of a single-stranded oligonucleotide DNA donor to potentially harness HDR. Because these competitors, as well as other companies and research institutions, hold numerous patents in this field, it is possible that these or other third parties could allege they have patent rights encompassing our product candidates, technologies or methods. For more information regarding competition and intellectual property, please see the section titled *"Risk Factors—Risks Related to Our Intellectual Property."*

Intellectual Property

Our business depends in part on our ability to preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating any valid and enforceable intellectual property rights of others. In addition, our historical business depended in part on our ability to obtain and maintain proprietary protection for our platform technology, our programs, and know-how related to our business, and defend and enforce our intellectual property rights, in particular, our patent rights. For more information regarding the risks related to our intellectual property, please see section titled *"Risk Factors—Risks Related to Our Intellectual Property."*

Our wholly owned and our in-licensed patent applications cover various aspects of our genome editing platform and proprietary components, as well as our programs directed to genome modification using chemically modified guide RNAs. We do not intend to continue to pursue patent protection on this technology.

As of December 31, 2023, we in-licensed from Stanford two issued U.S. patents and two pending U.S. patent applications, issued patents in Australia, Europe and China, and pending patent applications in Australia, Canada, China, Japan and South Korea directed to methods of genome modification using chemically modified guide RNA in primary cells. The in-licensed patents and patent applications, which are jointly owned by Stanford and Agilent, also relate to methods of using such genome modifications for therapeutic indications such as SCD and thalassemia. Our current in-licensed patents and patent applications from Stanford, if the appropriate maintenance fees are paid, are expected to expire 2036, excluding any additional term for patent term adjustments or patent term extensions. The in-licensed European patent is currently subject to an opposition proceeding at the European Patent Office ("EPO") Opposition Division, initiated by multiple opponents.

As of December 31, 2023, we in-licensed three U.S. patents, two U.S. patent applications, and patent applications in Australia, Canada, China, Europe, Japan and South Korea directed to compositions involving high-fidelity nucleases, gene editing systems using mutant Cas9 nucleases, and improved methods of gene editing thereof from IDT. Our current in-licensed patent and patent applications from IDT, if the appropriate maintenance fees are paid, are expected to expire in 2037, excluding any additional term for patent term adjustments or patent term extensions.

In August 2023, we entered into the LOA, pursuant to which we granted Kamau an option to acquire certain of our technology and intellectual property related to our nula-cel program and related pre-clinical platform assets. Our licenses from Stanford and IDT are included in the assets that are subject to the LOA and may be assigned to Kamau if and when it exercises the option.

For more information regarding our licensed patent applications, please see the sections titled *"Risk Factors—Risks Related to Our Intellectual Property."*

We also rely on trade secrets, know-how, continuing technological innovation, and confidential information to develop and maintain our proprietary position and protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have implemented measures to protect and preserve our trade secrets, such measures can be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Our Material Agreements

Exclusive License Agreement with the Board of Trustees of the Leland Stanford Junior University

In December 2020, we entered into an exclusive license agreement (the "License Agreement"), with The Board of Trustees of the Leland Stanford Junior University ("Stanford"), pursuant to which Stanford granted us a worldwide license to specified technology and patent rights to develop, manufacture and commercialize human prophylactic and therapeutic products. Other than with respect to specified, broadly applicable assays and procedures and subject to retained rights by Stanford, the license is exclusive with respect to human prophylactic and therapeutic products for the treatment of SCD, XSCID and beta thalassemia. The license is non-exclusive with respect to those broadly applicable assays and procedures and with respect to all human prophylactic and therapeutic products other than for the treatment of SCD, XSCID and beta thalassemia.

To date, pursuant to the License Agreement, we have paid an upfront license fee to Stanford of $50.0 thousand and issued to Stanford and its designees an aggregate of approximately 0.6 million shares of our common stock. The acquisition of the exclusive license, including patent rights and know-how, and clinical supplies was accounted for as an asset acquisition and as the acquired technology

and inventories did not have an alternative use, the total consideration of $2.8 million was recorded as research and development expense in the statements of operations and comprehensive loss for the year ended December 31, 2020. We are obligated to pay Stanford an annual license maintenance fee on each anniversary of the effective date of the License Agreement. The annual license maintenance fee initially is $5.0 thousand and will increase to $50.0 thousand in three increments over the first seven anniversaries of the effective date of the License Agreement. After the first commercial sale of a product falling within the scope of the license (the "Licensed Product"), the annual license maintenance fee is $200.0 thousand.

In May 2021, we issued 640,861 shares of our common stock in connection with the License Agreement. Subsequently, in June 2021, related to the License Agreement, we repurchased 624,845 shares of our common stock from investors and founders.

We are required to share with Stanford a portion of any non-royalty income we receive from sublicensing the licensed patent rights or technology, subject to specified exclusions. With respect to sublicenses granted to products for the treatment of SCD, XSCID and beta thalassemia, the portion of sublicense income we must share with Stanford varies by indication and declines from between a mid-teen to a second quartile double-digit percentage prior to the filing of an Investigational New Drug ("IND") to between a high single-digit to very low double-digit percentage upon achievement of a specified clinical milestone. With respect to sublicenses granted under the licensed technology rights and not licensed patent rights, the portion of sublicense income shared with Stanford declines from between a mid-single-digit and very low double-digit percentage prior to the filing of an IND to a low single-digit percentage after filing of an IND.

We are obligated to make payments to Stanford with respect to each Licensed Product of up to an aggregate of $12.8 million upon the achievement of certain development, regulatory and commercial milestones. Such amounts are payable only once upon the first occurrence of a particular milestone event with respect to each Licensed Product and only once with respect to each new indication covered by any of the Licensed Products.

We also are obligated to pay Stanford low single-digit royalties based on worldwide annual net sales of any Licensed Product, subject to specified reductions. We will be obligated to continue to pay royalties on a Licensed Product-by-Licensed Product and country-by-country basis, until the latest of (i) the expiration of the last valid claim under the licensed patents that covers the sale or manufacture of such Licensed Product in such country, (ii) the expiration of any period of regulatory exclusivity with respect to such Licensed Product in such country or (iii) the expiration of ten years after the first commercial sale of such Licensed Product in such country.

The term of the License Agreement expires on the later of (i) the expiration of the last patent or abandonment of the last patent application within the license patent rights or (ii) the expiration of all royalty terms with respect to Licensed Products. The License Agreement may be terminated by us at will or by Stanford if we remain in breach of the License Agreement following a cure period to remedy the breach.

We are required to use diligent efforts to manufacture, market and sell Licensed Products for the treatment of each of SCD, XSCID and beta thalassemia. In addition, we are required to achieve specified milestones by specified dates with respect to Licensed Products for the treatment of each of SCD, XSCID and beta thalassemia. If we fail to satisfy its diligence obligations, Stanford may terminate the License Agreement for its breach.

In August 2023, we entered into the LOA, pursuant to which we granted Kamau an option to acquire certain of our technology and intellectual property related to our nula-cel program and related pre-clinical platform assets. The License Agreement is included in the assets that are subject to the LOA and may be assigned to Kamau if and when it exercises the option.

Option Agreements with Stanford

First Option Agreement

In January 2021, we entered into an option agreement (the "First Option Agreement") with Stanford, pursuant to which Stanford granted us the right to obtain a license to specified patent rights relating to human prophylactic and therapeutic products. The option may be extended to specified technology at a later date and upon our agreement with Stanford. We may exercise the option in whole or in part to obtain a license under one or more of the optioned patent rights. Subject to retained rights by Stanford, the license is exclusive with respect to human prophylactic and therapeutic products for the treatment of SCD, XSCID and beta thalassemia and non-exclusive with respect to all other human prophylactic and therapeutic products.

Pursuant to the First Option Agreement, we agreed to grant Stanford 132,137 shares of our common stock if we exercise the option and execute and deliver an amendment to the License Agreement that incorporates the optioned patent rights and any optioned technology. Other than such shares of our common stock and a license execution fee of $10.0 thousand if we exercise the option with respect to a particular optioned patent right, no additional payments have been or will be made by us to Stanford under the First Option Agreement or upon the execution of an amendment to the License Agreement that incorporates the optioned patent rights and any optioned technology. The terms of the License Agreement will apply to any Licensed Products falling within the patent rights and technology licensed by us upon exercise of the option.

The term of the First Option Agreement expires 18 months after its effective date, subject to our right to extend such expiration date by up to an additional one-year periods upon notice to Stanford and by another additional one year upon the reasonable agreement of Stanford. The First Option Agreement will terminate if the License Agreement terminates. The First Option Agreement also may be

terminated by us at will. On June 23, 2022, we exercised our right to extend the term of the First Option Agreement for an additional year. On June 6, 2023, we agreed to extend the term of the First Option Agreement for another additional year. As of the date of this Form 10-K, we have not exercised the option and no fees have been paid for the First Option Agreement.

On June 6, 2023, we agreed with Stanford to extend the term of the First Option Agreement for another additional year.

In August 2023, we entered into the LOA, pursuant to which it granted Kamau an option to acquire certain of our technology and intellectual property related to our nula-cel program and related pre-clinical platform assets. The First Option Agreement is subject to the LOA and may be assigned to Kamau if and when it exercises the option.

Second Option Agreement

In April 2021, we entered into another option agreement (the "Second Option Agreement") with Stanford, pursuant to which Stanford granted us the exclusive right to obtain a license to specified patent rights relating to human prophylactic and therapeutic products. The option may be extended to specified technology at a later date and upon our agreement with Stanford. We may exercise the option in whole or in part to obtain a license under one or more of the optioned patent rights, subject to a specified waiting period with respect to certain specified patent rights. Subject to retained rights by Stanford and in the case of specified patent rights, the Department of Veterans Affairs, the license will be exclusive with respect to human prophylactic and therapeutic products for the treatment of Gaucher Disease, other diseases treated through insertion of a construct into the CCR5 locus, and diseases treated through insertion of a construct into the alpha globin locus. The license is non-exclusive with respect to all other human prophylactic and therapeutic products.

Pursuant to the Second Option Agreement, we agreed to pay Stanford option fees in an aggregate amount of $30.0 thousand over the term of the option. If we exercise the option with respect to a particular optioned patent right, Stanford and we would negotiate in good faith the terms of a license agreement or an amendment to the License Agreement that incorporates the optioned patent rights and any optioned technology. The terms of the license agreement or amendment could include additional payments to Stanford in excess of those set forth in the License Agreement.

The term of the Second Option Agreement expires 12 months after its effective date, subject to our right to extend such expiration date by two additional one-year periods upon notice to and the reasonable agreement of Stanford. The Second Option Agreement may be terminated by us at will or by Stanford if we remain in breach of the Second Option Agreement following a cure period to remedy the breach. The Second Option Agreement also will terminate automatically in the event of a filing of a bankruptcy petition by or against us. On April 13, 2022, we entered into an amendment to the Second Option Agreement which extended the term for an additional year and the maintenance fee of $10.0 thousand was paid in year ended December 31, 2022. On March 8, 2023, we terminated the Second Option Agreement without exercising the option to negotiate a license for additional technologies from Stanford.

We are required to use diligent efforts to conduct research on potential commercial applications of the optioned patents and any optioned technology. In addition, we are required to use reasonable efforts to achieve specified milestones during the term of the Second Option Agreement with respect to products incorporating two of therapeutic approaches covered by the optioned patent rights. Our diligence obligations are subject to good faith discussions regarding their modification upon any extension of the term of the Second Option Agreement by us. If we fail to satisfy our diligence obligations Stanford may terminate the Second Option Agreement for our breach.

License Agreement with Integrated DNA Technologies, Inc.

In June 2021, we entered into a License Agreement (the "IDT License Agreement") with Integrated DNA Technologies, Inc. ("IDT"). Pursuant to the IDT License Agreement, IDT granted to us and our affiliates a worldwide, non-exclusive, sublicensable license to research and develop products incorporating HiFi Cas9 protein variants for use in human therapeutic applications for SCD, XSCID and Gaucher disease (the "Field") and a worldwide, exclusive, sublicensable license to commercialize such products in the Field. We were also granted the right to expand the licensed Field to include human therapeutic applications in the additional fields of beta thalassemia disorder and lysosomal storage disorders upon the payment of an exercise fee in the amount of $0.5 million per additional field or $1.0 million for both additional fields.

We are solely responsible for the development, manufacture, regulatory approval and commercialization of the products in the Field and are required to use commercially reasonable efforts to achieve certain regulatory and commercial milestones with respect to licensed products.

In the event we do not achieve the applicable milestones within a specified time period, then, except with respect to the field of human therapeutic applications for SCD for which we had previously filed an IND, the exclusive license granted to us described above will immediately convert to a non-exclusive, non-sublicensable license, and all sublicenses granted by us to any sublicensees will immediately terminate.

In consideration of the licenses and rights granted to us under the IDT License Agreement, we agreed to pay to IDT an upfront payment in the amount of $3.0 million and up to $5.3 million (or $8.8 million if we expand the Field as described above to include both the beta thalassemia and lysosomal storage disorders fields) in total regulatory milestone payments. Each regulatory milestone payment is payable once on an indication-by-indication basis. In addition, we have agreed to pay IDT a low single-digit royalty on the net sales of products, subject to reductions in specified circumstances, and a low double digit percentage payment for certain sublicense revenue,

which is also subject to reduction in the event a sublicense includes other patent rights that are not patents licensed from IDT. As of December 31, 2023 and 2022, we have not achieved any of the regulatory milestones and have only paid the upfront license payment of $3.0 million.

The IDT License Agreement remains in effect on a country-by-country and product-by-product basis until the expiration of the royalty term for such product in such jurisdiction. We and IDT each have the right to terminate the IDT License Agreement for the other party's material breach of its obligations under the IDT License Agreement, subject to specified rights to cure. Additionally, we may terminate the IDT License Agreement for any reason.

Our current in-licensed patent and patent applications from IDT, if the appropriate maintenance fees are paid, are expected to expire in 2037, excluding any additional term for patent term adjustments or patent term extensions.

The IDT License Agreement includes customary representations and warranties by each party as are customarily found in transactions of this nature, including as to the licensed intellectual property. The IDT License Agreement also provides for certain mutual indemnities for breaches of representations, warranties and covenants.

In August 2023, we entered into the LOA, pursuant to which it granted Kamau an option to acquire certain of our technology and intellectual property related to our nula-cel program and related pre-clinical platform assets. The IDT License Agreement is included in the assets that are subject to the LOA and may be assigned to Kamau if and when it exercises the option.

Asset Purchase Agreement with Maro Bio Inc.

On August 1, 2023, we entered into an asset purchase agreement (the "APA") with Maro pursuant to which we sold to Maro, concurrently with the execution of the APA, certain assets related to our non-genotoxic conditioning technology in exchange for upfront consideration of $0.5 million. Additional consideration included certain contingent milestone payments totaling up to approximately $1.0 million in the aggregate, and potential fees upon the completion of certain transactions by the acquirer. The APA also provided for reimbursement of certain research and development amounts incurred prior to closing of approximately $0.6 million as well as certain transition services to be provided by us or Maro. Under the APA, Maro will also pay us a sub single digit percentage cash royalty of worldwide net sales of certain products incorporating the acquired technology. The royalty term will terminate on a product-by-product and country-by-country basis on the latest of (i) the ten (10) year anniversary of the first commercial sale of such product in such country, (ii) the expiration of the last-to-expire valid claim of a transferred patent that covers such product in such country, and (iii) the expiration of regulatory exclusivity with respect to such product in such country. The APA also includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

The disposal of certain assets sold pursuant to the APA was accounted for as a deconsolidation of a subsidiary or group of assets in accordance with ASC 810. During the year ended December 31, 2023, we recognized a loss on disposal of $0.1 million, which was recorded in other income. We will record amounts related to the contingent milestone payments, royalties, and potential transaction fees when contingencies are resolved and amounts are due in accordance with ASC 450. No contingencies were resolved and recorded as of December 31, 2023.

License and Option Agreement with Kamau Therapeutics, Inc.

On August 4, 2023, we entered into an LOA with Kamau pursuant to which we exclusively licensed to Kamau, and granted Kamau, an option to acquire certain intellectual property and materials related to our nula-cel program and related pre-clinical platform assets. The option includes rights to assume the License Agreement and the First Option Agreement with Stanford, as well as the IDT License Agreement, among other agreements. Exercise of the option is contingent on Kamau raising a minimum of $10 million in funds no later than August 4, 2024 (the "Financing Milestone"), which contingency may be waived by us. All rights to the intellectual property and materials will revert to us if the milestone is not achieved or if Kamau elects not to exercise the option. In return for this license and option, we received an equity interest in Kamau representing 20% of all outstanding shares on a fully diluted basis subject to dilution protection until the Financing Milestone. The LOA includes customary representations and warranties, limitations of liability and indemnification obligations for a transaction of this nature. The LOA automatically expires upon the first to occur of: (1) Kamau' exercise of the option, (2) Kamau' failure to exercise the option within a specified exercise period following achievement of the financing milestone, or (3) Kamau' failure to achieve the financing milestone by the pre-agreed deadline. In addition, either party has the right to terminate the LOA for the uncured material breach or insolvency of the other party, and we have the right to terminate the LOA if Kamau challenges any of the patent rights that are subject to the option. As a result of the 20% equity interest, we have the ability to

exert significant influence over Kamau and accounts for the interest as an equity method investment. we record its proportionate share of investee' equity in earnings or losses based on the most recently available financial information.

On September 12, 2023, we and Kamau entered into an amendment to the LOA, under which we agreed to assign certain contracts to Kamau prior to exercise of the option, and as of December 31, 2023, these contracts have been assigned to Kamau.

The 20% equity interest in Kamau had minimal value upon execution of the LOA and we did not record any amount related to the equity interest as of December 31, 2023. December 31, 2023, Kamau has not achieved the financial milestone and does not have the right to exercise the option.

Sublease Agreement with Soleil Labs, LLC

In October 2023, we entered into a sublease agreement (the "Sublease") with Soleil Labs, LLC ("Tenant") for certain premises constituting approximately 32,113 square feet of space in the building located at 233 E. Grand Avenue, South San Francisco, California (the "Premises"). We lease approximately 85,165 square feet of office space in the building located at 233 E. Grand Avenue, South San Francisco, California pursuant to a Lease dated as of December 16, 2021 (as amended, the "Master Lease"), by and between the Company and Bayside Area Development, LLC (the "Landlord"). The term of the Sublease (the "Term") commences on October 26, 2023 (the "Effective Date") and expires on December 31, 2024. Pursuant to the Sublease, Tenant agrees to make rent payments directly to the Landlord in the amount of $183,044.10 per month for the first twelve months and $189,450.64 per month for the remainder of the Term. The rights and obligations of Tenant under the Sublease are subject to the terms of the Master Lease.

In connection with the execution of the Sublease, the Landlord consented to the execution of the Sublease, agreed to perform all of our obligations under the Sublease, and indemnified Graphite from any liability under the Sublease. The Tenant also agreed not to hold us liable under the Sublease.

At the same time, we also entered into a First Amendment to Lease with the Landlord (the "Lease Amendment") to adjust the timeline for certain payments under the Master Lease and to effect the acceleration of the termination date of the Master Lease. The Lease Amendment provides that the Master Lease will terminate on December 31, 2024, and that the Landlord may further accelerate the termination date for the premises not subject to the Sublease by delivering written notice and paying us $20,000 per month for each month of further acceleration.

As consideration for Landlord's agreement to enter into the Lease Amendment, we have agreed to: (a) on the termination date, surrender the premises to the Landlord and convey all the furniture and equipment in the premises to the Landlord, subject to the interests of the Tenant, (b) upon execution of the Lease Amendment, prepay all remaining amounts payable during the term of the Master Lease (including the difference between the rent obligations due under the Master Lease and the rent to be paid by Tenant under the Sublease for the Premises), in an amount equal to $15,928,490, and (c) pay to the Landlord a lease termination payment of approximately $20,776,078. To the extent Graphite has made any rent payments pursuant to the Master Lease after October 31, 2023, such amounts shall be recalculated to take into account and provide a credit for any such rent payment. We will have no further rent obligations to Landlord pursuant to the Master Lease following the Effective Date, and the Landlord will return our letter of credit under the Master Lease within 60 days following the Effective Date.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we have been developing.

U.S. Biologics Regulation

In the United States, the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and the Public Health Service Act ("PHSA"), and their implementing regulations. Biological products are also subject to other federal, state, local and foreign statutes and regulations. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may result in delays to the conduct of a study, regulatory review and approval or subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license suspension or revocation, refusal to allow an applicant to proceed with clinical trials, imposition of a clinical hold, issuance of untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations or penalties.

Our product candidates must be approved by the U.S. Food and Drug Administration of the United States (the "FDA") through the Biologics License Application ("BLA"), process before they may be legally marketed in the United States. The process required by the FDA before biological product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and animal studies performed in accordance with applicable regulations, including the FDA's Good Laboratory Practices ("GLPs"), regulations and standards;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin;
- approval by an independent institutional review board ("IRB") or ethics committee representing each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations, Good Clinical Practices ("GCPs"), and other clinical trial-related regulations to establish the safety, purity and potency of the proposed biological product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA, which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacture and quality controls for the product candidate and proposed labeling;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practice requirements ("cGMPs") and to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity, and of selected clinical trial sites that generated the data in support of the BLA to assess compliance with the FDA's GCPs;
- satisfactory completion of an FDA Advisory Committee review, if applicable; and
- FDA review and approval, or licensure, of a BLA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns, non-compliance, or other issues affecting the integrity of the trial. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial and, once begun, issues may arise that could cause the trial to be suspended or terminated.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight at the local level as set forth in the National Institutes of Health ("NIH"), Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ("NIH Guidelines"). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an Institutional Biosafety Committee ("IBC"), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding for recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB or ethics committing at or servicing each site at which the clinical trial will be conducted must review and approve the plan for any clinical trial before the clinical trial begins at that site, and must monitor the study until completed. An IRB

is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

Clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The investigational product is typically administered to a small number of healthy volunteers. For gene therapies, the investigational product is typically initially introduced into patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with the investigational product, and, if possible, to gain early evidence on effectiveness.
- *Phase 2.* The investigational product is typically administered to a limited patient population to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- *Phase 3*. The investigational product is typically administered to an expanded patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for physician labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

When these phases overlap or are combined, the trials may be referred to as Phase 1/2 or Phase 2/3.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and further document clinical benefit in the case of drugs approved under accelerated approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical study investigators. Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the biologic, findings from animal or in vitro testing that suggest a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

The FDA, the sponsor or the IRB or may suspend a clinical study at any time on various grounds, including a finding that the research patients or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the biological product candidate has been associated with unexpected serious harm to patients. Additionally, if the trial is being overseen by a data safety monitoring board or committee, this group may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or on other grounds, such as interim data suggesting a lack of efficacy.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product candidate for one or more indications. The BLA must include all relevant data available from preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product candidate's chemistry, manufacturing, controls, and proposed labeling, among other things. Under the Prescription Drug User Fee Act ("PDUFA"), as amended, each BLA must be accompanied by a significant application user fee to the FDA, unless a waiver or exemption

applies, which is adjusted on an annual basis. The FDA has sixty days from the applicant's submission of a BLA to either issue a refusal to file letter or accept the BLA for filing, indicating that it is sufficiently complete to permit substantive review. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval, and may require additional preclinical, clinical or other studies before it accepts the filing.

Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may be significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product candidate is safe, pure and potent for its intended use, and whether the facility in which it is manufactured, processed, packed or held meets standards designed to assure and preserve the product's identity, safety, strength, quality, and purity. The FDA may convene an advisory committee, typically a panel that includes clinicians and other experts, to provide clinical insight on applications which present difficult questions of safety or efficacy and to review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will conduct a pre-approval inspection of the facility or facilities where the product is manufactured to determine whether the facilities comply with cGMPs. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically audit data from clinical trials to ensure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be manufactured, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification, which may include the potential requirement for additional clinical studies and/or other significant and time-consuming requirements related to preclinical studies and manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application or request a hearing. Even if such data and information is submitted, the FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for a particular indication(s) and may entail limitations on the indicated uses for which such product may be marketed. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. The FDA may also place other conditions on approvals including the requirement of a Risk Evaluation and Mitigation Strategy (REMS), to assure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new product candidates that meet certain criteria. Specifically, product candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation

applies to the combination of the product and the specific indication for which it is being studied. A sponsor may request fast track designation of a product candidate concurrently with, or at any time after, submission of an IND, and the FDA must determine if the product candidate qualifies for such designation within 60 day of receipt of the sponsor's request. The sponsor of a fast track product has opportunities for frequent interactions with the FDA review team during product development and, once a BLA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product candidate be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. The benefits of breakthrough therapy designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers and experienced review staff in a cross-disciplinary review.

As part of the 21st Century Cures Act, Congress amended the FDCA to create an expedited development program for RMATs, which include cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Gene therapies, including genetically modified cells that lead to a sustained effect on cells or tissues may meet the definition of a RMAT. The RMAT program is intended to facilitate efficient development and expedite review of RMATs, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition. A sponsor may request that FDA designate a product candidate as a regenerative medicine advanced therapy concurrently with or at any time after submission of an IND. FDA has 60 calendar days to determine whether the drug meets the criteria, including whether there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A new drug application or a BLA for a RMAT may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A RMAT that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval.

Any marketing application for a product candidate submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product candidate is eligible for priority review if it has the potential to provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition compared to available therapies. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review.

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product candidate generally provides a meaningful advantage over available therapies and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the sponsor fails to conduct such studies in a timely manner and send the necessary updates to the FDA, or if a confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination

or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, RMAT designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a biological product candidate intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more than individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a product for this type of disease or condition will be recovered from sales in the United States for that product. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product candidate that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same product for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or if the holder of the orphan exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan exclusivity does not prevent the FDA from approving a different product for the same disease or condition, or the same product for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Pediatric Trials and Exclusivity

Under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDCA requires that a sponsor who is planning to submit a marketing application for a product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP"), within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. Sponsors who conduct studies of their product candidate in children are eligible for pediatric exclusivity. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which attaches to the twelve-year exclusivity period for reference biologics, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Rare Pediatric Disease Designation and Priority Review Vouchers

Under the FDCA, as amended, the FDA incentivizes the development of drugs and biologics that meet the definition of a "rare pediatric disease," defined to mean a serious or life-threatening disease in which the serious of life-threatening manifestations primarily affect individuals aged from birth to 18 years and the disease affects fewer than 200,000 individuals in the United States or affects 200,000 or more in the United States and for which there is no reasonable expectation that the cost of developing and making in the United States a drug for such disease or condition will be received from sales in the United States of such drug. The sponsor of a product candidate for a rare pediatric disease may be eligible for a voucher that can be used to obtain a priority review for a subsequent human drug or biologic application after the date of approval of the rare pediatric disease drug product, referred to as a priority review voucher ("PRV"). A sponsor may request rare pediatric disease designation from the FDA prior to the submission of its NDA or BLA. A rare pediatric disease designation does not guarantee that a sponsor will receive a PRV upon approval of its NDA or BLA. Moreover, a sponsor who chooses not to submit a rare pediatric disease designation request may nonetheless receive a PRV upon approval of their marketing

application if they request such a voucher in their original marketing application and meet all of the eligibility criteria. If a PRV is received, it may be sold or transferred an unlimited number of times. Congress has extended the PRV program until September 30, 2024, with the potential for PRVs to be granted until September 30, 2026.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims or changes of the site of manufacture, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved BLA.

The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. Biological product manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biological products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict a manufacturer's communications on the subject of off-label use of their products.

U.S. Patent Term Restoration

Depending upon the timing, duration and specifics of the FDA approval of the use of our biological product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our patents, if and as applicable, to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Biosimilars and Reference Product Exclusivity

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act ("BPCIA"), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. This amendment to the PHSA attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. This does not include a supplement for the biological product or a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, unless that change is a modification to the structure of the biological product and such modification changes its safety, purity, or potency. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety, and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one

country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Regulation and Procedures Governing Approval of Medicinal Products in Europe

Clinical Trial Approval

In the European Union (the "EU"), our future products also may be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls.

In April 2014, the EU adopted the new Clinical Trials Regulation (EU) No 536/2014, (Regulation) which replaced the Clinical Trials Directive 2001/20/EC (Directive) on January 31, 2022. The transitory provisions of the Regulation provide that, by January 31, 2025, all ongoing clinical trials must have transitioned to the new Regulation.

The new Regulation is directly applicable in all EU Member States (and so does not require national implementing legislation in each Member State), and aims at simplifying and streamlining the approval of clinical studies in the EU. The main characteristics of the new Regulation include: a streamlined application procedure via a single-entry point through the Clinical Trials Information System, ("CTIS"); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted ("Concerned Member States") of a draft report prepared by a Reference Member State. Part II is assessed separately by each Concerned Member State. Strict deadlines have also been established for the assessment of clinical trial applications.

Marketing Authorization

To obtain a marketing authorization for a product in the European Union, an applicant must submit a marketing authorization application, either under the centralized procedure administered by the European Medicines Agency ("EMA") or one of the procedures administered by competent authorities in EU Member States (decentralized procedure, national procedure, or mutual recognition procedure).

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid throughout the EU, and in the additional Member States of the European Economic Area (Iceland, Liechtenstein and Norway), or EEA. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic-cell therapy and tissue-engineered products) and products with a new active substance indicated for the treatment of certain diseases, including HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interests of public health.

Specifically, the grant of a marketing authorization in the EU for products based on genes, tissues or cells, such as gene therapy or somatic-cell therapy medicinal products, is governed in part by Regulation (EC) No 1394/2007 on advanced therapy medicinal products ("ATMPs"). Regulation (EC) No 1394/2007 lays down specific rules concerning the authorization, supervision, and pharmacovigilance of ATMPs. Manufacturers of ATMPs must demonstrate the quality, safety, and efficacy of their products to the EMA's Committee for Advanced Therapies, which provides an opinion on the quality, safety and efficacy of each ATMP subject to marketing authorization application which is sent for final approval to the EMA's Committee for Medicinal Products for Human Use ("CHMP"). The CHMP recommendation is then sent to the European Commission, which adopts a decision on whether to grant a marketing authorization which is binding in all Member States. Under the centralized procedure, the maximum timeframe for the evaluation of a marketing authorization application is 210 days from receipt of a valid application, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions asked by CHMP. Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major public health interest, particularly from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

Now that the UK (which comprises Great Britain and Northern Ireland) has left the EU, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Ireland Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with an existing centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January 1, 2021. For a period of three years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA"), the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great

Britain marketing authorization. This is known as the EC Decision Reliance Procedure. On January 24, 2023, the MHRA announced that a new international recognition framework will be put in place from January 1, 2024, which will have regard to decisions on the approval of marketing authorizations made by the EMA and certain other regulators.

European Union Data and Marketing Exclusivity

In the EU, innovative medicinal products (including both small molecules and biological medicinal products) approved on the basis of a complete and independent data package, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents generic or biosimilar applicants from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU, for a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar medicinal product can be placed on the EU market until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company could nevertheless also market another version of the product if such company obtained a marketing authorization based on an application with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

European Union Orphan Designation and Exclusivity

In the EU, the EMA's Committee for Orphan Medicinal Products grants orphan designation in respect of a product if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (i) such condition affects no more than 5 in 10,000 persons in the EU when the application is made, or (ii) where it is unlikely that the marketing of the medicine, without the benefits derived from orphan status, would generate sufficient return in the EU to justify the necessary investment in its development; and (3)there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or, if such a method exists, the product would be of a significant benefit to those affected by that condition.

In the EU, orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers, and ten years of market exclusivity is granted following marketing approval for the orphan product. This period may be reduced to six years if, at the end of the fifth year, it is established that the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. During the period of market exclusivity, a marketing authorization may only be granted to a "similar medicinal product" for the same therapeutic indication if: (i) a second applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior; (ii) the marketing authorization holder for the authorized orphan product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized orphan product cannot supply enough orphan medicinal product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. Orphan designation must be requested before submitting an application for marketing authorization. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Regulatory Requirements After a Marketing Authorization has been Obtained

If an authorization for a medicinal product in the EU is obtained, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include:

- Compliance with the EU's stringent pharmacovigilance or safety reporting rules must be ensured. These rules can impose post-authorization studies and additional monitoring obligations.
- The manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the applicable EU laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the EU with the intention to import the active pharmaceutical ingredients into the EU.
- The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the EU. Direct-to-consumer advertising of prescription medicines is prohibited across the EU.

The aforementioned EU rules are generally applicable in the EEA.

Brexit and the Regulatory Framework in the United Kingdom

The UK formally left the EU on January 31, 2020 and the EU and the UK have concluded a trade and cooperation agreement (the "TCA"), which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework continues to apply in Northern Ireland). The regulatory regime in Great Britain therefore aligns in many ways with current EU regulations, however it is possible that these regimes will diverge more significantly in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of UK and EU pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of EU pharmaceutical legislation under the TCA, under the new framework mentioned above which will be put in place by the MHRA from January 1, 2024, the MHRA has stated that it will take into account decisions on the approval of marketing authorizations from the EMA (and certain other regulators) when considering an application for a Great Britain marketing authorization. On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (Great Britain and Northern Ireland) and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. Once the Windsor Framework is approved by the EU-UK Joint Committee, the UK Government and the EU will enact legislative measures to enact it into law.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we or our collaborators obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we or our collaborators receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such drug products.

Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. We or our collaborators may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Nonetheless, our product candidates may not be considered medically necessary or cost-effective. Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular drug candidate to currently available therapies. Other European Union countries allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly

high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other U.S. Healthcare Laws and Compliance Requirements

Healthcare providers, including physicians, and third-party payors play a primary role in the recommendation and prescription of any product candidates that we may develop for which we obtain marketing approval. Our current and future arrangements with third-party payors, healthcare providers and customers may implicate broadly applicable fraud and abuse and other healthcare laws and regulations. Restrictions under applicable federal and state healthcare laws and regulations, including certain laws and regulations applicable only if we have marketed products, include the following:

- the civil False Claims Act ("FCA"), prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties, for each false claim and treble the amount of the government's damages. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;
- the federal Anti-Kickback Statute prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. A violation of the federal Anti-Kickback Statute can also form the basis for FCA liability;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which, in addition to privacy protections applicable to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and its implementing regulations, including the final omnibus rule published on January 25, 2013, imposes, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive, maintain, transmit, or obtain, protected health information in connection with providing a service for or on behalf of a covered entity, and their covered subcontractors. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions;
- the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- federal transparency laws, including the federal Physician Payment Sunshine Act created under the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), and its implementing regulations, which requires manufacturers of certain drugs, devices, medical supplies, and biologics, among others, to track and disclose payments under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) and other transfers of value they make to U.S. physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as

ownership and investment interests held by physicians and their immediate family members. This information is subsequently made publicly available in a searchable format on a Centers for Medicare & Medicaid Services ("CMS"), website. Failure to disclose required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and/or other healthcare providers;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback, anti-bribery and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, track and report gifts, compensation and other remuneration made to physicians and other healthcare providers, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to also induce or reward improper performance generally is sometimes governed by the national anti-bribery laws of European Union Member States, and the Bribery Act 2010 in the United Kingdom. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the United Kingdom despite its departure from the EU.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been and continue to be ongoing efforts to implement legislative and regulatory changes regarding the healthcare system. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies.

Within the United States, the federal government and individual states have aggressively pursued healthcare reform, as evidenced by the passing of the ACA and the ongoing efforts to modify or repeal that legislation. The ACA substantially changed the way healthcare is financed by both governmental and private insurers and contains a number of provisions that affect coverage and reimbursement of drug products and/or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Modifications have been implemented under the previous presidential administration and additional modifications or repeal may occur.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, for example:

- The Budget Control Act of 2011 and subsequence legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the

American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.

- The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Bipartisan Budget Act ("BBA"), also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole."
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for drug products. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In addition, in February 2023, HHS issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HSS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effects of the IRA on our business and the healthcare industry in general is not yet known.

At the state level, legislatures have also been increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Employees and Human Capital Resources

As of December 31, 2023, we had six full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements.

We consider our relationship with our employees to be good. Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive

plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Corporate History and Information

We were incorporated in Ontario, Canada on June 1, 2017, as Longbow Therapeutics Inc. and were reincorporated in the State of Delaware in October 2019. In February 2020, we changed our name to Integral Medicines, Inc. and in August 2020, we changed our name to Graphite Bio, Inc. Research and development of our initial technology ceased at the end of 2018 and we did not have any significant operations or any research and development activities in 2019. We began research and development activities and operations around our currently owned product candidates in 2020.

Our principal executive office is located at 611 Gateway Blvd, Suite 120, South San Francisco, CA 94080, and our telephone number is (650) 484-0886. Our website address is https://graphitebio.com/. We do not incorporate the information on or accessible through our website into this Form 10-K, and you should not consider any information on, or that can be accessed through, our website as part of this Form 10-K. We have included our website address in this Form 10-K solely as an inactive textual reference.

We use various trademarks and trade names in our business, including without limitation our corporate name and logo. All other trademarks or trade names referred to in this Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-K may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, as defined in Rule 12b-2 under the Securities and Exchange Act of 1934, as amended (the "Exchange Act") and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We have taken advantage of reduced reporting requirements in this Form 10-K. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (1) are no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

Item 1A. Risk Factors.

This Form 10-K contains forward-looking information based on our current expectations. Because our business is subject to many risks and our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our common stock. You should carefully consider these risk factors, together with all of the other information included in this Form 10-K as well as our other publicly available filings with the SEC.

Risks Related to the Merger with LENZ

Failure to complete, or delays in completing, the potential merger with LENZ, announced on November 15, 2023 could materially and adversely affect our results of operations, business, financial results and/or common stock price.

On November 14, 2023, we entered into an Agreement and Plan of Merger (the "Merger Agreement"), with LENZ, pursuant to which, if all of the conditions to closing are satisfied or waived, our wholly-owned subsidiary will merge with and into LENZ, with LENZ surviving as our wholly-owned subsidiary. This transaction is referred to hereinafter as the "merger." Consummation of the merger is subject to certain closing conditions, a number of which are not within our control. Any failure to satisfy these required conditions to closing may prevent, delay or otherwise materially adversely affect the completion of the transaction. We cannot predict with certainty whether or when any of the required closing conditions will be satisfied or if another uncertainty may arise and cannot assure you that we will be able to successfully consummate the merger as currently contemplated under the Merger Agreement or at all.

Our efforts to complete the merger could cause substantial disruptions in, and create uncertainty surrounding, our business, which may materially adversely affect our results of operation and our business. Uncertainty as to whether the merger will be completed may affect our ability to recruit prospective employees or to retain and motivate existing employees. Employee retention may be particularly challenging while the transaction is pending because employees may experience uncertainty about their roles following the transaction. Uncertainty as to whether the merger will be completed could adversely affect our business and our relationship with collaborators, suppliers, vendors, regulators and other business partners. For example, vendors, collaborators and other counterparties may defer their decisions to work with us or seek to change their existing business relationships with us. Changes to, or termination of, existing business relationships could adversely affect our results of operations and financial condition, as well as the market price of our common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction or termination of the Merger Agreement.

The exchange ratio will not change or otherwise be adjusted based on the market price of our common stock as the exchange ratio depends on our net cash at the closing and not the market price of our common stock, so the merger consideration at the closing may have a greater or lesser value than at the time the Merger Agreement was signed.

At the effective time, as described in the Merger Agreement, outstanding shares of LENZ capital stock will be converted into shares of our common stock. Based on our and LENZ's capitalization as of November 9, 2023, the exchange ratio is estimated to be equal to approximately 1.4135. After applying this estimated exchange ratio, and giving effect to our private placement, our stockholders as of immediately prior to the merger are expected to own approximately 30.7% of the outstanding shares of capital stock of the combined company on a fully-diluted basis, former LENZ stockholders are expected to own approximately 56.3% of the outstanding shares of capital stock of the combined company on a fully-diluted basis and the investors issued shares of our common stock in our private placement are expected to own approximately 13.0% of the outstanding shares of capital stock of the combined company on a fully-diluted basis (excluding, in each case, any additional shares reserved under the 2024 Equity Incentive Plan (the "2024 Plan") and the 2024 Employee Stock Purchase Plan (the "2024 ESPP"), which are the combined company's 2024 Plan and 2024 ESPP, respectively), in each case subject to certain assumptions, including, but not limited to, our net cash as of closing being between $115 million and $175 million and a subscription amount of $53.5 million in the Graphite private placement. In the event our net cash is below $115 million, the exchange ratio will be adjusted such that the number of shares issued to the former LENZ securityholders will be increased, and our stockholders will own a smaller percentage of the combined company following the merger.

Any changes in the market price of our stock before the completion of the merger will not affect the exchange ratio or the number of shares LENZ stockholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the merger, the market price of our common stock increases from the market price on the date of the Merger Agreement, then LENZ stockholders could receive merger consideration with substantially higher value for their shares of LENZ capital stock than the parties had negotiated when they established the exchange ratio. Similarly, if before the completion of the merger the market price of our common stock decreases from the market price on the date of the Merger Agreement, then LENZ stockholders could receive merger consideration with substantially lower value than the parties had negotiated when they established the exchange ratio. The Merger Agreement does not include a price-based termination right.

Failure to complete the merger may result in us paying a termination fee to LENZ, and could harm our common stock price and future business and operations.

If the merger is not completed, we are subject to the following risks:

- if the Merger Agreement is terminated under specified circumstances, we could be required to pay LENZ a termination fee of $7.5 million;
- the price of our common stock may decrease and could fluctuate significantly; and
- we will incur substantial costs related to the merger, such as financial advisor, legal and accounting fees, a majority of which must be paid even if the merger is not completed.

If the Merger Agreement is terminated and the board of directors of LENZ determines to seek another business combination, there can be no assurance that we will be able to find another third party with whom to transact a business combination that would yield comparable or greater benefits.

If the conditions to the merger are not satisfied or waived, the merger may not occur.

Even if the merger is approved by our stockholders and the stockholders of LENZ, specified conditions must be satisfied or, to the extent permitted by applicable law, waived to complete the merger as set forth in the Merger Agreement. We cannot assure you that all of the conditions to the consummation of the merger will be satisfied or waived. If the conditions are not satisfied or waived, the merger may not occur or the closing may be delayed.

The merger may be completed even though a material adverse effect may result from the public announcement of the merger, industry-wide changes or other causes.

In general, neither we nor LENZ is obligated to complete the merger if there is a material adverse effect affecting the other party between November 14, 2023 (the date of the Merger Agreement) and the closing of the merger. However, certain types of events are excluded from the concept of a "material adverse effect." Such exclusions include but are not limited to changes in general economic or political conditions, industry-wide changes, changes resulting from the public announcement of the merger, natural disasters, pandemics (including the COVID-19 pandemic), public health events, other force majeure events, acts or threat of terrorism or war and changes in GAAP. Therefore, if any of these events were to occur and adversely affect us or LENZ, the other party would still be required to consummate the merger notwithstanding such material adverse effects. If any such adverse effects occur and we consummate the closing of the merger, the common stock price of the combined company may suffer. This, in turn, may reduce the value of the merger to the stockholders of ours, LENZ, or both.

If we complete the merger with Lenz, the combined company may need to raise additional capital by issuing equity securities or additional debt or through licensing arrangements, which may cause significant dilution to the combined company's stockholders or restrict the combined company's operations.

On November 14, 2023, we entered into a subscription agreement (the "Subscription Agreement") with certain investors, including existing investors of LENZ, pursuant to which the investors agreed to purchase, in the aggregate, $53.5 million in shares of our common stock immediately following the closing of the merger, which amount may be increased to up to $125 million through additional subscriptions under the subscription agreement from additional investors. The closing of our private placement is conditioned upon the satisfaction or waiver of the conditions to the closing of the merger, as well as certain other conditions. The shares of our common stock issued in our private placement will result in dilution to all securityholders of the combined company (i.e., both our securityholders and former LENZ securityholders). Our private placement is more fully described under "Item 5—Recent Sales of Unregistered Securities."

Even if the Graphite private placement closes as expected, the combined company may need to raise additional capital in the future. Additional financing may not be available to the combined company when it is needed or may not be available on favorable terms. To the extent that the combined company raises additional capital by issuing equity securities, such financing will cause additional dilution to all securityholders of the combined company, including our securityholders and former LENZ securityholders. It is also possible that the terms of any new equity securities may have preferences over the combined company's common stock. Any debt financing into which the combined company enters may involve covenants that restrict its operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of the combined company's assets, as well as prohibitions on its ability to grant liens, pay dividends, redeem its stock or make investments. In addition, if the combined company raises additional funds through licensing arrangements, the terms of such arrangements may not be favorable to the combined company.

Transfers of the combined company's securities utilizing Rule 144 of the Securities Act may be limited.

A significant portion of the combined company's securities will be restricted from immediate resale. Holders should be aware that transfers of the combined company's securities pursuant to Rule 144 may be limited as Rule 144 is not available, subject to certain exceptions, for the resale of securities initially issued by shell companies (other than business combination related shell companies) or issuers that have been at any time previously a shell company. Our disposal of our historical assets and operations in connection with our merger with LENZ has made us a shell company. We anticipate that following the consummation of the merger, the combined company will no longer be a shell company. As a result, we anticipate that holders will not be able to sell their restricted combined company securities pursuant to Rule 144 without registration until one year after we file the Current Report on Form 8-K following the closing that includes the required Form 10 information that reflects that the combined company is no longer a shell company.

Our disposal of our historical assets and operations in connection with our proposed merger with LENZ has made us a shell company. As a result, we are subject to more stringent reporting requirements, offering limitations and resale restrictions.

We have no remaining ongoing development programs and we have disposed of (or are in the process of disposing of) our legacy technology and intellectual property. As such, we are a shell company, and our merger with LENZ will be subject to the requirements applicable to shell company business combinations, which are as follows:

- the combined company will need to file a Form 8-K to report the Form 10 type information after closing with the SEC reflecting its status as an entity that is not a shell company;
- we are not and the combined company will not be eligible to use a Form S-3 until 12 full calendar months after closing;
- the combined company will need to wait at least 60 calendar days after closing to file a Form S-8 for any equity plans or awards;
- the combined company will be an "ineligible issuer" for three years following the closing, which will prevent the combined company from (i) incorporating by reference in its Form S-1 filings, (ii) using a free writing prospectus, or (iii) taking advantage of well-known seasoned issuer status despite its public float;
- investors who (i) were affiliates of LENZ at the time the merger was submitted for the vote or consent of LENZ's stockholders, (ii) receive securities of the combined company in the merger (i.e., Rule 145(c) securities) and (iii) publicly offer or sell such securities, will be deemed to be engaged in a distribution of such securities, and therefore to be underwriters with respect to resales of those securities, and accordingly such securities may not be included in the Form S-1 resale shelf registration statement anticipated to be filed after the closing of the merger unless such securities are sold only in a fixed price offering in which such investors are named as underwriters in the prospectus; and
- Rule 144(i)(2) will limit the ability to publicly resell Rule 145(c) securities per Rule 145(d), as well as any other "restricted" or "control" securities of the combined company per Rule 144 (i.e., holders of restricted securities and any affiliates of the public company are also affected) until one year after the Form 10 information is filed with the SEC.

The foregoing SEC requirements will increase the combined company's time and cost of raising capital, offering stock under equity plans, and complying with securities laws. Further, such requirements will add burdensome restrictions on the resale of combined company shares by affiliates of LENZ and any holders of "restricted" or "control" securities.

Some of our and LENZ directors and executive officers may have interests in the merger that are different from yours and that may influence them to support or approve the merger without regard to your interests.

Directors and executive officers of ours and LENZ may have interests in the merger that are different from, or in addition to, the interests of other of our stockholders generally. These interests with respect to our directors and executive officers may include, among others, acceleration of stock option or restricted stock unit vesting, retention bonus payments, extension of exercisability periods of previously issued stock option grants, severance payments if employment is terminated in a qualifying termination in connection with the merger and rights to continued indemnification, expense advancement and insurance coverage. One or more members of our board of directors may continue as directors of the combined company after the effective time, and, following the closing of the merger, may therefore be eligible to be compensated as non-employee directors of the combined company. These interests with respect to LENZ's directors and executive officers may include, among others, that certain of LENZ's directors and executive officers hold options, subject to vesting, to purchase shares of LENZ common stock which, after the effective time, will be converted into and become options to purchase shares of the common stock of the combined company; that LENZ's executive officers are expected to continue as executive officers of the combined company after the effective time and are expected to enter into new confirmatory offer letters to reflect their status as executive officers of a publicly-traded company and to provide for certain increases to annual base salary and annual target bonus opportunity; and that all of our and LENZ's directors and executive officers are entitled to certain indemnification and liability insurance coverage pursuant to the terms of the Merger Agreement.

In addition, certain of each of our and LENZ's directors are affiliated with investment funds which hold an interest in LENZ. Further, certain members of LENZ's current board of directors will continue as directors of the combined company after the effective time, and, following the closing of the merger, will be eligible to be compensated as non-employee directors of the combined company pursuant to a non-employee director compensation policy that is expected to be adopted in connection with the closing and take effect at the effective time.

Our and LENZ board of directors were aware of and considered those interests, among other matters, in reaching their decisions to approve and adopt the Merger Agreement, approve the merger, and recommend the approval of the Merger Agreement to our and LENZ stockholders. These interests, among other factors, may have influenced the directors and executive officers of ours and LENZ to support or approve the merger.

Our stockholders and LENZ's stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger, including the conversion shares of common stock issued in our private placement.

If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the merger, our stockholders and LENZ stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or will have only received part of the commensurate benefit resulting from the extent to which the combined company is able to realize the strategic and financial benefits currently anticipated from the merger.

If the merger is not completed, our stock price may decrease significantly.

The market price of our common stock is subject to significant fluctuations. Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market price of our common stock will likely be volatile based on whether stockholders and other investors believe that we can complete the merger or otherwise raise additional capital to support our operations if the merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market price of our common stock may be exacerbated by low trading volume. Additional factors that may cause the market price of our common stock to fluctuate include:

- the entry into, or termination of, our key agreements, including commercial partner agreements;
- announcements by our commercial partners or competitors of new commercial products, our clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the loss of our key employees;
- future sales of our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- our failure to meet industry analyst expectations; and
- period-to-period fluctuations in financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

Our and LENZ's securityholders will generally have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the merger as compared to their current ownership and voting interests in the respective companies.

After the completion of the merger, the current stockholders of ours and LENZ will generally own a smaller percentage of the combined company than their ownership of their respective companies prior to the merger. Immediately after the merger, and after giving effect to our private placement, our stockholders as of immediately prior to the merger are expected to own approximately 30.7% of the outstanding shares of capital stock of the combined company on a fully-diluted basis, former LENZ stockholders are expected to own approximately 56.3% of the outstanding shares of capital stock of the combined company on a fully-diluted basis and the investors issued shares of our common stock in our private placement are expected to own approximately 13.0% of the outstanding shares of capital stock of the combined company on a fully-diluted basis (excluding, in each case, any additional shares reserved under the 2024 Plan and the 2024 ESPP), subject to certain assumptions, including, but not limited to, our net cash as of closing totaling between $115.0 million and $175.0 million and a subscription amount of $53.5 million in the Graphite private placement.

During the pendency of the merger, neither we nor LENZ will be able to enter into a business combination with another party on more favorable terms because of restrictions in the Merger Agreement, which could adversely affect our respective business prospects.

Covenants in the Merger Agreement impede the ability of us and LENZ to make acquisitions during the pendency of the merger, subject to specified exceptions. As a result, if the merger is not completed, the parties may be at a disadvantage with respect to their competitors during that period. In addition, while the Merger Agreement is in effect, each party is generally prohibited from soliciting, seeking, initiating or knowingly encouraging, inducing or facilitating the communication, making, submission or announcement of any acquisition proposal or acquisition inquiry or taking any action that could reasonably be expected to lead to certain transactions involving a third party, including a merger, sale of assets or other business combination, subject to specified exceptions. Even if such a transaction would be favorable to such party's stockholders, such party would be unable to pursue it.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the transactions contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit each of us and LENZ from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals except in limited circumstances. In addition, if we terminate the Merger Agreement under specified circumstances, we will be required to pay LENZ a termination fee of $7.5 million. This termination fee may discourage third

parties from submitting competing proposals to us or our stockholders and may cause our or LENZ boards of directors to be less inclined to recommend a competing proposal.

Because the lack of a public market for LENZ common stock makes it difficult to evaluate the fair market value of its capital stock, the value of our common stock to be issued to LENZ stockholders may be more or less than the fair market value of LENZ common stock.

The outstanding capital stock of LENZ is privately held and is not traded on any public market. The lack of a public market makes it difficult to determine the fair market value of LENZ capital stock. Because the percentage of our equity to be issued to LENZ stockholders was determined based on negotiations between the parties, it is possible that the value of our common stock to be issued to LENZ stockholders will be more or less than the fair market value of LENZ capital stock.

If the merger does not qualify as a reorganization under the Internal Revenue Code of 1986, as amended (the "Code"), U.S. holders of LENZ capital stock may be taxed on the full amount of the consideration received in the merger.

Subject to certain limitations and qualifications, in the opinion of Wilson Sonsini Goodrich Rosati, P.C. ("Wilson Sonsini"), tax counsel to LENZ, the merger will qualify for U.S. federal income tax purposes as a "reorganization" within the meaning of Section 368(a) of the Code and no gain will be recognized by U.S. holders of LENZ capital stock who receive only our common stock in the merger. None of the parties to the Merger Agreement have sought or intend to seek any ruling from the IRS regarding the qualification of the merger as a reorganization within the meaning of Section 368(a) of the Code. If the merger does not qualify for the U.S. federal income tax treatment described herein, U.S. holders of LENZ capital stock may be taxed on any gain realized up to the full fair market value of any of our common stock they receive in the merger.

Lawsuits may be filed against us, LENZ, or any of the members of our respective boards of directors arising out of the merger, which may delay or prevent the merger.

Putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against us, our board of directors, LENZ, the LENZ board of directors and others in connection with the transactions contemplated by the Merger Agreement. The outcome of litigation is uncertain, and we or LENZ may not be successful in defending against any such future claims. Lawsuits that may be filed against us, our board of directors, LENZ, or the LENZ board of directors could delay or prevent the merger, divert the attention of our and LENZ's management and employees from their day-to-day business and otherwise adversely affect us and LENZ financially.

As of February 27, 2024, one complaint has been filed by a purported Graphite stockholder against us and our board of directors in connection with the proposed merger. Specifically, on February 1, 2024, a purported stockholder filed a complaint, captioned Chew v. Graphite Bio, Inc., et al., No. 3:24-cv-00613 (N.D.Cal.) (the "Complaint"), in federal court in California against us and our board of directors. The Complaint alleges that the defendants filed or caused to be filed a materially incomplete and misleading preliminary registration statement with the SEC and asserts claims under Sections 14(a) and 20(a) of the Exchange Act. The Complaint seeks an order enjoining the proposed merger, or in the event that the proposed merger is consummated, an order rescinding the merger or awarding rescissory damages, as well as costs, including attorneys' and experts' fees. In addition, we and our board of directors have received four additional demands from purported stockholders seeking additional disclosures in the registration statement (collectively, the "Demands"). We cannot predict the outcome of the Complaint or the Demands. We believe that the allegations and claims asserted in the Complaint and the Demands are without merit and intend to defend against them vigorously. Additional lawsuits and demand letters arising out of the merger may also be filed or received in the future, though we will not provide additional disclosures unless those new complaints or letters contain material differences from those received to date.

We are substantially dependent on our remaining employees to facilitate the consummation of the merger.

As of December 31, 2023, we had only six full-time employees. Our ability to successfully complete the merger depends in large part on our ability to retain certain remaining personnel. Despite our efforts to retain these employees, one or more employees may terminate their employment with us on short notice. The loss of the services of certain employees could potentially harm our ability to consummate the merger and run our day-to-day business operations, as well as fulfill our reporting obligations as a public company.

Risks Related to the Proposed Reverse Stock Split

The reverse stock split may not increase the combined company's stock price over the long-term.

Our board of directors believes that a reverse stock split may be desirable for a number of reasons. Our common stock is currently, and is expected to continue to be, following the completion of the merger, listed on Nasdaq. According to the applicable Nasdaq rules, in order for our common stock to continue to be listed on Nasdaq, Graphite must satisfy certain requirements established by Nasdaq. The Graphite board of directors expects that a reverse stock split of our common stock will increase the market price of our common stock so that we will be able to maintain compliance with the relevant Nasdaq listing requirements for the foreseeable future, although we cannot assure holders of our common stock that it will be able to do so. Our board of directors also believes a higher stock price may help generate investor interest in the combined company, help the combined company attract and retain employees, increase trading

volume in the combined company's common stock, and facilitate future financings by the combined company. While it is expected that the reduction in the number of outstanding shares of common stock will proportionally increase the market price of our common stock, it cannot be assured that the reverse stock split will increase the market price of our common stock by a multiple of the reverse stock split ratio mutually agreed by us and LENZ, or result in any permanent or sustained increase in the market price of our common stock, which is dependent upon many factors, including our business and financial performance, general market conditions and prospects for future success. Thus, while our stock price might meet the listing requirements for Nasdaq initially after the reverse stock split, it cannot be assured that it will continue to do so.

The reverse stock split may decrease the liquidity of the combined company's common stock.

Although our board of directors believes that the anticipated increase in the market price of the combined company's common stock resulting from the proposed reverse stock split could encourage interest in our common stock and possibly promote greater liquidity for our stockholders, such liquidity could also be adversely affected by the reduced number of shares outstanding after the reverse stock split. The reduction in the number of outstanding shares may lead to reduced trading and a smaller number of market makers for the combined company's common stock. In addition, the reverse stock split may not result in an increase in the combined company's stock price necessary to satisfy Nasdaq's initial listing requirements for the combined company.

The reverse stock split may lead to a decrease in the combined company's overall market capitalization.

Should the market price of the combined company's common stock decline after the reverse stock split, the percentage decline may be greater, due to the smaller number of shares outstanding, than it would have been prior to the reverse stock split. A reverse stock split is often viewed negatively by the market and, consequently, can lead to a decrease in the combined company's overall market capitalization. If the per share market price does not increase in proportion to the reverse stock split ratio, then the value of the combined company, as measured by its stock capitalization, will be reduced. In some cases, the per-share stock price of companies that have effected reverse stock splits subsequently declined back to pre-reverse split levels, and accordingly, it cannot be assured that the total market value of the combined company's common stock will remain the same after the reverse stock split is effected, or that the reverse stock split will not have an adverse effect on the combined company's stock price due to the reduced number of shares outstanding after the reverse stock split.

Risks Related to Our Financial Position, Limited Operating History and Need for Additional Capital in the Event the Merger is not Consummated

We have incurred significant losses since our inception, we expect to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.

Since our inception, we have incurred significant net losses, have not generated any revenue from product sales to date and have financed our operations principally through the net proceeds raised in our initial public offering (the "IPO") and private placements of our redeemable convertible preferred stock. Our net loss for the fiscal years ended December 31, 2023 and 2022 was $124.7 and $101.1 million, respectively. As of December 31, 2023, we had an accumulated deficit of $367.1 million. We expect to continue to incur significant and increasing losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Should we resume development of product candidates, we anticipate that our expenses would increase substantially if and as we:

- initiate and conduct clinical trials for any product candidates that we may identify and develop;
- initiate new research and discovery programs and preclinical development of product candidates from any new research programs;
- seek to identify additional research programs and additional product candidates;
- hire additional research and development and clinical personnel;
- maintain, expand, enforce, defend and protect our intellectual property portfolio and provide reimbursement of third-party expenses related to our patent portfolio;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;
- establish our manufacturing capability, including developing our contract development and manufacturing relationships, and should we decide to do so, building and maintaining a commercial-scale current Good Manufacturing Practices (cGMP), manufacturing facility;
- ultimately establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- add operational, financial, and management information systems and personnel;

- acquire or in-license product candidates, intellectual property and technologies; and
- operate as a public company.

To date, we have not successfully completed a clinical trial for any product candidate. To become and remain profitable, we would have to develop and eventually commercialize products with significant market potential. This would require us to be successful in a range of challenging activities, including identifying product candidates, completing preclinical testing and clinical trials of product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing, and selling those products for which we may obtain marketing approval, obtaining market acceptance for such products and satisfying any post- marketing requirements. We may never succeed in these activities and, even if it does, may never generate revenue in an amount sufficient to achieve profitability. We currently have no ongoing programs. We commenced our Phase 1/2 clinical trial of nulabeglogene autogedtemcel (nula-cel), in SCD in November 2021, and in February 2023 announced that it was discontinuing our development of nula-cel. In August 2023, we entered into an agreement pursuant in which we granted Kamau rights to acquire our technology and intellectual property related to our nula-cel program and related pre-clinical platform assets, and a separate agreement pursuant to which we transferred to Maro our rights to our pre-clinical non-genotoxic conditioning program. Following these transactions, we had no remaining ongoing development programs. However, we continue to hold, maintain and preserve the technology, licenses and intellectual property related to its nula-cel program and related preclinical platform assets subject to Kamau's option using its remaining workforce. Because of the numerous risks and uncertainties associated with developing gene therapy and gene editing product candidates, we are unable to predict the extent of any future losses or when we will become profitable, if ever. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and our stock price and could impair our ability to raise capital, maintain and fund our research and development efforts, expand our business, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our limited operating history may make it difficult for you to evaluate the performance of our business to date and to assess our future viability.

We are an early-stage company. We were founded in 2017 and commenced operations in 2020. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our platform and technology, identifying potential product candidates, establishing and maintaining our intellectual property portfolio, undertaking preclinical studies and preparing for clinical trials. Other than nula-cel, which was being evaluated in a Phase 1/2 clinical trial, and which we terminated development of in February 2023, all of our research programs were still in the preclinical or research stage of development. We have not demonstrated an ability to initiate or successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop a new product from the time it is discovered to when it is available for treating patients. Consequently, any predictions you make about the likelihood of our future success or viability may not be as accurate as they could be if we had a longer operating history.

Our limited operating history, particularly in light of the rapidly evolving gene editing field, may make it difficult to evaluate our technology and industry and predict our future performance. Our very short history as an operating company makes any assessment of the likelihood of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by very early-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer.

In addition, as a new business, we may encounter other unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have never generated revenue from product sales, may never generate any revenue from product sales and may never become profitable.

Our ability to generate revenue from product sales and achieve profitability, if ever, depends on our ability, alone or with collaborative partners, to initiate and successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, any product candidates we may identify for development. We do not anticipate generating revenues from product sales for the next several years, if ever.

Even if one or more of the product candidates we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations.

We will need substantial additional funding. If we are unable to raise capital when needed on acceptable terms, or at all, we would be forced to delay, reduce, or terminate our research and product development programs, future commercialization efforts or other operations.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate and conduct clinical trials of, and seek marketing approval for, any product candidates we may identify. In addition, if we obtain marketing approval for any product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution to the extent that such sales, marketing, manufacturing, and distribution are not the responsibility of a collaborator. Other unanticipated costs may also arise. Furthermore, we expect to incur substantial costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our research and product development programs, future commercialization efforts or other operations.

As of December 31, 2023, our cash and cash equivalents were $184.3 million. We expect that these funds will enable us to fund our operating expenses and capital expenditure requirements beyond the next 12 months. However, our operating plan may change as a result of factors currently unknown to us, and we may need to seek funding sooner than planned. Our future capital requirements will depend on many factors, including:

- the timing, scope, progress, results and costs of any product candidates that we may identify and develop;
- the costs, timing, and outcome of regulatory review of the product candidates we develop;
- the costs of continuing to build our gene editing platform;
- the timing, scope, progress, results, and costs of discovery, preclinical development and formulation development for the product candidates we develop;
- the costs of preparing, filing, and prosecuting patent applications, establishing, maintaining and enforcing our intellectual property and proprietary rights, and defending intellectual property-related claims;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing, distribution, coverage and reimbursement for any product candidates for which we receive regulatory approval;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- our ability to negotiate favorable terms in strategic alternatives including, but not limited to, any collaboration, licensing or other arrangements into which we may enter in the future and performing our obligations in such collaborations;
- the success of any collaborations that we may establish and of our license agreements;
- the continued effect of the COVID-19 pandemic on our business;
- the extent to which we acquire or in-license product candidates, intellectual property and technologies; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. We have no committed sources of additional capital and, if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Without sufficient funding, our license agreements and any future collaboration agreements may also be terminated if we are unable to meet the payment or other obligations under such agreements.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and licensing arrangements. To the extent that we raise additional

capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, and possibly other restrictions.

If we raise funds through additional collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates we develop, or we may have to grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We may be subject to adverse legislative or regulatory tax changes that could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders', tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

Our ability to use our U.S. net operating loss carryforwards and certain other U.S. tax attributes may be limited.

As of December 31, 2023 and 2022, we had U.S. federal net operating loss carryforwards of $164.3 and $75.7 million, respectively, (which are not subject to expiration) and minimal state net operating loss carryforwards. Our ability to use our U.S. federal and state net operating losses to offset potential future taxable income and reduce income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses.

Under current law, unused U.S. federal net operating losses generated in taxable years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. For taxable years beginning after December 31, 2020, however, the deductibility of such U.S. federal net operating losses is limited to 80% of our taxable income in such taxable years. In addition, both our current and our future unused U.S. federal net operating losses and tax credits may be subject to limitation under Sections 382 and 383 of the Code if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of our equity offerings or subsequent shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law.

We face risks related to health epidemics, pandemics and other widespread outbreaks of contagious disease, including the COVID-19 pandemic, which could significantly disrupt our operations, impact our financial results or otherwise adversely impact our business.

Significant outbreaks of contagious diseases, and other adverse public health developments, could have a material impact on our business operations and operating results. The continued effects of COVID-19, have affected segments of the global economy as well as our operations. For example, COVID-19 impacted clinical trial site resourcing, staffing and operations, resulting in longer timeframes than initially anticipated for participant screening and enrollment. In particular, treatment of the first patient in our Phase 1/2 clinical trial of nula-cel was delayed due to screen failure as a result of a prospective participant becoming infected with COVID-19. As a result of the COVID-19 pandemic or similar public health crises that may arise, we may experience further disruptions that could adversely impact our operations, research and development, including preclinical studies, clinical trials and manufacturing activities, including:

- delays or disruptions in clinical trials that we may be conducting, including patient screening, patient enrollment, patient dosing, clinical trial site activation, and study monitoring;
- delays or disruptions in preclinical experiments and IND-enabling and clinical trial application-enabling studies due to restrictions related to our staff being on site;
- interruption or delays in the operations of the FDA, the EMA and comparable foreign regulatory agencies;
- interruption of, or delays in, receiving, supplies of drug substance and drug product from our CMOs or delays or disruptions in our pre-clinical experiments or clinical trials performed by CROs due to staffing shortages, production and research slowdowns or stoppages and disruptions in delivery systems or research;
- limitations imposed on our business operations by local, state, or federal authorities to address such pandemics or similar public health crises could impact our ability to conduct preclinical or clinical activities, including conducting IND-enabling studies or our ability to select future development candidates;

- the impact of the COVID-19 pandemic on our corporate culture; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations, cyber security and data accessibility, or communication or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.

The trading prices for biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic, and we may face similar volatility in our stock price.

We cannot predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, financial condition, our results of operations and prospects.

Risks Related to Our Business if Merger is not Consummated

We may not be successful in completing the merger or any strategic transactions that it may consummate in the future could have negative consequences.

We are exploring and evaluating strategic transactions, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and we may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

If we are successful in completing the merger, we may be exposed to other operational and financial risks.

The consummation of the merger or any other strategic transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business. The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of ours or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If the merger is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that the merger will be completed. If the merger is not completed, our board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate the merger depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate the merger depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In February 2023 and again in August 2023, we undertook an organizational restructuring that significantly reduced our workforce in order to conserve our capital resources. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete the merger depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of the merger as well as business operations.

Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected, and could disrupt our business.

In February 2023, and again in August 2023, we undertook organizational restructurings that significantly reduced our workforce, including the departure of our chief business officer and chief scientific officer. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees. Employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. We may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. For example, the workforce reduction may negatively impact our clinical, regulatory, technical operations, and commercial functions, should we choose to continue to pursue them, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our product candidates. Our future financial performance and our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be. In addition, given the substantial restructuring of our operations, it may be difficult to evaluate our current business and future prospects on the basis of historical operating performance.

We may become involved in securities class action litigation that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Risks Related to Our Discovery, Development, and Commercialization

We may not be successful in our efforts to identify and develop potential product candidates. If these efforts are unsuccessful, it may never become a commercial stage company or generate any revenues.

The success of our business depends primarily upon our ability to identify, develop, and commercialize product candidates. Our research programs may fail to identify potential product candidates for clinical development for a number of reasons: our research methodology may be unsuccessful in identifying potential product candidates; our potential product candidates may be shown to have harmful side effects in preclinical in vitro experiments or animal model studies; our product candidates may not show promising signals of therapeutic effect in such experiments or studies; or our product candidates may have other characteristics that may make the product candidates impractical to manufacture, unmarketable, or unlikely to receive marketing approval.

If any of these events occur, we may be forced to abandon our research or development efforts for a program or programs, which would have a material adverse effect on our business, financial condition, results of operations, and prospects and could potentially cause us to cease operations. For instance, in February 2023, we announced that it had discontinued development of our lead program, and subsequently announced that it had discontinued development of all our development programs. Research programs to identify new product candidates require substantial technical, financial, and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful, which would be costly and time-consuming.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain and may prevent us from obtaining approvals for the commercialization of our product candidates. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, it will not be able to commercialize, or will be delayed in commercializing, product candidates it develops, and our ability to generate revenue will be materially impaired.

Any product candidates we develop and the activities associated with their development and commercialization, including their design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale, import, export, and distribution, are subject to comprehensive regulation by the FDA, the EMA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the biological product candidate's safety, purity, and potency. Securing regulatory approval also requires the submission of extensive information about the product manufacturing process, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities, or other characteristics that may preclude us from obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications among many potential options. As a result, it may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, it may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Any such event could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Even if we complete the necessary clinical trials, it cannot predict when, or if, it will obtain regulatory approval to commercialize a product candidate we may develop in the United States or any other jurisdiction, and any such approval may be for a more narrow indication than it seeks.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. Even if our product candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials, and the review process.

Regulatory authorities also may approve a product candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. These regulatory authorities may require labeling that includes precautions or contraindications with respect to conditions of use, or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates and materially adversely affect our business, financial condition, results of operations, and prospects.

Marketing approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking regulatory approval outside the United States could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our product candidates will be unrealized.

Our product candidates may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

The commercial success of any of our product candidates will depend upon its degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Ethical, social, and legal concerns about genetic medicines generally and gene editing technologies specifically could result in additional regulations restricting or prohibiting the marketing of our product candidates. Even if our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, and others in the medical community. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of such product candidates as demonstrated in clinical trials;
- the potential and perceived advantages compared to alternative treatments;
- the limitation to our targeted patient population and limitations or warnings contained in approved labeling by the FDA or other regulatory authorities;
- the ability to offer our products for sale at cost-effective or competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product candidate is approved by the FDA, the EMA, or other regulatory agencies;
- public attitudes regarding genetic medicine generally and gene editing technologies specifically;
- the willingness of the target patient population to try novel therapies and of physicians to prescribe these therapies, as well as their willingness to accept a therapeutic intervention that involves the editing of the patient's gene;
- product labeling or product insert requirements of the FDA, the EMA, or other regulatory authorities,
- including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- the strength and effectiveness of sales, marketing and distribution efforts;

- sufficient third-party coverage and adequate reimbursement, including the ability to supply product that is cost-effective and acceptable to the pricing or reimbursement authorities in different countries; and
- the prevalence and severity of any side effects.

Even if any of our product candidates obtain regulatory approval, such products may not achieve an adequate level of acceptance, we may not generate or derive sufficient product revenues, and we may not become profitable.

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer, less expensive or more advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize our product candidates.

The development and commercialization of new drug products is highly competitive. Moreover, the gene editing field is characterized by rapidly changing technologies, significant competition, and a strong emphasis on intellectual property. We will face competition with respect to any product candidates that we may develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we have research programs. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches.

There are several other companies advancing gene editing and gene editing and gene therapy product candidates in preclinical or clinical development in sickle cell disease, including Beam Therapeutics Inc., bluebird bio, Inc., Cellectis SA, CRISPR Therapeutics AG, Editas Medicine, Inc., Intellia Therapeutics, Inc., and Sangamo Therapeutics, Inc. Companies advancing gene therapy programs in beta-thalassemia include bluebird bio, Inc., CRISPR Therapeutics AG, Sangamo Therapeutics, Inc. and Edigene Inc. Companies advancing gene therapy programs in XSCID include Mustang Bio, Inc. Companies advancing gene therapy programs in Gaucher Disease include AVROBio, Inc. and Freeline Therapeutics Holdings plc. Companies advancing gene editing and gene therapy programs in preclinical development for AAT deficiency include Beam Therapeutics Inc., Editas Medicine, Inc., Intellia Therapeutics, Inc., Krystal Biotech Inc., Apic Bio Inc., and LogicBio Therapeutics Inc. Companies combining CRISPR with HDR (homology directed repair) include CRISPR Therapeutics AG, which, for oncology applications, inserts a chimeric antigen receptor ("CAR") construct into the TCR alpha constant ("TRAC") locus in T-cells using HDR. Additionally, an academic collaboration between the University of California, San Francisco and the University of California, Los Angeles is seeking to correct the sickle cell mutation using CRISPR followed by delivery of a single-stranded oligonucleotide DNA donor to potentially harness HDR.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future that are approved to treat the same diseases for which we may obtain approval for our product candidates. This may include other types of therapies, such as small molecule, antibody, and/or protein therapies.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products. Mergers and acquisitions in the pharmaceutical, biotechnology, and gene therapy industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop or that would render any product candidates that we may develop obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

In addition, as a result of the expiration or successful challenge of our patent rights, we could face more litigation with respect to the validity and/or scope of patents relating to our competitors' products. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidates that we may develop and commercialize.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have limited experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved products for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors;
- restricted or closed distribution channels that make it difficult to distribute our product candidates to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenues or the profitability of these product revenues to us may be lower than if we were to market and sell any products we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Adverse public perception of genetic medicines and gene editing in particular, may negatively impact regulatory approval of, and/or demand for, our potential products, if approved.

Our potential therapeutic products historically involved editing the human genome. The clinical and commercial success of our potential products will depend in part on public understanding and acceptance of the use of gene editing therapy for the prevention or treatment of human diseases. Public perception and related media coverage of potential gene therapy-related efficacy or safety issues, including adoption of new therapeutics or novel approaches to treatment, as well as ethical concerns related specifically to gene editing, may adversely influence the willingness of subjects to participate in clinical trials, or if any therapeutic is approved, of physicians and patients to accept these novel and personalized treatments. Physicians, health care providers and third-party payors often are slow to adopt new products, technologies and treatment practices, particularly those that may also require additional upfront costs and training. Physicians may not be willing to undergo training to adopt these novel and potentially personalized therapies, may decide the particular therapy is too complex or potentially risky to adopt without appropriate training, and may choose not to administer the therapy. Further, due to health conditions, genetic profile or other reasons, certain patients may not be candidates for the therapies.

In addition, responses by federal and state agencies, congressional committees and foreign governments to negative public perception, ethical concerns or financial considerations may result in new legislation, regulations, or medical standards, such as stricter labeling requirements, that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. New government requirements may be established that could delay or prevent regulatory approval of our product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be. Based on these and other factors, health care providers and payors may decide that the benefits of these new therapies do not or will not outweigh their costs.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair our development and commercialization of product candidates or demand for our product candidates. Adverse

events in our preclinical studies or clinical trials or those of our competitors or of academic researchers utilizing gene editing technologies, even if not ultimately attributable to product candidates we identify and develop, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of potential product candidates we identify and develop, stricter labeling requirements for those product candidates that are approved, and a decrease in demand for any such product candidates. Use of gene editing technology by a third party or government to develop biological agents or products that threaten U.S. national security could similarly result in such negative impacts to us.

Due to the novel nature of our technology and the potential for our product candidates to offer therapeutic benefit in a single administration or limited number of administrations, we face uncertainty related to pricing and reimbursement for these product candidates. Likewise, even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices, or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, and reimbursement for new products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or might even prevent our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates we develop, even if any of our product candidates obtain marketing approval. See the section titled *"Business—Government Regulation—Pharmaceutical Coverage, Pricing and Reimbursement."*

In the United States, no uniform policy exists for coverage and reimbursement for products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate a payor will pay for the product. One third-party payor's decision to cover a particular product or service does not ensure that other payors will also provide coverage for the medical product or service. Third-party payors may limit coverage to specific products on an approved list or formulary, which may not include all FDA-approved products for a particular indication.

We expect the cost of a single administration of a gene editing therapy, such as those we have historically sought to develop, to be substantial, when and if they achieve regulatory approval. Coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of any such product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of any of our product candidates will be paid by government authorities, private health plans, and other third-party payors. Payors may not be willing to pay high prices for a single administration. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor's determination that use of a product is:

- a covered benefit under our health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any products that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical, and cost-effectiveness data. There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize any of our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

Our initial target patient populations are relatively small, as a result of which the pricing and reimbursement of any of our product candidates, if approved, must be adequate to support the necessary commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any such product candidates will be adversely affected. The manner and level at which reimbursement is provided for services related to any product candidates we develop (e.g., for administration of our product candidate to patients) is also important. Inadequate reimbursement for such services may lead to physician and payor resistance and adversely affect our ability to market or sell our product candidates. In addition, we may need to develop new reimbursement models

in order to realize adequate value. Payors may not be able or willing to adopt such new models, and patients may be unable to afford that portion of the cost that such models may require them to bear. If we determine such new models are necessary but we are unsuccessful in developing them, or if such models are not adopted by payors, our business, financial condition, results of operations, and prospects could be adversely affected.

There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA, the EMA or other regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

If the market opportunities for any product candidates we may develop are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer. Because the target patient populations for many of our product candidates are small, we must be able to successfully identify patients and achieve a significant market share to maintain profitability and growth.

We have focused our research and product development on treatments for rare genetically defined diseases. Many of our historical product candidates were expected to target a single mutation; as a result, the relevant patient population may therefore be small. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our product candidates, or may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations, and prospects. Additionally, because of the potential that any product candidates we develop could cure a target disease, we may not receive recurring revenues from patients and may deplete the patient population prevalence through curative therapy.

Genetic medicines are novel, and any product candidates we develop may be complex and difficult to manufacture. We could experience delays in complying with regulatory requirements or production problems that result in delays in our development or commercialization programs, limit the supply of our product candidates, or otherwise harm our business.

Our product candidates will likely require processing steps that are more complex than those required for most chemical pharmaceuticals. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a biologic such as the product candidates we have historically developed generally cannot be fully characterized. As a result, assays of the finished product candidate may not be sufficient to ensure that the product candidate will perform in the intended manner. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in unusable products, product recalls, product liability claims, insufficient inventory, or potentially delay progression of our potential IND filings. We may also encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA, EMA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. For example, the current approach of manufacturing AAV vectors may fall short of supplying required number of doses needed for advanced stages of pre-clinical studies or clinical trials, and the FDA may ask us to demonstrate that we have the appropriate manufacturing processes in place to support the higher-dose group in our future pre-clinical studies or clinical trials.

In addition, the FDA, the EMA, and other regulatory authorities may require us to submit samples of any of the approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA, or other regulatory authorities may require that we not distribute a sample until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in product recalls. Product recalls could cause us to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations, and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality control, and manufacturing personnel needed to manage our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Given the nature of biologics manufacturing, including for AAV vectors, there is a risk of contamination during manufacturing. Any contamination could materially harm our ability to produce product candidates on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we anticipate will be required in our manufacturing process are derived from

biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall, or restriction on the use of biologically derived substances in the manufacture of our current or future product candidates could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could materially harm our development timelines and our business, financial condition, results of operations, and prospects.

Any problems in our manufacturing process or the facilities with which we contract could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of our product candidates.

We face an inherent risk of product liability exposure related to the testing in human clinical trials of our product candidates and will face an even greater risk if we commercially sell any products we develop. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any of our current or future product candidates;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant time and costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize our product candidates.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our relationships with healthcare providers, physicians, and third-party payors will be subject to applicable anti-kickback, fraud and abuse, anti-bribery and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors play a primary role in the recommendation and prescription of any product candidates that we may develop for which we obtain marketing approval. Our current and future arrangements with third-party payors, healthcare providers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our products for which we obtain marketing approval. See the section titled *"Business—Government Regulation—Government Other U.S. Healthcare Laws and Compliance Requirements."*

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to it, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government health care programs, such as Medicare and Medicaid, individual imprisonment, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

Healthcare and other reform legislation may increase the difficulty and cost for us and any collaborators we may have to obtain marketing approval of and commercialize any product candidates we may develop, and affect the prices we, or our collaborators, may obtain.

In the United States and some foreign jurisdictions, there have been and continue to be ongoing efforts to implement legislative and regulatory changes regarding the healthcare system. Such changes could prevent or delay marketing approval of any product candidates that Graphite may develop, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Although we cannot predict what healthcare or other reform efforts will be successful, such

efforts may result in more rigorous coverage criteria, in additional downward pressure on the price that we, or our future collaborators, may receive for any approved products or in other consequences that may adversely affect our ability to achieve or maintain profitability. See the section titled *"Graphite's Business—Government Regulation—Healthcare Reform."*

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believes is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Within the United States, the federal government and individual states have aggressively pursued healthcare reform, as evidenced by the passing of the ACA and the ongoing efforts to modify or repeal that legislation. The ACA substantially changed the way healthcare is financed by both governmental and private insurers and contains a number of provisions that affect coverage and reimbursement of drug products and/or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business. Modifications have been implemented under the previous presidential administration and additional modifications or repeal may occur. Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize any products we may develop.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruption, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Any third-party contract manufacturers and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent and other intellectual property protection for any product candidates we develop and for our platform technology, or if the scope of the patent and other intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our product candidates, and our platform technology may be adversely affected.

Our commercial success will depend in large part on our ability to obtain and maintain patent, trademark, trade secret and other intellectual property protection of our platform technology, product candidates and other technology, methods used to manufacture them and methods of treatment, as well as successfully defending our patent and other intellectual property rights against third-party challenges. It is difficult and costly to protect our platform technology and product candidates, and we may not be able to ensure their protection. Our ability to stop unauthorized third parties from making, using, selling, offering to sell, importing or otherwise commercializing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. In February 2023, we announced that we had discontinued development of our lead program and subsequently announced that we had discontinued development of all our development programs, and we do not intend to continue to seek or maintain intellectual property protection on the technology underlying these programs. In addition, we have sold or intend to sell in the future certain intellectual property rights to one or more third parties, and any intellectual property rights sold in the manner will no longer provide benefit or protection to us.

We have historically sought to protect our proprietary position by in-licensing intellectual property relating to our platform technology and filing patent applications in the United States and abroad related to our platform technology and product candidates that are important to our business. If we or our licensors are unable to obtain or maintain patent protection with respect to our platform technology and our product candidates, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to us and our ability to commercialize our product candidates may be adversely affected.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

No consistent policy regarding the scope of claims allowable in the field of gene editing has emerged in the United States. The scope of patent protection outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patent rights. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications us and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will be valid and enforceable and provide sufficient protection from competitors. Further, it is anticipated that in mid-2023, European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the

Unitary Patent Court ("UPC"). This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether any of our platform advances and product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications may in the future be, co-owned by us with third parties. If we are unable to obtain an exclusive license to such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patent rights in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Our rights to develop and commercialize our gene editing platform technology and product candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We depend on intellectual property licensed from third parties, and our licensors may not always act in our best interest. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that are important to our business.

We have licensed and are dependent on certain patent rights and proprietary technology from third parties that are important or necessary to the development of our gene editing technology and product candidates. For example, we are a party to a license agreement with Stanford pursuant to which we in-license key patent applications for our gene editing platform technology and product candidates (the "Stanford License Agreement"). This license agreement imposes various diligence, milestone payment, royalty, insurance, and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate our license, in which event we would not be able to develop or market our gene editing platform or any other technology or product candidates covered by the intellectual property licensed under this agreement. For example, under the Stanford License Agreement, we are required to initiate clinical trial programs in accordance with the development plan and development milestones for the development of a licensed product covered by the licensed patent rights. If we fail to initiate such clinical trial programs, our rights with respect to the licensed patent rights may terminate. We may be able to license our rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patent applications in order to enforce such patent rights against third parties, and such cooperation may not be provided to us.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

For example, the licensing or acquisition of third-party intellectual property rights is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

The intellectual property landscape around the technologies we use or plan to use, including gene editing technology, is highly dynamic, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating

their intellectual property rights, the outcome of which would be uncertain and may prevent, delay or otherwise interfere with our product discovery and development efforts.

Because of the large number of patents issued and patent applications filed in our field, third parties may allege they have patent rights encompassing our product candidates, technologies or methods. Third parties may assert that we are employing or have employed their proprietary technology without authorization and may file patent infringement claims or lawsuits against us, and if we are found to infringe such third-party patents, we may be required to pay damages, cease commercialization of the infringing technology, or obtain a license from such third parties, which may not be available on commercially reasonable terms or at all. In addition, we have in the past, and may in the future, receive an offer for license from third parties regarding their proprietary intellectual property for which they may believe encompass our product candidates and technologies. We will evaluate such offers for relevance to our business.

The field of gene editing is still in its infancy, and no such therapeutic product candidates have reached the market. Due to the intense research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is evolving and in flux, and it may remain uncertain for the coming years. There may be significant intellectual property related litigation and proceedings relating to our owned and in-licensed, and other third-party, intellectual property and proprietary rights in the future.

Our commercial success depends upon our ability and the ability of our collaborators and present and future licensors to develop, manufacture, market, and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating, or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be subject to and may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our platform technology and our product candidates, including interference proceedings, post-grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the EPO. Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates and they may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our platform technology and product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. There may also be third-party patents of which we are currently unaware with claims to technologies, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents.

Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. Some of our product candidates make use of CRISPR-based technology, which is a field that is highly active for patent filings. As of June 2019, it was reported that approximately 2072 patent families worldwide related to CRISPR gene editing inventions and uses as the description and/or claims of these patent families specifically focus on a CRISPR-type system. The extensive patent filings related to CRISPR make it difficult for us to assess the full extent of relevant patents and pending applications that may cover our gene editing platform technology and product candidates and their use or manufacture. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our gene editing platform technology and product candidates. For example, we are aware of a patent portfolio that is co-owned by the University of California, University of Vienna and Emmanuelle Charpentier, or the University of California Portfolio, which contains multiple patents and pending applications directed to gene editing. We are also aware of patents and patent applications directed to gene editing owned or co-owned by the Broad Institute, MIT and Harvard University, Toolgen, and Sigma Aldrich. Our ability to commercialize our product candidates may be adversely affected if we do not obtain a license to these patents. We may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be nonexclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our gene editing platform technology or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Our ability to commercialize our product candidates in the United States and abroad may be adversely affected if we cannot obtain a license on commercially reasonable terms to relevant third-party patents that cover our product candidates or platform technology. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize our product candidates and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the

validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to infringe a third-party's intellectual property rights, and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third-party to continue developing, manufacturing, and marketing our product candidates and our technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our platform technology or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

Defense of third-party claims of infringement of misappropriation, or violation of intellectual property rights involves substantial litigation expense and would be a substantial diversion of management and employee time and resources from our business. Some third parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and biopharmaceutical industries, we employ or have employed individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our technology and product candidates, we also rely on know-how and trade secret protection, as well as confidentiality agreements, non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed by or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In the case of consultants and other third parties, the agreements provide that all inventions conceived in connection with the services provided are our exclusive property. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access

to our trade secrets or proprietary technology and processes. Additionally, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. In addition, trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed.

In addition, some courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Relationships with Third Parties

We expect to rely on third parties to conduct clinical trials and some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research, or testing.

We have historically relied and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct certain aspects of research and preclinical testing we may conduct, and we expect to rely on third parties to help conduct any potential clinical trials. Any of these third parties may terminate their engagements with us at any time under certain criteria. If we need to enter into alternative arrangements, it may delay our product development activities.

Our reliance on these third parties to conduct any potential clinical trials and for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of any potential clinical trial we choose to conduct is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA, the EMA and other regulatory authorities require us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected.

Although we may design clinical trials for future product candidates we may choose to develop, CROs will conduct some or all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct current and future preclinical studies and future clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with third parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Third parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs and other third parties do not perform preclinical studies and future clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs and other third parties, we could be required to repeat, extend the duration of, or increase the size of any preclinical studies or clinical trials we conduct and this could

significantly delay commercialization and require greater expenditures, which could have a material adverse effect on our business, financial condition, result of operations, and prospects.

We also expect to rely on third parties to store and distribute drug supplies for any clinical trials we conduct. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our therapies, producing additional losses and depriving us of potential product revenue.

Dr. Matthew Porteus, our co-founder and a member of our board of directors, may have actual or potential conflicts of interest because of his position with Stanford.

Dr. Porteus serves on our board of directors, our Scientific & Clinical Advisory Board and as our paid consultant and retains his position and affiliation with Stanford. Furthermore, Dr. Porteus holds shares of our restricted common stock subject to vesting based, among other things, on his continued service to us as a director, employee or consultant. Dr. Porteus' position at Stanford creates, or may create the appearance of, conflicts of interest when we ask Dr. Porteus to make decisions that could have different implications for Stanford than the decisions have for us or for himself, including decisions related to our license of intellectual property rights from Stanford and other contractual relationships we may enter into from time to time with Stanford.

We contract with third parties for the manufacture of materials for our research programs and preclinical studies and expect to continue to do so for clinical trials and for commercialization of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of such materials, product candidates, or any products that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost or timelines, which could delay, prevent, or impair our development or commercialization efforts.

We do not have any manufacturing facilities at the present time. We have historically relied on third-party manufacturers for the manufacture of materials for our research programs and preclinical studies, including our viral vectors, GMP plasmids, RNA guides and Cas9.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms for one or more of our material needs. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible failure of the third party to manufacture product candidates according to our schedule, or at all, including if the third party gives greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and harm our business, financial condition, results of operations, and prospects.

Any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of suppliers or manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay any potential clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturer cannot perform as agreed, we may be required to replace that manufacturer, or we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different third-party manufacturer, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original third-party manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party manufacturers for any reason, we will be required to verify that the new third-party manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The

delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such third-party manufacturer owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third- party manufacturer in order to have another third-party manufacturer manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or any products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We may enter into collaborations with third parties for the research, development, and commercialization of certain of the product candidates we may develop. If any such collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

We may seek third-party collaborators for the research, development, and commercialization of certain of the product candidates we may develop. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of any product candidates we may seek to develop with them. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot predict the success of any collaboration that we enter into.

Collaborations involving our research programs or our product candidates pose numerous risks to us, including the following:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations.
- Collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished, or terminated.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- Collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such products.
- Collaborators may not properly obtain, maintain, enforce, or defend our intellectual property or proprietary rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development, or commercialization of our therapies or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- Collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates.
- We may lose certain valuable rights under circumstances identified in our collaborations, including if we undergo a change of control.
- Collaborators may require us to incur non-recurring and other charges, increase our near- and long- term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.
- Collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates we develop.

- Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all.

If our collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed, and we may need additional resources to develop product candidates. In addition, if one of our collaborators terminates its agreement with us, we may find it more difficult to find a suitable replacement collaborator or attract new collaborators, and our development programs may be delayed or the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval, and commercialization described here apply to the activities of our collaborators.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic licensors, collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Some of our academic licensors, collaborators and strategic partners are conducting multiple product development efforts within each area that is the subject of the license or collaboration with us. Our licensors, collaborators or strategic partners, however, may develop, either alone or with others, products in related fields that are competitive with the product candidates we develop that are the subject of these collaborations with us. Competing products, either developed by the licensors, collaborators or strategic partners or to which the licensors, collaborators or strategic partners have rights, may result in the withdrawal of partner support for our product candidates.

Some of our collaborators or strategic partners could also become our competitors in the future. Our collaborators or strategic partners could develop competing products, preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

If we are not able to establish collaborations on a timely basis, on commercially reasonable terms, or at all, we may have to alter, reduce or delay our development and commercialization plans, or increase our expenditures to fund development or commercialization activities at our own expense.

For some of the product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborations and collaborations are complex and time-consuming to negotiate and document. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us.

We may also be restricted under existing collaboration agreements from entering into future collaboration agreements on certain terms with potential collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators, which further increases competition we face in seeking potential collaborations.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to develop product candidates or bring them to market and generate product revenue.

Risks Related to Our Employee Matters, Managing Growth, Public Health and Information Technology

Our future success depends on our ability to retain our executive officers and other key employees and to attract, retain, and motivate qualified personnel.

We are highly dependent on its executive officers, as well as the other principal members of our management and scientific teams. Each of our executive officers and such other principal members are employed "at will," meaning we or they may terminate the employment

at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development, and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing, and sales and marketing personnel is critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating its research and development and commercialization strategy. Our consultants and advisors, including its scientific co-founders, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The inability to recruit, or loss of services of certain executives, key employees, consultants, or advisors, may impede the progress of our research, development, and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our internal computer systems, or those of our third-party vendors, collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

Our internal computer systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants are vulnerable to damage or interruption from computer viruses, malware (including ransomware), phishing attacks, computer hackers, malicious code, employee theft or misuse, intentional or accidental action or lack of action by our employees or any contractors with access to our systems that leads to the introduction of vulnerabilities, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, supply chain attacks, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we seek to protect our information technology systems from system failure and we seek to identify and manage specific cyber security risks, accident and security breach, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets, personal information, or other proprietary information or other disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counter-parties and data subjects could be material. In addition, our remediation efforts may not be successful. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our or our third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential, personal or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

Our operations are vulnerable to interruption by fire, earthquakes, power loss, telecommunications failure, terrorist activity, pandemics and other events beyond our control, which could harm our business.

We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major flood, fire, earthquake, power loss, terrorist activity, pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses

or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Risks Related to Ownership of Our Common Stock

We do not know whether a market will develop for our common stock or what the market price of our common stock will be, and, as a result, it may be difficult for you to sell your shares of our common stock.

Although our common stock is listed on the Nasdaq Global Market, an active trading market for our common stock may not be sustained. If a market for our common stock is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade in the future. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock has been and may continue to be volatile and the value of an investment in our common stock may decline, which could result in substantial losses for investors.

The market price of our common stock has been and is likely to continue to be highly volatile. From February 7, 2022 through February 27, 2024, the trading price of our common stock ranged between a low sales price of $1.59 and a high sales price of $11.30. As a result of this volatility, a holder may not be able to sell our common stock at or above the price at which such holder acquired shares of our common stock.

The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- the success of existing or new competitive product candidates or technologies;
- the timing and results of preclinical studies and clinical trials for our product candidates;
- failure or discontinuation of any of our product development and research programs;
- results of preclinical studies, clinical trials, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- developments or changing views regarding the use of genetic medicines, including those that involve gene editing;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs, clinical development programs, or product candidates that we may develop;
- the results of our efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts, if any, that cover our stock;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- the COVID-19 pandemic, natural disasters, or major catastrophic events;
- general economic, industry, and market conditions; and
- the other factors described in this "Risk Factors" section.

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. Persons who were our stockholders prior to our IPO continue to hold a substantial number of shares of our common stock. Significant portions of these shares are held by a small number of stockholders. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, certain shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered or intend to register all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates. In addition, our directors, executive officers and certain affiliates may establish programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2023, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 78.4% of our common stock. This group of stockholders has the ability to control us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that a stockholder may feel are in such stockholder's best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with the interests of our other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "JOBS Act") and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("SOX"), not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. Accordingly, the information contained in our disclosure may be different from the information you receive from other public companies in which you hold stock. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller

reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

We have broad discretion in the use of the capital we have raised and may not use it effectively.

We cannot specify with certainty the particular uses of the capital we have raised, including the net proceeds from our IPO. Accordingly, our stockholders will have to rely upon the judgment of our management with respect to the use of these funds, with only limited information concerning management's specific intentions. Our management may spend a portion or all of the net proceeds from our prior financings, including our IPO in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and prospects. Pending their use, we may invest the net proceeds from our prior financings, including our IPO in a manner that does not produce income or that loses value.

Provisions in our amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management, which could depress the trading price of our common stock.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. Our amended and restated certificate of incorporation and bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only (i) for cause or (ii) by the affirmative vote of the holders of 75% or more of the outstanding shares of capital stock then entitled to vote at an election of directors;
- expressly authorize our board of directors to make, alter, amend or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws, provided, however, if our board of directors recommends that our stockholders approve the amendment at a meeting of stockholders, the amendment shall only require the affirmative vote of the majority of the outstanding shares of capital stock entitled to vote on such amendment.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware as the exclusive forum for certain state law litigation that may be initiated by our stockholders and the U.S. federal district courts as the exclusive forum for certain securities law actions, which could limit our stockholders' ability to litigate disputes with us in a different judicial forum and increase the costs for our stockholders to pursue certain claims against us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or employees to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws (including their interpretation, validity or enforceability); or (iv) any action asserting a claim governed by the internal affairs doctrine. Unless we consent in writing to the selection of an alternate forum, the United States federal district courts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to these exclusive forum provisions. The forum selection provisions in our amended and restated bylaws may limit our stockholders' ability to litigate disputes with us in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, these forum selection provisions may impose additional litigation costs for stockholders who determine to pursue any such lawsuits against us.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cyber Risk Management and Strategy

At Graphite Bio, we recognize the importance of assessing, identifying, and managing risks from cybersecurity threats. We have implemented a cybersecurity risk management process in accordance with our risk profile and business that is informed by industry standards.

We leverage the support of third-party information technology and security providers, including for periodic security testing and vulnerability scanning, as part of our risk management process, designed to identify, assess, and manage cybersecurity risks.

We maintain an incident response and notification plan designed to assist us in identifying, responding to, and recovering from cybersecurity incidents, and we have a process to assess the security practices of certain third-party vendors.

Although risks from cybersecurity threats have to date not materially affected us, our business strategy, results of operations or financial condition, we have, from time to time, experienced threats to and breaches of our and our third-party vendors' data and systems. For more information about these risks, please refer to the section entitled "Risk Factors" in this Annual Report on Form 10-K.

Governance Related to Cybersecurity Risks

Our Chief Executive Officer, with the assistance of the Company's third-party information technology providers, is responsible for the strategic leadership and direction of the Company's cybersecurity program.

The Company's audit committee has oversight over cybersecurity risks. With the input of other members of Company management and the Company's information technology providers, the Chief Executive Officer provides periodic presentations to the audit committee on the Company's cyber program, including updates on security testing and assessments, cyber risks, and related cyber strategy, as applicable.

Item 2. Properties.

We lease 3,983 square feet of office and laboratory space in South San Francisco under a lease that expires in March 2025.

We believe that our facilities are sufficient to meet our current needs. Information as to material lease commitments is included in Financial Note 8, "Operating Leases," to the financial statements appearing in this Form 10-K.

Item 3. Legal Proceedings.

On February 1, 2024, a complaint was filed by a purported stockholder against us and our board of directors in connection with the proposed merger. The complaint is captioned Chew v. Graphite Bio, Inc., et al., No. 3:24-cv-00613 (N.D.Cal., filed Feb. 1, 2024) (the "Complaint"). The Complaint alleges that the defendants filed or caused to be filed materially incomplete and misleading preliminary registration statement with the SEC and asserts claims under Sections 14(a) and 20(a) of the Exchange Act. In addition, we and our board of directors have received four additional demands from purported stockholders seeking additional disclosures in the registration statement (collectively, the "Demands"). We cannot predict the outcome of the Complaint or the Demands. We believe that the allegations and claims asserted in the Complaint and the Demands are without merit and intend to defend against them vigorously. Additional lawsuits and demand letters arising out of the merger may also be filed or received in the future.

From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock trades on the Nasdaq Global Select Market under the symbol "GRPH." Trading of our common stock commenced on June 25, 2021 in connection with our IPO. Prior to that time, there was no established public trading market for our common stock.

Holders

As of February 23, 2024, we had approximately 17 holders of record of our common stock. This number does not include beneficial owners whose shares were held in street name.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. Further, prior to the effective time of the merger with LENZ, our board of directors will declare and set aside the aggregate cash amount to be paid in accordance with a special cash dividend (the "special cash dividend") to holders of record of outstanding shares of our common stock as of a record date prior to the effective time of the merger, to be set by our board of directors as close as reasonably practicable to (but not later than) the anticipated closing. The aggregate amount of the special cash dividend is expected to be $60.0 million, subject to certain adjustments depending on our net cash and our private placement.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Form 10-K.

Recent Sales of Unregistered Securities

On November 14, 2023, concurrently with the execution of the Merger Agreement, we entered into a subscription agreement (the "Subscription Agreement") with certain institutional investors (the "PIPE investors"), pursuant to which, and on the terms and subject to the conditions of which, the PIPE investors have collectively subscribed for approximately $53.5 million of shares of our common stock, which amount may be increased to up to $125 million through additional subscriptions under the Subscription Agreement from additional PIPE investors (the "Graphite private placement").

The closing of the Graphite private placement is expected to occur concurrently with, and is conditioned upon, the closing of the merger. Following the closing of the merger and Graphite private placement, assuming a subscription amount of $53.5 million, the former LENZ stockholders are expected to own approximately 56.3% of the outstanding shares of our common stock on a fully-diluted basis, our stockholders as of immediately prior to the effective time of the merger are expected to own approximately 30.7% of the outstanding shares of our common stock on a fully-diluted basis and the investors issued shares of our common stock in the Graphite private placement are expected to own approximately 13.0% of the outstanding shares of our common stock on a fully-diluted basis (excluding any shares reserved for future grants under the 2024 Plan and the 2024 ESPP).

The Graphite private placement was exempt from registration under Section 4(a)(2) of the Securities Act and/or Rule 506 of Regulation D promulgated by the SEC thereunder. The common stock in the Graphite private placement was sold to "accredited investors", as defined in Regulation D.

Use of Proceeds from the Initial Public Offering of Common Stock

On June 29, 2021, we completed our IPO and issued 14,000,000 shares of our common stock at an initial offering price of $17.00 per share. On July 2, 2021, we issued 2,100,000 shares of our common stock to the underwriters of the IPO pursuant to the exercise of their option to purchase additional shares at a price of $17.00 per share less underwriting discounts and commissions. We received net proceeds from the IPO of approximately $251.3 million, after deducting underwriting discounts and commissions of approximately $19.1 million and offering expenses of approximately $3.2 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates. Morgan Stanley & Co. LLC, BofA Securities, Inc., Cowen and Company, LLC and SVB Leerink, LLC acted as book-running managers for the IPO.

Shares of our common stock began trading on The Nasdaq Global Market on June 25, 2021. The offer and sale of the shares were registered under the Securities Act on a registration statement on Form S-1 (Registration No. 333-256838), which was declared effective on June 24, 2021.

As of December 31, 2023, we have used approximately $229.2 million of the net proceeds received in the IPO. Cash used since the IPO is described elsewhere in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of our

periodic reports filed with the SEC. There has been no material change in the planned use of proceeds from our IPO as described in the registration statement on Form S-1. We invested the funds received in cash equivalents and other marketable securities in accordance with our investment policy.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Reserved.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Management's discussion and analysis of financial condition and results of operations, referred to as the "Financial Review," is intended to assist the reader in the understanding and assessment of significant changes and trends related to the results of operations and financial position of Graphite Bio (the "Company," "Graphite," "we," "our," or "us" and other similar pronouns). This discussion and analysis should be read in conjunction with the financial statements and accompanying financial notes in Item 8 of Part II of this Form 10-K.

Certain statements in this report constitute forward-looking statements. See Cautionary Note Regarding Forward-Looking Statements of this Form 10-K for additional factors relating to these statements and Item 1A - Risk Factors in Part I of this Form 10-K for a list of certain risk factors applicable to our business, financial condition, and results of operations.

Overview

We have historically been a clinical-stage, next-generation gene editing company. In January 2023, Graphite announced a voluntary pause of its Phase 1/2 CEDAR study of nulabeglogene autogedtemcel (nula-cel), for sickle cell disease ("SCD") due to a serious adverse event in the first patient dosed, which Graphite concluded is likely related to study treatment. Nula-cel was being developed as a highly differentiated approach to treating SCD, with the potential to directly correct the mutation that causes SCD and restore normal adult hemoglobin expression.

In February 2023, we announced our decision to discontinue the development of nula-cel and initiate a process to explore strategic alternatives. As a result of this decision, we announced a corporate restructuring that resulted in an approximately 45.0% reduction in our workforce. In August 2023, we further reduced our workforce with an additional 33.1% of our total workforce, and in aggregate, a total of 78.1% of our total workforce. We also disclosed our intention to continue research activities associated with our pre-clinical non-genotoxic conditioning program, with the goal of advancing toward one or more potential development candidates. As part of the corporate restructuring, we also elected not to utilize the portion of our facilities space subject to our lease agreement with Bayside Area Development for purposes of our own operations.

In August 2023, we entered into the LOA, pursuant to which we granted Kamau an option to acquire certain of our technology and intellectual property related to our nula-cel program and related pre-clinical platform assets. We also entered into an asset purchase agreement pursuant to which we transferred to Maro our pre-clinical non-genotoxic conditioning program, including technology and intellectual property, while we continued to explore strategic alternatives. On September 12, 2023, we and Kamau entered into an amendment to the LOA, under which we agreed to assign certain contracts to Kamau prior to exercise of the option, and as of December 31, 2023, these contracts have been assigned to Kamau.

In October 2023, we entered into a sublease for a portion of the facility leased to us by Bayside Area Development, as well as an amendment to the master lease, which provided for an accelerated termination of the lease and a release of liabilities under the lease and the new sublease upon payment of a lump sum at the time of signing. Following this transaction, we are no longer obligated for any rent payments under our lease with Bayside Area Development.

After a comprehensive review of strategic alternatives, including identifying and reviewing potential candidates for a strategic transaction, on November 14, 2023, we entered into the Merger Agreement with LENZ, pursuant to which Merger Sub will merge with and into LENZ, with LENZ surviving as our wholly-owned subsidiary. The merger was unanimously approved by our board of directors, and the board of directors resolved to recommend approval of the Merger Agreement to our stockholders. The closing is subject to approval by our stockholders and LENZ's stockholders, as well as other customary closing conditions, including the effectiveness of a registration statement on Form S-4 filed with the SEC in connection with the merger and Nasdaq's approval of the listing of the shares of the Graphite common stock to be issued in connection with the transaction. If the merger is completed, the business of LENZ will continue as the business of the combined company.

Our future operations are highly dependent on the success of the merger and there can be no assurances that the merger or any other strategic transaction will be successfully consummated. If the strategic review process is unsuccessful, our board of directors may decide to pursue a dissolution and liquidation.

We were incorporated in Ontario, Canada in June 2017 as Longbow Therapeutics Inc. and were reincorporated in the State of Delaware in October 2019. In February 2020, we changed our name to Integral Medicines, Inc. and in August 2020, we changed our name to Graphite Bio, Inc. Research and development of our initial technology ceased at the end of 2018 and we did not have any significant operations or any research and development activities in 2019. In March 2020, we identified new gene editing technology which it sought to further develop, and it licensed the related intellectual property rights from Stanford in December 2020.

Since our inception in June 2017, we have devoted substantially all of our resources to performing research and development, enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and product candidates, organizing and staffing the company, performing business planning, establishing our intellectual property portfolio, raising capital and providing general and administrative support for these activities. We have had one product candidate that has an accepted IND, which has been transferred to Kamau in connection with our execution of the LOA. All of our other product candidates

were in preclinical development, and we do not have any products approved for sale and have not generated any revenue from product sales. To date, we have funded our operations primarily with an aggregate of $197.7 million in aggregate gross proceeds from the sales of its redeemable convertible preferred stock and the issuance of convertible notes. In June and July 2021, we completed the IPO and issued 16,100,000 shares of our common stock for $17.00 a share with a total net proceeds of approximately $251.3 million, and total underwriting costs of $19.1 million and issuance costs of $3.2 million. We will continue to require additional capital to fund our operations for the foreseeable future and ensure we have adequate personnel, can pay for accounting, audit, legal, and consulting services, and can pay costs associated with maintaining compliance with Nasdaq listing rules and the requirements of the SEC, director and officer liability insurance and other expenses associated with operating as a public company. Accordingly, until such time as we can generate significant revenue from product sales, if ever, we expect to finance our cash needs through public or private equity or debt financings, and collaborations, strategic alliances and licensing arrangements with third parties.

We have incurred significant operating losses since inception. As of December 31, 2023, we had cash and cash equivalents of $184.3 million and an accumulated deficit of $367.1 million. We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon successful development, approval and commercialization of our product candidates and upon achievement of sufficient revenues to support our cost structure. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take at least several years. We may never achieve profitability, and unless and until then, we will need to continue to raise additional capital.

Based upon our current operating plan, we estimate that our cash, cash equivalents and restricted cash as of December 31, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months.

We expect to continue to incur significant expenses in connection with the merger or the process of evaluating other strategic alternatives if the merger is unsuccessful. There can be no assurance, however, that we will be able to successfully consummate the merger or any other strategic transaction. The process of continuing to evaluate strategic transactions may be very costly, time-consuming and complex, and we have incurred, and may in the future incur, significant costs related to these processes, such as legal, accounting and advisory fees and expenses and other related charges. A considerable portion of these costs will be incurred regardless of whether the merger or any other strategic transaction is completed. Any such expenses will decrease the remaining cash available for use in our business. In addition, the merger or any other strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. There can be no assurances that any particular course of action, business arrangement, transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value or achieve the anticipated results. Any failure of the merger or any other strategic business combination or other transactions to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

Should we resume development of product candidates, our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more product candidates. In addition, we will incur substantial research and developments costs and other expenditures to develop such product candidates, particularly as it:

- advances any product candidates through preclinical studies and clinical trials;
- manufactures supplies for our preclinical studies and clinical trials;
- seeks marketing approval for product candidates that successfully complete clinical development, if any;
- maintains compliance with applicable regulatory requirements;
- develops and scales up our capabilities to support preclinical activities and clinical trials for product candidates and commercialization of product candidates for which we obtain marketing approval, if any;
- retains key personnel to continue our go-forward operations;
- operates as a public company;
- explores and executes on our strategic alternative process or a potential strategic transaction;
- implements and maintains operational, financial and management systems; and
- obtains, maintains, expands and protects our portfolio of intellectual property rights;

We have relied and may in the future rely on third parties in the conduct of its preclinical studies and clinical trials and for manufacturing and supply of our product candidates if we resume any development activities. We have no internal manufacturing capabilities, and we may continue to rely on third parties for our preclinical and clinical trial materials, of which the main suppliers are single-source suppliers. Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure.

Accordingly, if we obtain regulatory approval for any future product candidates, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from sales of any product for which we receive regulatory approval, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Stanford Exclusive License Agreement and Option Agreement

In December 2020, we entered into an exclusive license agreement (the "License Agreement"), with The Board of Trustees of the Leland Stanford Junior University ("Stanford"), pursuant to which Stanford granted us a worldwide license to specified technology and patent rights to develop, manufacture and commercialize human prophylactic and therapeutic products. Other than with respect to specified, broadly applicable assays and procedures and subject to retained rights by Stanford, the license is exclusive with respect to human prophylactic and therapeutic products for the treatment of SCD, XSCID and beta thalassemia. The license is non-exclusive with respect to those broadly applicable assays and procedures and with respect to all human prophylactic and therapeutic products other than for the treatment of SCD, XSCID and beta thalassemia.

To date, pursuant to the License Agreement, we have paid an upfront license fee to Stanford of $50.0 thousand and issued to Stanford and its designees an aggregate of approximately 0.6 million shares of our common stock. The acquisition of the exclusive license, including patent rights and know-how, and clinical supplies was accounted for as an asset acquisition and as the acquired technology and inventories did not have an alternative use, the total consideration of $2.8 million was recorded as research and development expense in the statements of operations and comprehensive loss for the year ended December 31, 2020. We are obligated to pay Stanford an annual license maintenance fee on each anniversary of the effective date of the License Agreement. The annual license maintenance fee initially is $5.0 thousand and will increase to $50.0 thousand in three increments over the first seven anniversaries of the effective date of the License Agreement. After the first commercial sale of a product falling within the scope of the license (the "Licensed Product"), the annual license maintenance fee is $200.0 thousand.

In May 2021, we issued 640,861 shares of our common stock in connection with the License Agreement. Subsequently, in June 2021, related to the License Agreement, we repurchased 624,845 shares of our common stock from investors and founders.

We are required to share with Stanford a portion of any non-royalty income we receive from sublicensing the licensed patent rights or technology, subject to specified exclusions. With respect to sublicenses granted to products for the treatment of SCD, XSCID and beta thalassemia, the portion of sublicense income we must share with Stanford varies by indication and declines from between a mid-teen to a second quartile double-digit percentage prior to the filing of an IND to between a high single-digit to very low double-digit percentage upon achievement of a specified clinical milestone. With respect to sublicenses granted under the licensed technology rights and not licensed patent rights, the portion of sublicense income shared with Stanford declines from between a mid-single-digit and very low double-digit percentage prior to the filing of an IND to a low single-digit percentage after filing of an IND.

We are obligated to make payments to Stanford with respect to each Licensed Product of up to an aggregate of $12.8 million upon the achievement of certain development, regulatory and commercial milestones. Such amounts are payable only once upon the first occurrence of a particular milestone event with respect to each Licensed Product and only once with respect to each new indication covered by any of the Licensed Products.

We also are obligated to pay Stanford low single-digit royalties based on worldwide annual net sales of any Licensed Product, subject to specified reductions. We will be obligated to continue to pay royalties on a Licensed Product-by-Licensed Product and country-by-country basis, until the latest of (i) the expiration of the last valid claim under the licensed patents that covers the sale or manufacture of such Licensed Product in such country, (ii) the expiration of any period of regulatory exclusivity with respect to such Licensed Product in such country or (iii) the expiration of ten years after the first commercial sale of such Licensed Product in such country.

The term of the License Agreement expires on the later of (i) the expiration of the last patent or abandonment of the last patent application within the license patent rights or (ii) the expiration of all royalty terms with respect to Licensed Products. The License Agreement may be terminated by us at will or by Stanford if we remain in breach of the License Agreement following a cure period to remedy the breach.

We are required to use diligent efforts to manufacture, market and sell Licensed Products for the treatment of each of SCD, XSCID and beta thalassemia. In addition, we are required to achieve specified milestones by specified dates with respect to Licensed Products for

the treatment of each of SCD, XSCID and beta thalassemia. If we fail to satisfy our diligence obligations, Stanford may terminate the License Agreement for our breach. For more details on the License Agreement, please see Note 5 of the Notes to Financial Statements.

In January 2021, we entered into an option agreement (the "First Option Agreement"), with Stanford, pursuant to which Stanford granted us the right to obtain a license to specified patent rights relating to human prophylactic and therapeutic products. We may exercise the option in whole or in part to obtain a license under one or more of the optioned patent rights.

Subject to our exercise of the option under the First Option Agreement and our execution of an amendment to the Stanford License Agreement that incorporates the optioned patent rights and any optioned technology, we have agreed to issue to Stanford 132,137 shares of our common stock and pay a license execution fee of $10.0 thousand. The term of the First Option Agreement expires 18 months after its effective date, subject to our right to extend such expiration date by up to an additional one year upon notice to Stanford and by another additional one year upon the reasonable agreement of Stanford. The First Option Agreement will terminate if the Stanford License Agreement terminates. On June 23, 2022, we exercised our right to extend the term of the First Option Agreement for an additional year. On June 6, 2023, we agreed to extend the term of the First Option Agreement for another additional year. As of December 31, 2023, we have not exercised the option and no fees have been paid for the First Option Agreement.

In August 2023, the Company entered into the LOA, pursuant to which we granted Kamau an option to acquire certain of our technology and intellectual property related to our nula-cel program and related pre-clinical platform assets. The License Agreement and First Option Agreement is included in the assets that are subject to the LOA and may be assigned to Kamau if and when it exercises the option.

In April 2021, we entered into an option agreement (the "Second Option Agreement") with Stanford to negotiate the license for additional technologies from Stanford. Pursuant to the Second Option Agreement, we agreed to pay Stanford option fees in an aggregate amount of $30.0 thousand over the term of the option. On April 13, 2022, we entered into an amendment to the Second Option Agreement which extended the term for an additional year. On March 8, 2023, we terminated the Second Option Agreement without exercising the option to negotiate a license for additional technologies from Stanford.

LCGM Service Agreement

On August 30, 2021, we entered into a Master Manufacturing and Service Agreement with the Laboratory for Cell & Gene Medicine ("LCGM") at Stanford ("LCGM MSA"). Pursuant to the LCGM MSA, LCGM will conduct clinical manufacturing, release testing, and product release for nula-cel in our Phase 1 clinical trial to treat SCD. During 2021, we entered into various SOWs under the LCGM MSA under which we received technology transfer and related services for HBB Beta-Globin Gene Variant for SCD, manufacturing engineer test runs, the exclusive use of a manufacturing suite at the LCGM facility, and Phase 1/2 clinical development and manufacturing of the HBB Variant for SCD. We have recognized $1.7 and $6.1 million in research and development expense in connection with the LCGM MSA during the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, the LCGM MSA has been terminated and we do not expect to incur any additional expenses.

IDT License Agreement

On June 7, 2021, we entered into a License Agreement (the "IDT License Agreement") with Integrated DNA Technologies, Inc. ("IDT"). Pursuant to the IDT License Agreement, IDT granted us and our affiliates a worldwide, non-exclusive, sublicensable license to research and develop products incorporating HiFi Cas9 protein variants for use in human therapeutic applications for SCD, XSCID and Gaucher disease (the "Field") and a worldwide, exclusive, sublicensable license to commercialize such products in the Field. We have also been granted the right to expand the licensed Field to include human therapeutic applications in the additional fields of beta thalassemia disorder and lysosomal storage disorders upon the payment of an exercise fee in the amount of $0.5 million per additional field or $1.0 million for both additional fields.

In consideration of the licenses and rights granted to us under the IDT License Agreement, we agreed to pay to IDT an upfront payment in the amount of $3.0 million and up to $5.3 million (or $8.8 million if we elect to expand the Field as described above to include both the beta thalassemia and lysosomal storage disorders fields) in total regulatory milestone payments. Each regulatory milestone payment is payable once on an indication-by-indication basis. In addition, we have agreed to pay IDT a low single-digit royalty on the net sales of products, subject to reductions in specified circumstances. The acquisition of the license was accounted for as an asset acquisition and as the acquired technology did not have an alternative use, the total consideration of $3.0 million was recorded as research and development expense in the statement of operations and comprehensive loss for the year ended December 31, 2021. There are no milestones probable as of December 31, 2023; therefore, no milestone payments have been recognized or paid in during the year ended December 31, 2023.

The IDT License Agreement remains in effect on a country-by-country and product-by-product basis until the expiration of the royalty term for such product in such jurisdiction. We and IDT each have the right to terminate the IDT License Agreement for the other party's

material breach of its obligations under the IDT License Agreement, subject to specified rights to cure. Additionally, we may terminate the IDT License Agreement for any reason upon written notice.

In August 2023, we entered into the LOA, pursuant to which we granted Kamau an option to acquire certain of our technology and intellectual property related to our nula-cel program and related preclinical platform assets. The IDT License Agreement is included in the assets that are subject to the LOA and may be assigned to Kamau if and when it exercises the option.

During the year ended December 31, 2023, and as of December 31, 2023, we did not and do not expect to incur any expenses associated with the IDT License Agreement.

Sale of Non-Genotoxic Targeted Conditioning Technology Assets

On August 1, 2023, we entered into an asset purchase agreement (the "APA") with Maro pursuant to which we sold to Maro, concurrently with the execution of the APA, certain assets related to our non-genotoxic conditioning technology in exchange for upfront consideration of $0.5 million. Additional consideration included certain contingent milestone payments totaling up to approximately $1.0 million in the aggregate, and potential fees upon the completion of certain transactions by the acquirer. The APA also provided for reimbursement of certain research and development amounts incurred prior to closing of approximately $0.6 million as well as certain transition services to be provided by us or Maro. Under the APA, Maro will also pay us a sub single digit percentage cash royalty of worldwide net sales of certain products incorporating the acquired technology. The royalty term will terminate on a product-by-product and country-by-country basis on the latest of (i) the ten (10) year anniversary of the first commercial sale of such product in such country, (ii) the expiration of the last-to-expire valid claim of a transferred patent that covers such product in such country, and (iii) the expiration of regulatory exclusivity with respect to such product in such country. The APA also includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

The disposal of certain assets sold pursuant to the APA was accounted for as a deconsolidation of a subsidiary or group of assets in accordance with ASC 810. During the year ended December 31, 2023, we recognized a loss on disposal of $0.1 million, which was recorded in other expense. We will record amounts related to the contingent milestone payments, royalties, and potential transaction fees when contingencies are resolved and amounts are due in accordance with ASC 450. No contingencies were resolved and recorded as of December 31, 2023.

License and Option to Acquire Nula-Cel Assets

On August 4, 2023, we entered into the LOA with Kamau pursuant to which we exclusively licensed to Kamau, and granted Kamau, an option to acquire certain intellectual property and materials related to our nula-cel program and related pre-clinical platform assets. The option includes rights to assume the License Agreement and the First Option Agreement with Stanford, as well as the IDT License Agreement, among other agreements. Exercise of the option is contingent on Kamau raising a minimum of $10 million in funds no later than August 4, 2024 (the "Financing Milestone"), which contingency may be waived by Graphite. All rights to the intellectual property and materials will revert to us if the milestone is not achieved or if the counterparty elects not to exercise the option. In return for this license and option, we received an equity interest in the counterparty representing 20% of all outstanding shares on a fully diluted basis subject to dilution protection until the Financing Milestone. The LOA includes customary representations and warranties, limitations of liability and indemnification obligations for a transaction of this nature. The LOA automatically expires upon the first to occur of: (1) Kamau's exercise of the option, (2) Kamau's failure to exercise the option within a specified exercise period following achievement of the financing milestone, or (3) Kamau's failure to achieve the financing milestone by the pre-agreed deadline. In addition, either party has the right to terminate the LOA for the uncured material breach or insolvency of the other party, and we have the right to terminate the LOA if Kamau challenges any of the patent rights that are subject to the option. As a result of the 20% equity interest, we have the ability to exert significant influence over Kamau and account for the interest as an equity method investment. We record our proportionate share of investee's equity in earnings or losses based on the most recently available financial information.

On September 12, 2023, we and Kamau entered into an amendment to the LOA, under which we agreed to assign certain contracts to Kamau prior to exercise of the option, and as of December 31, 2023, these contracts have been assigned to Kamau.

The 20% equity interest in Kamau had minimal value upon execution of the LOA and we did not record any amount related to the equity interest as of December 31, 2023. As of December 31, 2023, Kamau has not achieved the financial milestone and does not have the right to exercise the option.

Components of Results of Operations

Operating Expenses

Research and Development

Research and development costs consist primarily of external and internal costs incurred for our research activities and the development of our gene editing platform and associated rights which we licensed in December 2020.

External costs include:

- costs incurred under agreements with third-party CROs, CMOs and other third parties that conduct preclinical and clinical activities on our behalf and manufacture our product candidates;
- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses; and
- other costs associated with our research and development programs, including laboratory materials and supplies and consulting fees.

Internal costs include:

- employee-related costs, including salaries, benefits and stock-based compensation expense, for our research and development personnel; and
- facilities and other expenses incurred in connection with our research and development programs, including expenses for allocated rent and facilities maintenance, and depreciation and amortization.

Research and development costs are expensed as incurred. Since inception, we have not tracked our internal indirect costs and external research and development costs by program. The intellectual property we licensed in late 2020 is fundamental to our platform and we did not focus on any specific programs.

The process of conducting preclinical research is costly and time-consuming. We are unable to determine the duration and completion costs of our research projects or if, when and to what extent they will lead to product candidates and enter into clinical research. If we resume any development of product candidates, our future research and development costs may vary significantly based on factors such as:

- the scope, rate of progress, expense and results of our discovery and preclinical development activities;
- the costs and timing of our CMC activities, including fulfilling GMP-related standards and compliance, and identifying and qualifying suppliers;
- per patient clinical trial costs;
- the number and duration of clinical trials required for approval of our product candidates;
- the number of sites included in our clinical trials;
- the countries in which the trials are conducted;
- delays in adding a sufficient number of trial sites and recruiting suitable patients to participate in our clinical trials;
- the number of patients that participate in the trials;
- patient drop-out or discontinuation rates;
- potential partial reimbursement from governmental agencies for our clinical activities;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates; the timing, receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates;
- significant and changing government regulation and regulatory guidance;

- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials; and
- the extent to which we establish additional strategic collaborations or other arrangements.

General and Administrative Expenses

General and administrative expenses consist primarily of expenses related to employee-related costs, including salaries, benefits and stock-based compensation expense, for our executive, business development, finance and accounting, human resources and other administrative functions; legal services, including relating to intellectual property and corporate matters; accounting, auditing, consulting and tax services; insurance; and facility and other allocated costs not otherwise included in research and development expenses. We expect to continue to incur significant general and administrative expenses for the foreseeable future as we implement our restructuring plan, pursue potential strategic alternatives and conduct our operations generally. We also expect to continue to incur significant expenses associated with being a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with applicable Nasdaq and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Restructuring and Impairment Costs

Restructuring and other charges consist primarily of costs incurred related to the corporate restructuring and the halting of research activities during the year ended December 31, 2023, including severance as well as lease termination, loss on disposal of property and equipment, and impairment of assets held for sale.

Other Income (Expense), Net

Interest and other income, net, consists of interest income and miscellaneous income and expense unrelated to our core operations.

Results of Operations

Years Ended December 31, 2023 and 2022

The following table summarizes our statements of operations and comprehensive loss for the respective years (in thousands):

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 32,137	$ 72,787
General and administrative	40,973	32,852
Restructuring and impairment costs	62,081	—
Total operating expenses	135,191	105,639
Loss from operations	(135,191)	(105,639)
Other income (expense), net:		
Interest income, net	10,949	4,587
Loss on disposal of assets	(71)	—
Other expense	(338)	—
Total other income, net	10,540	4,587
Net loss	$ (124,651)	$ (101,052)
Unrealized gain (loss) on investments	1,048	(1,048)
Comprehensive loss	$ (123,603)	$ (102,100)

Operating Expenses

Research and Development Expenses

Research and development expenses were $32.1 million for the year ended December 31, 2023 compared to $72.8 million for the year ended December 31, 2022, a decrease of $40.7 million. Research and development expenses decreased in the year ended December 31, 2023 compared to the year ended December 31, 2022 primarily due to the Company's announcement on February 22, 2023 to cease its sickle cell disease program. Accordingly, the Company began to wind down certain clinical trial-related and contract manufacturing activities and had a decrease of $22.7 million in clinical expenses. Employee related expenses, including associated stock-based compensation expense, decreased by $12.4 million primarily due to reduction in workforce for R&D employees. Office- related expenses also decreased by $3.3 million, and related depreciation expense also decreased by $0.6 million, due to the termination of the LCGM

and Explora embedded leases. Other professional services decreased by $1.6 million due to wind down of research and development activities and decrease in consultant spend.

General and Administrative Expenses

General and administrative expenses were $41.0 million for the year ended December 31, 2023 compared to $32.9 million for the year ended December 31, 2022, an increase of $8.1 million. The increase in general and administrative expenses was comprised of an increase of $4.5 million primarily related to facilities costs and lease expense and an increase of $3.9 million in professional service agreements and general costs related to our reverse merger. This was partially offset by a decrease in personnel-related costs, including associated stock-based compensation expense as a result in the reductions in force throughout the year.

Restructuring and Impairment Costs

Restructuring and impairment costs for the year ended December 31, 2023 consisted primarily of costs incurred related to the corporate restructuring, including $45.5 million of non-cash impairment related to the decision not to utilize the Bayside Area Development lease,
$8.1 million related to severance expense incurred as part of the Restructuring Plan, $7.1 million related to the impairment and loss on the disposal of property and equipment, and $1.4 million of non-cash impairment related to the decision not to utilize the South San Francisco lease.

Other Income, Net

The other income (expense), net for the years ended December 31, 2023 and 2022 comprised of interest income from the investments in marketable securities and income from money market funds.

Liquidity and Capital Resources

We have incurred losses since inception and have incurred negative cash flows from operations from inception through December 31, 2023. As of December 31, 2023, we had $184.3 million of cash and cash equivalents and our accumulated deficit was $367.1 million. In June and July 2021, we raised net proceeds of $251.3 million in our IPO, pursuant to which we sold an aggregate of 16,100,000 shares of common stock.

Prior to our IPO, we funded our operations primarily from the sale of redeemable convertible preferred stock and issuance of convertible promissory notes.

On July 21, 2022, we filed the shelf registration statement on Form S-3 (the "2022 Shelf") with the SEC in relation to the registration of up to an aggregate offering price of $300.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof. We also simultaneously entered into a Sales Agreement to provide for the offering, issuance and sale by us of up to an aggregate of $75.0 million of our common stock from time to time in "at-the-market" offerings under the 2022 Shelf and subject to the limitations thereof. We will pay to the Sales Agent cash commissions of up to 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement. We have not issued any shares or received any proceeds from any offerings under the 2022 Shelf through December 31, 2023.

Future Funding Requirements

Historically, our primary uses of cash were to fund our operations, which consisted primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant general and administrative expenses for the foreseeable future as we pursue other strategic alternatives, advance potential product candidates, maintain our corporate infrastructure, including the costs associated with being a public company, scale our laboratory and manufacturing operations, and incur marketing costs associated with potential commercialization. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan, we believe that, absent completing the merger, our existing cash, cash equivalents and restricted cash will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. Until we can generate sufficient revenues from the commercialization of product candidates or from collaboration agreements with third parties, if ever, we expect to finance our future cash needs through public or private equity or debt financings, collaborations and other strategic alliances and licensing arrangements, or any combination of these approaches. The sale of equity or convertible debt securities may result in dilution to our stockholders and, in the case of preferred equity securities or convertible debt, those securities could provide for rights, preferences or privileges senior to those of our common stock. Debt financings may subject us to covenant limitations or restrictions on our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Our ability to raise additional funds may be adversely impacted by negative global economic conditions and any disruptions to and volatility in the credit and financial markets in the United States and worldwide that have resulted and may result from inflationary pressures or other factors. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable or acceptable to us. If we are unable to obtain adequate financing when needed or on terms

favorable or acceptable to us, we may be forced to delay, reduce the scope of or eliminate one or more of our research and development programs.

Because our resource requirements could materially change depending on the outcome of our ongoing strategic alternative review process, we are unable to estimate the exact amount of our working capital requirements. In addition to factors related to the strategic alternative review process, if we resume clinical development, our future capital requirements may depend on many other factors, including:

- the timing, scope, progress, results and costs of research and development, discovery, preclinical and non-clinical studies and clinical trials for our current and future product candidates;
- the number, scope and duration of clinical trials required for regulatory approval of our current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates, including any requirement to conduct more studies or generate additional data beyond that which we currently expect would be required to support a marketing application;
- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the revenue, if any, received from commercial sales of any product candidates for which we may receive marketing approval;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payers;
- the costs to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing our patents or other intellectual property rights;
- expenses needed to attract, hire and retain skilled personnel; and
- the costs of operating as a public company.

A change in the outcome of any of these or other variables could significantly change the costs and timing associated with the development of our product candidates. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such change.

Cash Flows

The following table summarizes our sources and uses of cash for the periods presented (in thousands):

	Year Ended December 31,	
	2023	**2022**
Net cash used in operating activities	$ (90,007)	$ (87,980)
Net cash provided by (used in) investing activities	226,346	(241,863)
Net cash provided by financing activities	190	597
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 136,529	$ (329,246)

Cash Flows from Operating Activities

Net cash used in operating activities was $90.0 million for the year ended December 31, 2023, which was primarily attributable to our net loss of $124.7 million and net changes in operating assets and liabilities of $39.2 million, adjusted for net noncash charges of $73.9 million. Net noncash charges included approximately $36.6 million in impairment of assets, $10.6 million in stock-based compensation expense, $4.3 million in noncash lease expense, $2.4 million in depreciation and amortization expense, $1.5 million in net amortization of premiums and discounts in marketable securities, and $0.1 million in loss on disposal of assets, which was partially offset by $1.6 million in gain on asset abandonment. Net changes in operating assets and liabilities primarily consists of $41.4 million in operating lease liabilities, $2.4 million in accounts payable, and $2.3 million in accrued compensation, offset by $5.7 million in prepaid expenses and $1.8 million in accrued expenses.

Net cash used in operating activities was $88.0 million for the year ended December 31, 2022, which was primarily attributable to our net loss of $101.1 million and net changes in operating assets and liabilities of $7.2 million, adjusted for net noncash charges of $20.3 million. Net noncash charges included approximately $13.5 million in stock-based compensation expense, $6.0 million in noncash lease expense, $2.4 million in depreciation and amortization expense, which was partially offset by $1.6 million in net amortization of premiums and discounts in marketable securities. Net changes in operating assets and liabilities primarily consists of $5.5 million in operating lease liabilities, $3.2 million in prepaid expenses, offset by $1.1 million in accrued compensation and $0.4 million in accounts payable and accrued expenses.

Cash Flows from Investing Activities

Net cash provided by investing activities was $226.3 million for the year ended December 31, 2023, which was primarily attributable to sales and maturities from our investments in current and non-current marketable securities of $263.4 million and proceeds from sale of property and equipment of $1.9 million, offset by purchases of investments in marketable securities of $28.1 million and lab equipment of $10.8 million for use at our headquarters.

Net cash used in investing activities was $241.9 million for the year ended December 31, 2022, which was primarily attributable to investment in current and non-current marketable securities of $405.5 million and the purchase of lab equipment of $6.6 million for use at our headquarters, offset by proceeds from our investments in current and non-current marketable securities of $170.2 million.

Cash Flows from Financing Activities

Net cash provided by financing activities was $0.2 million for the year ended December 31, 2023, which consisted primarily of proceeds from issuance of common stock related to stock option grants and employee stock purchase plan of $0.3 million, which was partially offset by repurchases of unvested early exercised stock grants and founders' shares of $0.1 million.

Net cash provided by financing activities was $0.6 million for the year ended December 31, 2022, which consisted primarily of proceeds from issuance of common stock related to stock option grants and employee stock purchase plan of $0.7 million, which was partially offset by repurchases of unvested early exercised stock grants of $0.1 million.

Recently Adopted Accounting Pronouncements

For information on new accounting standards, see Note 2 to our financial statements included in Part II in this Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including but not limited to those related to accrued research and development costs, investments in marketable securities, and common stock and stock-based compensation expense, the valuation of deferred tax assets, and uncertain income tax positions. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued research and development expenses

As part of the process of preparing our financial statements, we estimate our accrued research and development expenses at each balance sheet date. This process involves reviewing purchase orders and open contracts, communicating with our personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments as necessary. The significant estimates in its accrued research and development expenses include the costs incurred for services performed by CROs and CMOs in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and

development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Stock-based compensation

We measure stock options and other stock-based awards granted to our employees, directors, consultants or founders based upon their fair value on the date of the grant and recognize stock-based compensation expense over the requisite service period, which is generally the vesting period of the respective award. We recognize forfeitures as they occur.

The majority of our stock-based compensation awards are subject to either service- or performance-based vesting conditions. We apply the straight-line method of expense recognition to all awards with service-based vesting and recognize stock-based compensation for performance-based awards over the service period using the accelerated attribution method to the extent achievement of the of performance condition is probable.

We estimate the fair value of each stock option grant on the date of grant using the Black-Scholes option-pricing model, which uses inputs such as the fair value of our common stock, assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. The fair value of our common stock is used to determine the fair value of restricted stock awards.

Prior to our IPO in June 2021, there was no public market for our common stock. As a result, prior to our IPO, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. Following our IPO, the fair value of our common stock is determined based on the quoted market price of our common stock.

Leases

ASU No. 2016-02, Leases (Topic 842), or ASC 842, requires the recognition of the right-of-use assets and related operating and finance lease liabilities on the balance sheet. For contracts entered into on or after the effective date, at the inception of a contract, we assess whether the contract is, or contains, a lease. The assessment is based on: (1) whether the contract involves the use of a distinct identified asset, (2) whether we obtain the right to substantially all the economic benefit from the use of the asset throughout the period, and (3) whether we have the right to direct the use of the asset. At inception of a lease, we allocate the consideration in the contract to each lease component based on its relative stand-alone price to determine the lease payments.

Leases are classified as either finance leases or operating leases. A lease is classified as a finance lease if any one of the following criteria are met: the lease transfers ownership of the asset by the end of the lease term, the lease contains an option to purchase the asset that is reasonably certain to be exercised, the lease term is for a major part of the remaining useful life of the asset or the present value of the lease payments equals or exceeds substantially all of the fair value of the asset. A lease is classified as an operating lease if it does not meet any of these criteria.

For all leases at the lease commencement date, a right-of-use asset and a lease liability are recognized. The right-of-use asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease.

The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any initial direct costs incurred, if any, less any lease incentives received. All right-of-use assets are reviewed for impairment. The lease liability is initially measured at the present value of the lease payments, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, our secured incremental borrowing rate for the same term as the underlying lease. For real estate leases and other operating leases, we use our secured incremental borrowing rate. For finance leases, we use the rate implicit in the lease or our secured incremental borrowing rate if the implicit lease rate cannot be determined.

Lease payments included in the measurement of the lease liability comprise the following: the fixed noncancelable lease payments, payments for optional renewal periods where it is reasonably certain the renewal period will be exercised, and payments for early termination options unless it is reasonably certain the lease will not be terminated early.

Lease cost for operating leases consists of the lease payments plus any initial direct costs, primarily brokerage commissions and is recognized on a straight-line basis over the lease term. Included in lease cost are any variable lease payments incurred in the period that are not included in the initial lease liability and lease payments incurred in the period for any leases with an initial term of 12 months or

less. Lease cost for finance leases consists of the amortization of the right-of-use asset on a straight-line basis over the lease term and interest expense determined on an amortized cost basis. The lease payments are allocated between a reduction of the lease liability and interest expense.

Leasehold improvements are not unique and are retained by the lessor at the end of the lease. However, we are the accounting owner of the leasehold improvements in the case of a space designed to be suitable for our specific real estate needs if we are also responsible for cost overruns.

We elected to make an accounting policy of the short-term leases exemption to leases with a remaining lease term of less than 12 months as at the date of initial adoption.

Impairment of Long-Lived Assets

We assess the impairment of long-lived assets whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. In the case of property and equipment and right-of-use assets for our leases, we determine whether there has been an impairment by comparing the carrying value of the asset to the anticipated undiscounted net cash flows associated with the asset. If such cash flows are less than the carrying value, we write down the asset to its fair value, which may be measured as anticipated discounted net cash flows associated with the asset.

As discussed in Note 13 to our financial statements included elsewhere in this Form 10-K, in connection with our Restructuring Plan, we have made the decision not to utilize the Bayside Area Development premises (the "Bayside lease") and have been seeking to sublease the vacated premises while still maintaining sufficient office and laboratory space for our normal operations. As a result, we reviewed the Bayside lease for impairment as of April 2023 when we received access to the premises and as part of our impairment evaluation of the Bayside lease, we separately compared the estimated undiscounted income to the net book value of the related long-term assets, which include right-of-use assets and certain property and equipment, primarily leasehold improvements. We estimated sublease income using market participant assumptions, including the length of time to enter into a sublease and sublease payments, which we evaluated using sublease negotiations or agreements where applicable, current real estate trends, and market conditions. If such income exceeded the net book value of the related assets, we did not record an impairment charge. Otherwise, we recorded an impairment charge by reducing the net book value of the assets to their estimated fair value, which we determined by discounting the estimated sublease cash flows using the estimated borrowing rate of a market participant subtenant. Determination of these key assumptions is complex and highly judgmental.

For certain impairment charges, we used the terms of active sublease negotiations or agreements to estimate sublease income. Our estimate of future cash flows on the remaining floors, including the time to enter into a sublease and the terms of sublease payments, including estimated free rent periods, are based on current real estate trends and market conditions. Accordingly, if our estimates for the time to enter the sublease and estimated free rent periods were longer (shorter), the impairment charge would be higher (lower), and if our estimates for the rental rates were lower (higher), the impairment charge would be higher (lower). Given the current office lease market rental conditions in the Bay Area, our estimates are subject to significant uncertainty. The ultimate amount of sublease income may be significantly lower or higher than the amounts used to record our impairment charges, and we may record additional impairment charges in future periods as our estimates change or when we enter into sublease negotiations or execute a sublease agreement.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation and less extensive disclosure about our executive compensation arrangements. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act.

However, as described in Note 2 to our financial statements included elsewhere in this Form 10-K, we early adopted certain accounting standards, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies to the extent early adoption is permitted. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenues of $1.235 billion or more, (ii) December 31, 2026, (iii) the date on which we are deemed to be a "large accelerated filer," under the rules of the SEC, which means the market value of equity securities that is held by non-affiliates exceeds $700.0 million as of

the prior June 30th and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

If we are a "smaller reporting company" at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Under SEC rules and regulations, as a smaller reporting company, we are not required to provide the information required by this item.

Item 8. Financial Statement and Other Supplementary Information.

Graphite Bio, Inc.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the shareholders and the Board of Directors of Graphite Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Graphite Bio, Inc. (the "Company") as of December 31, 2023 and 2022, the related statements of operations and comprehensive loss, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

San Francisco, California

February 27, 2024

We have served as the Company's auditor since 2021.

Graphite Bio, Inc.
Balance Sheets
(in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 184,259	$ 47,730
Investments in marketable securities, current	—	220,499
Restricted cash, current	1,602	—
Prepaid expenses and other current assets	2,160	7,136
Total current assets	188,021	275,365
Restricted cash, non-current	114	1,716
Investments in marketable securities, non-current	—	15,322
Property and equipment, net	—	22,630
Operating lease right-of-use assets	321	5,580
Other assets	—	1,289
Total assets	$ 188,456	$ 321,902
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 250	$ 2,608
Accrued compensation	1,534	3,799
Accrued research costs	—	720
Accrued expenses and other current liabilities	2,728	1,871
Operating lease liabilities, current	285	4,045
Total current liabilities	4,797	13,043
Operating lease liabilities, non-current	77	1,749
Other long- term liabilities	—	10,819
Total liabilities	4,874	25,611
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.00001 par value, 10,000,000 shares authorized as of December 31, 2023 and 2022; and no shares issued and outstanding as of December 31, 2023 and 2022	—	—
Common stock, $0.00001 par value, 300,000,000 shares authorized as of December 31, 2023 and 2022; 58,008,396 and 58,221,760 shares issued and outstanding as of December 31, 2023 and 2022, respectively	1	1
Additional paid-in capital	550,635	539,741
Accumulated other comprehensive loss	—	(1,048)
Accumulated deficit	(367,054)	(242,403)
Total stockholders' equity	183,582	296,291
Total liabilities and stockholders' equity	$ 188,456	$ 321,902

The accompanying notes are an integral part of these financial statements.

Graphite Bio, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 32,137	$ 72,787
General and administrative	40,973	32,852
Restructuring and impairment costs	62,081	—
Total operating expenses	135,191	105,639
Loss from operations	(135,191)	(105,639)
Other income (expense), net:		
Interest income, net	10,949	4,587
Loss on disposal of assets	(71)	—
Other expense, net	(338)	—
Total other income, net	10,540	4,587
Net loss	$ (124,651)	$ (101,052)
Unrealized gain (loss) on investments in marketable securities	1,048	(1,048)
Comprehensive loss	$ (123,603)	$ (102,100)
Net loss per share attributable to common stockholders—basic and diluted	$ (2.19)	$ (1.84)
Weighted-average shares used in computing net loss per share—basic and diluted	57,015,159	54,873,675

The accompanying notes are an integral part of these financial statements.

Graphite Bio, Inc.
Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	58,010,823	$ 1	$ 525,400	$ —	$ (141,351)	$ 384,050
Common shares issued upon exercise of options	67,196	—	20	—	—	20
Common shares issued under ESPP	333,155	—	656	—	—	656
Vesting of early exercised shares	—	—	131	—	—	131
Repurchase of unvested early exercised shares	(189,414)	—	—	—	—	—
Stock-based compensation expense	—	—	13,534	—	—	13,534
Unrealized loss on investments in marketable securities	—	—	—	(1,048)	—	(1,048)
Net loss	—	—	—	—	(101,052)	(101,052)
Balance at December 31, 2022	58,221,760	$ 1	$ 539,741	$ (1,048)	$ (242,403)	$ 296,291
Common stock issued upon exercise of options	101,900	—	100	—	—	100
Common stock issued under ESPP	65,222	—	157	—	—	157
Vesting of early exercised shares	—	—	63	—	—	63
Repurchase of founders' shares	(152,694)	—	—	—	—	—
Repurchase of unvested early exercised shares	(227,792)	—	—	—	—	—
Stock-based compensation expense	—	—	10,574	—	—	10,574
Unrealized gain on investments in marketable securities	—	—	—	1,048	—	1,048
Net loss	—	—	—	—	(124,651)	(124,651)
Balance at December 31, 2023	58,008,396	$ 1	$ 550,635	$ —	$ (367,054)	$ 183,582

The accompanying notes are an integral part of these financial statements

Graphite Bio, Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (124,651)	$ (101,052)
Adjustments to reconcile net loss to net cash used in operating activities:		
Net amortization of premiums and discounts on investments in marketable securities	1,543	(1,600)
Depreciation and amortization	2,407	2,352
Non-cash lease expense	4,289	5,994
Stock-based compensation expense	10,574	13,534
Gain on ROU asset abandonment	(1,638)	—
Loss on sale/ disposal of assets	71	—
Impairment of assets	56,621	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets and other assets	5,676	(3,211)
Accounts payable	(2,358)	194
Accrued compensation	(2,265)	1,110
Accrued research costs	(720)	87
Accrued expenses and other current liabilities and other liabilities	1,806	94
Operating lease liabilities	(41,362)	(5,482)
Net cash used in operating activities	(90,007)	(87,980)
Cash flows from investing activities:		
Purchases of property and equipment	(10,856)	(6,594)
Proceeds from sales of property and equipment	1,904	—
Purchases of investments in marketable securities	(28,129)	(405,519)
Proceeds from sales and maturities of marketable securities	263,427	170,250
Net cash provided by (used in) investing activities	226,346	(241,863)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of vested stock options	100	20
Proceeds from employee stock purchase plan	157	656
Repurchase of unvested early exercised shares and founders' shares	(67)	(79)
Net cash provided by financing activities	190	597
Net increase (decrease) in cash, cash equivalents and restricted cash	136,529	(329,246)
Cash, cash equivalents and restricted cash, at beginning of period	49,446	378,692
Cash, cash equivalents and restricted cash, at end of period	$ 185,975	$ 49,446
Reconciliation of cash, cash equivalents and restricted cash to statement of financial position:		
Cash and cash equivalents	184,259	47,730
Restricted cash	1,716	1,716
Cash, cash equivalents and restricted cash in statement of financial position	$ 185,975	$ 49,446
Supplemental disclosures of non-cash investing and financing information:		
Property and equipment purchases in accounts payable and accrued expenses	$ —	$ (36)
Lessor funded lease incentive additions included in property and equipment	$ 7,193	$ 11,920
Additions to ROU assets from new operating lease liabilities	$ 31,974	$ —
Vesting of early exercised stock options	$ 63	$ 131
Repurchase of unvested early exercised shares included in accounts payable	$ —	$ (17)

The accompanying notes are an integral part of these financial statements.

Graphite Bio, Inc.
Notes to Financial Statements

1. Description of Business, Organization and Liquidity

Organization and Business

Graphite Bio, Inc. (the "Company") has historically been a clinical-stage, next-generation gene editing company. In January 2023, the Company announced a voluntary pause of its Phase 1/2 CEDAR study of nulabeglogene autogedtemcel ("nula-cel"), the Company's lead product candidate for sickle cell disease ("SCD"), due to a serious adverse event in the first patient dosed, which the Company concluded is likely related to study treatment. Nula-cel was designed to provide a highly differentiated approach with the potential to directly correct the mutation that causes SCD and restore normal adult hemoglobin expression.

The Company was incorporated in Ontario, Canada in June 2017 as Longbow Therapeutics Inc., and was reincorporated in the State of Delaware in October 2019. In February 2020, the Company changed its name to Integral Medicines, Inc., and again in August 2020, changed the name to Graphite Bio, Inc. Research and development of the Company's initial technology ceased at the end of 2018, and the Company did not have any significant operations or any research and development activities in 2019. In March 2020, the Company identified new gene editing technology which the Company sought to further develop, and the Company licensed the related intellectual property rights from The Board of Trustees of the Leland Stanford Junior University ("Stanford") in December 2020 (Note 6).

In February 2023, the Company announced its decision to discontinue the development of nula-cel and initiate a process to explore strategic alternatives (the "Restructuring Plan"). As a result of this decision, the Company conducted a corporate restructuring that resulted in an approximately 50% reduction in force in February 2023 and additional reductions in August 2023 that resulted in a total reduction in force of 78.1%. In August 2023, the Company subleased some of its facilities to recover a portion of the total costs. Together, these restructuring actions are intended to reduce the Company's operational cash burn in an effort to maximize its strategic optionality.

The Company had previously disclosed its intention to continue research activities associated with its pre-clinical non-genotoxic conditioning program, with the goal of advancing toward one or more potential development candidates. In August, the Company entered into an asset purchase agreement pursuant to which the Company transferred to Maro Bio, Inc. ("Maro") its pre-clinical non-genotoxic conditioning program, including its technology and intellectual property. Also in August 2023, the Company entered into a license and option agreement (the "LOA"), pursuant to which it granted another third-party an option to acquire certain of the Company's technology and intellectual property related to its nula-cel program and related pre-clinical platform assets. On September 12, 2023, the Company and Kamau Therapeutics, Inc. ("Kamau") entered into an amendment to the LOA, under which we agreed to assign certain contracts to Kamau prior to exercise of the option, and as of December 31, 2023, these contracts have been assigned to Kamau.

In October 2023, the Company entered into an amendment to the master lease, with Bayside Area Development, which provided for an accelerated termination of the lease. The amendment to the master lease also provided for a release of liabilities under the master lease, as well as under the new sublease entered into for a portion of the facility leased to it by Bayside Area Development in October 2023, upon payment of a lump sum at the time of signing. Following this transaction, the Company is no longer obligated for any rent payments under its master lease with Bayside Area Development.

After a comprehensive review of strategic alternatives, including identifying and reviewing potential candidates for a strategic transaction, on November 14, 2023, the Company entered into the Merger Agreement with LENZ, pursuant to which a wholly-owned subsidiary of the Company will merge with and into LENZ, with LENZ surviving as the Company's wholly-owned subsidiary. The merger was unanimously approved by the Company's board of directors, and the board resolved to recommend approval of the Merger Agreement to the stockholders. The closing of the merger is subject to approval by the Company and LENZ's stockholders, as well as other customary closing conditions, including the effectiveness of a registration statement filed with the SEC in connection with the transaction and Nasdaq's approval of the listing of the shares of the Graphite common stock to be issued in connection with the transaction. If the merger is completed, the business of LENZ will continue as the business of the combined company.

From its inception in 2017, the Company's primary activities have been to perform research and development, undertake preclinical studies and enable manufacturing activities in support of its product development efforts, organize and staff the Company, establish its intellectual property portfolio, and raise capital to support and expand such activities. The Company's future operations are highly dependent on the success of the merger and there can be no assurances that the merger will be successfully consummated. There can be no assurance that the strategic review process or any transaction relating to a specific asset, including the merger or any asset sale, will result in the Company pursuing such a transaction(s), or that any transaction(s), if pursued, will be completed on terms favorable to the Company and its stockholders. If the strategic review process is unsuccessful, its board of directors may decide to pursue a dissolution and liquidation of the Company.

Liquidity Matters

The Company has incurred significant operating losses since inception and has primarily relied on private equity and convertible debt financings to fund its operations. As of December 31, 2023, the Company had an accumulated deficit of $367.1 million. The Company expects to continue to incur substantial losses. The Company may never achieve profitability, and unless and until then, the Company

will need to continue to raise additional capital. Management expects that the existing cash and cash equivalents of $184.3 million as of December 31, 2023 will be sufficient to fund the Company's current operating plan for at least the next 12 months from the date of issuance of these financial statements.

On July 21, 2022, the Company filed a shelf registration statement on Form S-3 (the "2022 Shelf") with the SEC in relation to the registration of up to an aggregate offering price of $300.0 million of common stock, preferred stock, debt securities, warrants and units or any combination thereof. The Company also simultaneously entered into a Controlled Equity Offering[SM] Sales Agreement with Cantor Fitzgerald & Co. (the "Sales Agent"), to provide for the offering, issuance and sale by the Company of up to an aggregate of $75.0 million of its common stock from time to time in "at-the-market" offerings under the 2022 Shelf and subject to the limitations thereof (the "Sales Agreement"). The Company will pay to the Sales Agent cash commissions of up to 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement. The Company has not issued any shares or received any proceeds from any offerings under the 2022 Shelf through December 31, 2023.

2. Summary of Significant Accounting Policies

Basis of Presentation

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. On an ongoing basis, the Company evaluates estimates and assumptions, including but not limited to those related to the fair value of the marketable securities, stock-based compensation expense, accruals for research and development costs, lease assets and liabilities, the valuation of deferred tax assets, uncertain income tax positions, and impairment of long-lived assets. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from those estimates.

Principles of Consolidation

The Company assesses entities for consolidation based on the specific facts and circumstances surrounding that entity. The Company first considers whether an entity is considered a variable interest entity ("VIE") and therefore whether to apply the consolidation guidance under the VIE model. Entities that do not qualify as VIEs are assessed for consolidation as voting interest entities ("VOE") under the voting interest model.

An entity is considered to be a VIE if any of the following conditions exist: (i) the equity investment at risk is not sufficient to finance the activities of the entity without additional subordinated financial support, (ii) as a group, the holders of the equity investment at risk lack the power to direct the activities that most significantly impact the entity's economic performance or the obligation to absorb the expected losses or right to receive the expected residual returns, and (iii) the voting rights of some holders of the equity investment at risk are disproportionate to their obligation to absorb losses or right to receive returns, and substantially all of the activities are conducted on behalf of the holder of equity investment at risk with disproportionately few voting rights.

The Company consolidates all VIEs in which it is the primary beneficiary. An entity is determined to be the primary beneficiary if it holds a controlling financial interest in a VIE. The consolidation guidance requires an analysis to determine (i) whether an entity in which the Company holds a variable interest is a VIE and (ii) whether the Company's involvement, through holding interest directly or indirectly in the entity or contractually through other variable interests, would give it a controlling financial interest. Performance of that analysis requires judgment.

Concentration of Credit Risk

Cash and cash equivalents are financial instruments that potentially subject the Company to concentrations of credit risk. Substantially all of the Company's cash and cash equivalents are deposited in accounts with major financial institution and amounts may exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institution in which the cash and cash equivalents are held. The Company has not experienced any losses on deposits of cash and cash equivalents.

Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on the future financial position or results of operations: the timing of, and the Company's ability to advance its current and future product candidates into and through clinical development; costs and timelines

associated with the manufacture of clinical supplies of the Company's product candidates; regulatory approval and market acceptance of, and reimbursement for its product candidates; performance of third-party CROs and CMOs; competition from pharmaceutical companies with greater financial resources or expertise; protection of the intellectual property; litigation or claims against the Company based on intellectual property or other factors; and its ability to attract and retain employees necessary to support its growth. Disruption from CROs', CMOs' or suppliers' operations would likely have a negative impact on the Company's business, financial position and results of operations.

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment. The chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's long-lived assets are based in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with a maturity of three months or less at the date of purchase to be cash equivalents. As of December 31, 2023 and 2022, cash and cash equivalents consisted of cash, money market funds, and commercial paper.

Restricted Cash

Restricted cash of $0.1 million and $1.7 million as of December 31, 2023 and 2022, respectively, represented security deposits in the form of letters of credit issued in connection with the Company's leases. A lease amendment was executed in October 2023 for the Company's intended headquarters at 233 E. Grand Ave, whereby the Company did not have any further rent obligations to the landlord following the effective date. As of December 31, 2023, the letter of credit of $1.6 million is expected to be returned within a year and is presented as Restricted cash, current on the balance sheet. The remaining letter of credit is related to the Company's former headquarters at 201 Haskins Way, which will be returned upon lease termination.

Marketable Securities

The Company's marketable securities are accounted for as available-for-sale and recorded at fair value with the related unrealized gains and losses included in accumulated other comprehensive gain (loss).

The Company reviews its investment portfolio to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The carrying amounts of financial instruments, including restricted cash, prepaid expenses and other current assets, accounts payable, accrued compensation, accrued expenses, and other liabilities, approximate fair value due to their short-term maturities. The cash invested in money-market funds are carried at fair value.

Property and Equipment, Net

Property and equipment are recorded at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally three to five years. Repairs and maintenance expenditures, which are not considered improvements and do not extend the useful life of property and equipment, are expensed as incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in the statements of operations and comprehensive loss in the period realized.

Leases

Effective January 1, 2021, the Company adopted ASC Topic 842, Leases ("ASC 842") using the optional transition method and applied the standard only to leases that existed at that date. Under the optional transition method, the Company does not need to restate the comparative periods in transition and will continue to present financial information and disclosures for periods before January 1, 2021 in accordance with ASC Topic 840. The Company has elected the package of practical expedients allowed under ASC Topic 842, which permits the Company to account for its existing operating leases as operating leases under the new guidance, without reassessing the Company's prior conclusions about lease identification, lease classification and initial direct cost. As a result of the adoption of the new lease accounting guidance on January 1, 2021, the Company recognized no cumulative adjustment to accumulated deficit since the Company had only one operating lease with a term of less than 12 months and no plans to extend the lease.

The Company determines the initial classification and measurement of its right-of-use assets and lease liabilities at the lease commencement date and thereafter if modified. The lease term includes any renewal options and termination options that the Company

is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its incremental borrowing rate. The incremental borrowing rate is determined by using the rate of interest that the Company would pay to borrow on a collateralized basis an amount equal to the lease payments for a similar term and in a similar economic environment.

Fixed lease expense for operating leases is recognized on a straight-line basis, unless the right-of-use assets have been impaired, over the reasonably assured lease term based on the total lease payments and is included in operating expenses in the statements of operations and comprehensive loss. Variable lease expenses are recognized as incurred. Fixed and variable lease expense on operating leases is recognized within operating expenses in the statements of operations and comprehensive loss.

For operating leases for which the right-of-use assets have been impaired, the Company will recognize the amortization of the right-of-use assets on a straight-line basis over the remaining respective lease term with lease expense included in operating expenses in the statements of operations and comprehensive loss.

For all leases, rent payments that are based on a fixed index or rate at the lease commencement date are included in the measurement of lease assets and lease liabilities at the lease commencement date.

The Company has elected the practical expedient to not separate lease and non-lease components. The Company's non-lease components are primarily related to maintenance, insurance and taxes, which varies based on future outcomes and is thus recognized in lease expense when incurred.

Asset Acquisitions

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is charged to research and development expense at the acquisition date. Please refer to Note 6 for more details on asset acquisition.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparing the carrying amount to the future undiscounted net cash flows which the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows generated by the assets. During the year ended December 31, 2023, the Company recognized $54.1 million related to the impairment of its leases and long- lived assets. There were no such impairments of long-lived assets in the year ended December 31, 2022. Please refer to Note 13 for more details on impairment.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development costs include salaries, stock-based compensation, and benefits for employees performing research and development activities, an allocation of facility and overhead expenses, expenses incurred under agreements with consultants, CMOs, CROs and investigative sites that conduct preclinical studies, other supplies and costs associated with product development efforts, preclinical activities, and regulatory operations.

Accrued Research and Development Expenses

The Company has historically entered into various agreements with outsourced vendors, CROs and CMOs. Research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued research costs on the balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered. To date, there have been no material differences between estimates of such expenses and the amounts actually incurred.

Tax Credit Receivable

The Company is eligible for federal and California research and development credits for its research and development activities performed within the United States and California, respectively. The credits are, generally, available to offset federal and California income tax liabilities as applicable. The Company has applied $0.3 million of federal research and development credits to offset its federal payroll tax expenses as of the year ended December 31, 2023 due to its small business status.

Income Taxes

The Company accounts for income taxes using the asset and liability method. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets

and liabilities are determined based on the difference between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

In evaluating the ability to recover deferred income tax assets, the Company considers all available positive and negative evidence, including operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company determines that it would be able to realize deferred income tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the valuation allowance that would reduce the provision for income taxes. Conversely, in the event that all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period when such determination is made. As of December 31, 2023 and 2022, the Company has recorded a full valuation allowance on deferred tax assets.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

Stock-Based Compensation Expense

The Company's stock-based equity awards include restricted stock awards and stock options that are granted to employees and consultants that are accounted at fair value on the award grant date. Stock-based compensation expense is recognized over the awards' vesting period on a straight-line basis and recorded as either research and development or general and administrative expenses in the statements of operations and comprehensive loss based on the function to which the related services are provided. Forfeitures are accounted for as they occur.

As there was no public market for the Company's common stock prior to the initial public offering of its common stock in June 2021, the estimated fair value of common stock was determined by the Company's board of directors as of the date of each option grant, with input from management, considering third-party valuations of its common stock, as well as the Company's board of directors' assessment of additional objective and subjective factors that it believed were relevant, and which may have changed from the date of the most recent third-party valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately Held Company Equity Securities Issued as Compensation. Following the closing of the initial public offering, the fair value of the Company's common stock is determined based on the quoted market price of common stock. The Company also lacks company-specific historical and implied volatility information for its stock. The Company estimates its expected stock price volatility and expected term based on the historical volatility and expected term of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. There is no expected dividend yield since the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Employee Stock Purchase Plan

The Company recognizes stock-based expense related to shares issued pursuant to its Employee Stock Purchase Plan ("ESPP") on a straight-line basis over the offering period, which is typically 6 months. The ESPP allows eligible employees to purchase shares of the Company's common stock at a 15 percent discount on the lower price of either (i) the offering period begin date or (ii) the purchase date. The Company estimates the fair value of shares to be issued under the ESPP using the Black-Scholes option-pricing model. There are no employees enrolled in the ESPP as of December 31, 2023.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss includes net loss as well as other changes in stockholders' deficit which includes certain changes in equity that are excluded from net loss. The Company's only element of other comprehensive loss is unrealized gains and losses on marketable securities.

Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, redeemable convertible preferred stock, common stock subject to repurchase, restricted common shares issued, and stock options are considered to be potentially dilutive securities.

Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities. Restricted shares issued to the founders and upon early exercise of stock options also participate in dividends from the issuance date and are considered participating securities. Participating securities do not have a contractual obligation to share

in losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Adopted and Recent Accounting Pronouncements

The Company is a smaller reporting company and an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Thus, the Company has elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) the Company is no longer an emerging growth company or (ii) the Company affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. However, the Company may early adopt certain accounting standards, as the JOBS Act does not preclude an emerging growth company from adopting a new or revised accounting standard earlier than the time that such standard applies to private companies to the extent early adoption is permitted.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). This update requires entities to disclose significant segment expenses by reportable segment if they are regularly provided to the Chief Operating Decision Maker and included in each reported measure of segment profit or loss and requires disclosure of other segment items by reportable segment and a description of its composition. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, with early adoption permitted. ASU 2023-07 should be applied retrospectively to all prior periods presented in the financial statements. The Company operates and discloses its operations as a single segment and does not expect the adoption of this standard to have a material impact on its annual and interim disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-00"). This update requires entities to consistently categorize and provide greater disaggregation of information in the rate reconciliation and to further disaggregate income taxes paid by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. ASU 2023-07 may be applied retrospectively or prospectively. The Company is currently evaluating the planned adoption date and the impact of this standard on its annual and interim disclosures.

3. Fair Value Measurements

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets, as well as assets and liabilities measured at fair value on a non-recurring basis or disclosed at fair value, are categorized based upon the level of judgment associated with inputs used to measure their fair values. The accounting guidance for fair value provides a framework for measuring fair value and requires certain disclosures about how fair value is determined. Fair value is defined as the price that would be received upon the sale of an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date.

The accounting guidance also establishes a three-level valuation hierarchy that prioritizes the inputs to valuation techniques used to measure fair value based upon whether such inputs are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions made by the reporting entity. The three-level hierarchy for the inputs to valuation techniques is briefly summarized as follows:

Level 1 — Inputs are unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date;

Level 2 — Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level 3 — Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. An assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. The Company recognizes transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs.

As of December 31, 2023 and 2022, Level 1 securities consist of U.S. Treasury and money market funds, for which the carrying amounts are based on the quoted market prices in active markets.

As of December 31, 2022, Level 2 securities consist of highly rated commercial paper, U.S. agency securities, and asset-backed securities, for which fair value is determined through the use of models or other valuation methodologies.

During the periods presented, the Company did not have any Level 3 securities.

The following tables set forth the financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy as of December 31, 2023 and 2022 (in thousands):

	December 31, 2023			
	Total Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds [1]	$ 184,259	$ 184,259	$ —	$ —
Commercial paper [1]	—	—	—	—
Total cash equivalents	$ 184,259	$ 184,259	$ —	$ —

	December 31, 2022			
	Total Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds [1]	$ 45,739	$ 45,739	$ —	$ —
Commercial paper [1]	1,991	—	1,991	—
Total cash equivalents	47,730	45,739	1,991	—
Marketable securities:				
U.S. treasuries [2]	65,391	65,391	—	—
Commercial paper [2]	115,061	—	115,061	—
U.S. agency securities [2]	53,455	—	53,455	—
Asset-backed securities [2]	1,914	—	1,914	—
Total marketable securities	235,821	65,391	170,430	—
Total cash equivalents and marketable securities	$ 283,551	$ 111,130	$ 172,421	$ —

(1) Included within cash and cash equivalents on the balance sheet.
(2) Included within investments in marketable securities, current and investments in marketable securities, non-current on the balance sheet.

4. Marketable Securities

The Company did not hold any marketable securities as of December 31, 2023. The amortized cost, gross unrealized holding gains or losses, and fair value of the Company's marketable securities by major security type as of December 31, 2022 are summarized in the table below (in thousands):

	December 31, 2022			
	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Available-for-sale securities				
U.S. treasuries	$ 65,807	$ —	$ (416)	$ 65,391
Commercial paper	115,381	13	(333)	115,061
U.S. agency securities	53,767	15	(327)	53,455
Asset-backed securities	1,914	—	—	1,914
Total available-for-sale securities	$ 236,869	$ 28	$ (1,076)	$ 235,821

The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. As of December 31, 2023, the Company did not hold any securities in an unrealized loss with remaining maturities of less than one year. As a result, the Company determined it did not hold any investments with a credit loss at December 31, 2023.

There were minimal realized gains (losses) recognized on the sale or maturity of available-for-sale securities during year ended December 31, 2023, and as a result, there was a reclassification out of accumulated other comprehensive gain (loss) for the same period. There were no realized gains or losses recognized on the sale or maturity of available-for-sale securities during year ended December 31, 2022, and as a result, there were no reclassifications out of accumulated other comprehensive gain (loss) for the same period.

The Company did not hold any marketable securities as of December 31, 2023.

5. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Advances to suppliers	—	$ 2,486
Prepaid insurance	780	1,343
Other prepaid expenses	1,380	3,307
Total prepaid expenses and other current assets	$ 2,160	$ 7,136

Property and Equipment, Net

Property and equipment, net as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Furniture and fixtures	$ —	$ 321
Computers and network equipment	—	251
Lab equipment	—	12,521
Leasehold improvements	—	304
Construction-in-progress	—	12,440
Total property and equipment	—	25,837
Less: accumulated depreciation	—	(3,207)
Total property and equipment, net	$ —	$ 22,630

Depreciation expense was $2.4 million for each of the years ended December 31, 2023 and 2022.

As a result of the modification of our leases (see Note 8), we disposed of leasehold improvements, computer equipment, lab and office equipment, and furniture and fixtures and recorded a $0.1 million loss within Loss on disposal of assets and $11.3 million within Restructuring and impairment costs on the statement of operations and comprehensive loss during the year ended December 31, 2023.

Accrued Expenses

Accrued expenses as of December 31, 2023 and 2022 consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Professional fees	$ 1,029	$ 367
Early exercise liability	21	150
Other accrued expenses	143	1,354
Accrued employee termination benefits	1,535	—
Total accrued expenses and other current liabilities	$ 2,728	$ 1,871

6. Significant Agreements

Stanford Exclusive License Agreement

License Agreement

In December 2020, the Company entered into an exclusive license agreement (the "License Agreement") with The Board of Trustees of the Leland Stanford Junior University (Stanford), pursuant to which Stanford granted the Company a worldwide license to specified technology and patent rights to develop, manufacture and commercialize human prophylactic and therapeutic products. Other than with respect to specified, broadly applicable assays and procedures and subject to retained rights by Stanford, the license is exclusive with respect to human prophylactic and therapeutic products for the treatment of SCD, XSCID and beta thalassemia. The license is non-exclusive with respect to those broadly applicable assays and procedures and with respect to all human prophylactic and therapeutic products other than for the treatment of SCD, XSCID and beta thalassemia.

Pursuant to the License Agreement, the Company paid an upfront license fee of $50.0 thousand and as additional consideration for the license, the Company agreed to issue to Stanford approximately 0.6 million shares of common stock. As of December 31, 2020, the Company recorded its obligations to issue Stanford shares of common stock at an estimated fair value of $2.8 million to additional paid in capital. The shares of common stock were expected to be issued when Stanford provided the inventors' names for allocation of the shares. Stanford also received an option to purchase up to 10% of newly issued shares in the future private financings at the price paid by other participating investors. During the year ended December 31, 2021, the Company entered into an amendment to the License Agreement, pursuant to which it extended the time when the shares would be issued to May 7, 2021.

On May 7, 2021, the Company issued an aggregate of 640,861 shares of the Company's common stock to Stanford and certain individuals designated by Stanford in consideration for rights granted to the Company under the Company's exclusive license agreement.

On June 18, 2021, the Company exercised its right to repurchase an aggregate of 624,845 shares from each founder and investor under the Stanford Adjustment Repurchase Right as described below.

The acquisition of the exclusive license, including patent rights and know-how, and clinical supplies was accounted for as an asset acquisition and as the acquired technology and inventories did not have an alternative use, the total consideration of $2.8 million was recorded as research and development expense in the statements of operations and comprehensive loss for the year ended December 31, 2020.

In connection with the License Agreement, the Company reimbursed Stanford $0.2 million for previously incurred patent costs, which were recorded in general and administrative expenses for the year ended December 31, 2020 and in addition, is obligated to reimburse future patent costs. The Company is also obligated to pay annual maintenance fees as follows: $5.0 thousand in the first year, $10.0 thousand in each year 2 and 3, $25.0 thousand in each year 3 through 6, $50.0 thousand each subsequent year until first commercial sale and $200.0 thousand each subsequent year after the first commercial sale. No fees were recorded during the year ended December 31, 2023. The Company did not record any patent fees during the year ended December 31, 2023.

The Company is obligated to make future development and regulatory milestone payments in total of up to $5.3 million, sales based milestone payments of up to $7.5 million and royalties on future sales at percentage rates ranging in the low single digits. In addition, if the Company receives any sublicense income, it is required to share it with Stanford as a certain percentage defined for each milestone in the License Agreement. The Company will record the maintenance fees, when payable, and will record milestones when contingencies are resolved and milestones are due. No milestones were achieved and recorded as of December 31, 2023.

In August 2023, the Company entered into a license and option agreement (the "LOA"), pursuant to which the Company granted a third party an option to acquire certain of the Company's technology and intellectual property related to its nula-cel program and related pre-clinical platform assets. The License Agreement is included in the assets that are subject to the LOA and may be assigned to this third party if and when it exercises the option.

First Option Agreement

In January 2021, the Company entered into an option agreement (the "First Option Agreement") with Stanford, pursuant to which Stanford granted the Company the right to obtain a license to specified patent rights relating to human prophylactic and therapeutic products. The Company may exercise the option in whole or in part to obtain a license under one or more of the optioned patent rights.

Subject to the Company's exercise of the option under the First Option Agreement and its execution of an amendment to the License Agreement that incorporates the optioned patent rights and any optioned technology, the Company has agreed to issue to Stanford 132,137 shares of its common stock and pay a license execution fee of $10.0 thousand.

The term of the First Option Agreement expires 18 months after its effective date, subject to the Company's right to extend such expiration date by up to an additional one year upon notice to Stanford and by another additional one year upon the reasonable agreement of Stanford. The First Option Agreement will terminate if the License Agreement terminates. On June 23, 2022, the Company exercised its right to extend the term of the First Option Agreement for an additional year. On June 6, 2023, the Company and Stanford agreed to extend the term of the First Option Agreement for another additional year. As of December 31, 2023, the Company had not exercised the option under the First Option Agreement and no fees have been paid for the First Option Agreement.

In August 2023, the Company entered into the LOA, pursuant to which it granted a third party an option to acquire certain of the Company's technology and intellectual property related to its nula-cel program and related preclinical platform assets. The First Option Agreement is included in the assets that are subject to the LOA and may be assigned to this third party if and when it exercises the option.

Second Option Agreement

In April 2021, the Company entered into an option agreement (the "Second Option Agreement") with Stanford to negotiate the license for additional technologies from Stanford. Pursuant to the Second Option Agreement, the Company agreed to pay Stanford option fees in an aggregate amount of $30.0 thousand over the term of the option. On April 13, 2022, the Company entered into an amendment to the Second Option Agreement which extended the term for an additional year. On March 8, 2023, the Company terminated the Second Option Agreement without exercising the option to negotiate a license for additional technologies from Stanford. No maintenance fees were paid during the year ended December 31, 2023.

LCGM Service Agreement

On August 30, 2021, the Company entered into a Master Manufacturing and Service Agreement with the Laboratory for Cell & Gene Medicine at Stanford ("LCGM MSA"). Pursuant to the LCGM MSA, LCGM will conduct clinical manufacturing, release testing, and product release for nula-cel in the Company's Phase 1/2 CEDAR clinical trial to treat SCD. During 2021, the Company entered into various Statements of Work under the LCGM MSA under which it received technology transfer and related services for HBB

Beta-Globin Gene Variant for SCD, manufacturing engineer test runs, the exclusive use of a manufacturing suite at the LCGM facility, and Phase 1/2 CEDAR clinical development and manufacturing of the HBB Variant for SCD. During the years ended December 31, 2023 and 2022, the Company has recognized $1.7 and $6.1 million in research and development expense in connection with the LCGM MSA. As of December 31, 2023, the LCGM MSA has been terminated and Graphite does not expect to incur any additional expenses.

IDT License Agreement

On June 7, 2021, the Company entered into a License Agreement ("IDT License Agreement") with Integrated DNA Technologies, Inc. ("IDT"). Pursuant to the IDT License Agreement, IDT granted the Company and its affiliates a worldwide, non-exclusive, sublicensable license to research and develop products incorporating HiFi Cas9 protein variants for use in human therapeutic applications for SCD, XSCID and Gaucher disease (the "Field") and a worldwide, exclusive, sublicensable license to commercialize such products in the Field. The Company has also been granted the right to expand the licensed Field to include human therapeutic applications in the additional fields of beta thalassemia disorder and lysosomal storage disorders upon the payment of an exercise fee in the amount of $0.5 million per additional field or $1.0 million for both additional fields.

In consideration of the licenses and rights granted to the Company under the IDT License Agreement, the Company agreed to pay to IDT an upfront payment in the amount of $3.0 million and up to $5.3 million (or $8.8 million if the Company elects to expand the Field as described above to include both the beta thalassemia and lysosomal storage disorders fields) in total regulatory milestone payments. Each regulatory milestone payment is payable once on an indication-by-indication basis. In addition, the Company has agreed to pay IDT a low single-digit royalty on the net sales of products, subject to reductions in specified circumstances. As the acquisition of the license was accounted for as an asset acquisition and as the acquired technology did not have an alternative use, the total consideration of $3.0 million was recorded as research and development expense in the statement of operations and comprehensive loss during the year ended December 31, 2021.

The IDT License Agreement remains in effect on a country-by-country and product-by-product basis until the expiration of the royalty term for such product in such jurisdiction. The Company and IDT each have the right to terminate the IDT License Agreement for the other party's material breach of its obligations under the IDT License Agreement, subject to specified rights to cure. Additionally, the Company may terminate the IDT License Agreement for any reason upon written notice.

During the year ended December 31, 2023, the Company has not recognized any research and development expense in connection with the IDT License Agreement. There are no milestones probable as of December 31, 2023; therefore, no milestone payments have been recognized in the year ended December 31, 2023. As of December 31, 2023, the Company does not expect to incur any additional expenses associated with the IDT License Agreement.

In August 2023, the Company entered into the LOA, pursuant to which it granted a third party an option to acquire certain of the Company's technology and intellectual property related to its nula-cel program and related preclinical platform assets. The IDT License Agreement is included in the assets that are subject to the LOA and may be assigned to this third party if and when it exercises the option.

Sale of Non-Genotoxic Targeted Conditioning Technology Assets

On August 1, 2023, the Company entered into an asset purchase agreement (the "APA") with a third party pursuant to which the Company sold to the counterparty, concurrently with the execution of the APA, certain assets related to the Company's non-genotoxic conditioning technology in exchange for upfront consideration of $0.5 million. Additional consideration included certain contingent milestone payments totaling up to approximately $1.0 million in the aggregate as well as royalties on net sales by the acquirer of certain products incorporating the acquired technology, and potential fees upon the completion of certain transactions by the acquirer. The APA also provided for reimbursement of certain research and development amounts incurred prior to closing of approximately $0.6 million.

The disposal of certain assets sold pursuant to the APA was accounted for as a deconsolidation of a subsidiary or group of assets in accordance with ASC 810. During the year ended December 31, 2023, the Company recognized a loss on disposal of $0.1 million, which was recorded in other expense. The Company will record amounts related to the contingent milestone payments, royalties, and potential transaction fees when contingencies are resolved and amounts are due in accordance with ASC 450. No contingencies were resolved and recorded as of December 31, 2023.

License and Option to Acquire Nula-Cel Assets

On August 4, 2023, the Company entered into an LOA with a third party pursuant to which the Company exclusively licensed to the counterparty, and granted the counterparty, an option to acquire certain intellectual property and materials related to the Company's nula-cel program and related pre-clinical platform assets. Exercise of the option is contingent on the counterparty timely achieving a financing milestone, and all rights to the intellectual property and materials will revert to the Company if the milestone is not achieved or if the counterparty elects not to exercise the option. In return for this license and option, the Company received an equity interest in the counterparty representing 20% of all outstanding shares on a fully diluted basis. As a result of the 20% equity interest, the Company has the ability to exert significant influence over the counterparty and accounts for the interest as an equity method investment. The

Company records its proportionate share of investee's equity in earnings or losses based on the most recently available financial information.

The Company assessed the entity under the VIE model to assess whether to apply the consolidation guidance in accordance with ASC 810. The Company holds variable interests in the entity, and the entity was determined to be a VIE which is not consolidated as it is determined the Company lacks the power to direct the activities that most significantly impact the entity's economic performance. The balance sheet does not contain assets and liabilities related to the Company's interest in the non-consolidated VIE. Additionally, the Company's maximum exposure to loss is limited to the carrying value of the equity interest in the counterparty. No arrangements exist where additional financial support would need to be provided by the Company.

The 20% equity interest in the counterparty had minimal value upon execution of the LOA and the Company did not record any amount related to the equity interest as of December 31, 2023. As of December 31, 2023, the counterparty has not achieved the financial milestone and does not have the right to exercise the option.

7. Commitments and Contingencies

Research and Development Agreements

The Company enters into contracts in the normal course of business with CROs for clinical trials, with CMOS or other vendors for preclinical studies, supplies and other services and products for operating purposes. These contracts generally provide for termination on notice or may have a potential termination fee if a purchase order is cancelled within a specified time. As of December 31, 2023 and 2022, there were no amounts accrued related to termination and cancellation charges as the Company does not expect to incur any additional expenses associated with termination and cancellation charges.

License Agreements

The Company enters into license agreements (Note 6), pursuant to which the Company may acquire or license other patents, patent applications or know-how from various third parties to access intellectual property covering product candidates that the Company is developing. Under these acquisitions or licensing agreements, the Company may be liable for certain diligence obligations and payments, which are contingent upon achieving various development, regulatory and commercial milestones. Also, pursuant to the terms of some of these license agreements, when and if commercial sales of a product commence, the Company may be obligated to pay royalties to such third parties on net sales of the respective products. No such milestones were achieved or probable as of December 31, 2023 and 2022.

Legal Contingencies

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of business. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount. Management is currently not aware of any legal matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. Its exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at a request in such capacity. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2023 and 2022, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

8. Operating Leases

As of December 31, 2023, the current and non-current portions of the total liability for operating leases was $0.3 million and $0.1 million, respectively. As of December 31, 2023 and 2022, the weighted average remaining lease term on the operating lease was 15 and 19 months, respectively. As of December 31, 2023 and 2022, the weighted average incremental borrowing rate used to determine the operating lease liabilities included on the balance sheets was 9.0% and 8.5%, respectively.

Facility leases

South San Francisco

On January 27, 2021, the Company entered into a new lease agreement for office and lab space in South San Francisco, California that included two office suites. The lease terms for the two office suites commenced during July and August 2021, respectively. The term of

the lease is 44 months for the first office suite and 43 months for the second office suite with an option to extend the term for an additional two years on the same terms and conditions. This option to extend the lease term was not determined to be reasonably certain and therefore has not been included in the Company's calculation of the associated operating lease liability under ASC 842. The corresponding right-of-use assets and lease liabilities related to the two office suites were recorded on the Company's balance sheet upon the lease commencement date, which was the date the Company was deemed to have obtained control of the premises.

In August 2023, the Company subleased one of its office suites in the South San Francisco lease for 20 months starting from August 2023 for aggregate sublease payments of $0.5 million. The sublease income, while it reduces the rent expense, is not considered in the value of the right-of-use assets or lease liabilities. The Company's sublease income was $0.1 million for the year ended December 31, 2023. The Company did not have any sublease income during the year ended December 31, 2022.

In November 2023, the Company subleased its second office suite in the South San Francisco lease through the end of the lease term in March 2025. The third party agreed to assume all of the Company's obligations under the head lease, including the obligation to make rent payments, as well as all of the Company's obligations under the services agreement associated with the head lease, and to indemnify the Company for all obligations under the head lease and the associated services agreement, in exchange for the Company's payment to the third party of approximately $1.4 million. As the Company was relieved of its primary obligations under the head lease, the Company accounted for the sublease as a lease termination, recording a loss on lease termination of $0.1 million, calculated as the carrying value of the lease liability on the date of termination, net of the payment made to the subtenant for assuming the lease. Additionally, following the sublease, the Company no longer has use of the related leasehold improvements. Therefore, the Company accounted for these assets as abandoned, recording a loss on abandonment of $0.1 million included in restructuring and impairment expenses on the statement of operations and comprehensive loss.

Bayside

On December 16, 2021, the Company entered into a lease agreement with Bayside Area Development, LLC ("Bayside") for 85,165 square feet of office and laboratory space in South San Francisco, CA. The lease for the office and laboratory space commenced in April 2023. The term of the lease was 120 months with the option to extend the term up to an additional ten years. This option to extend the lease term was not determined to be reasonably certain and therefore was not included in the Company's calculation of the associated operating lease liability. During the second quarter of 2023, the Company took possession of the lease and recognized a $32.0 million right-of-use asset and corresponding lease liability upon the lease commencement date. In addition, the Company recognized $27.2 million in leasehold improvements. Bayside provided a tenant improvement allowance of up to $14.9 million, which was fully utilized and recorded in lease liability.

In August 2023, the Company recognized an impairment in conjunction with its restructuring activities related to its Bayside lease (Note 13).

In October 2023, the Company subleased approximately 32,113 square feet of space in the Bayside premises. The term of the sublease commenced on October 26, 2023 and expires on December 31, 2024. Pursuant to the sublease, the subtenant agreed to make rent payments directly to Bayside. The subtenant assumed all rights and obligations of the Bayside lease relative to the subleased premises.

Also in October 2023, the Company entered into an amendment to the Bayside lease to adjust the timeline for certain payments under the lease and to effect the acceleration of the termination date of the Bayside lease to terminate on December 31, 2024, subject to that the ability of Bayside to accelerate the termination date for the premises at its discretion. The Company prepaid all amounts payable during the amended term of the Bayside lease, in an amount equal to $15.9 million, as well as a lease termination payment of $20.8 million. Concurrent with the amendment, the Company sold all furniture, fixtures and equipment residing at the Bayside premises to the landlord for a nominal amount. Following the amendment and sublease, the Company no longer has use of any of the Bayside premises and has no further obligation thereunder.

The Company accounted for the amendment to the Bayside lease as a lease modification, remeasuring the lease liability equal to the present value of the remaining lease payments over the amended term. Additionally, as the subtenant assumed all remaining rights and obligations under the head lease, there is no right-of-use asset or lease liability associated with the subleased space on the Company's balance sheet. In November, the Company determined that it had no use of the Bayside premises and accounted for the remeasured right-of-use asset and related leasehold improvements as abandoned. In the aggregate, the Company recorded a net loss on modification, abandonment and sale of fixed assets of $10.8 million.

As of December 31, 2023, the Company's only operating lease with an associated right-of-use asset and lease liability related to the South San Francisco lease that was subleased without relieving the Company of its primary obligation under the head lease. As of December 31, 2023, the Company had an operating lease right-of-use asset of $0.3 million and operating lease liability of $0.4 million recorded on its balance sheet.

Embedded leases

The Company evaluated its vendor contracts to identify embedded leases, if any, and determined that two agreements with contract manufacturing suppliers constituted a lease under ASC 842 as the Company has the right to substantially all of the economic benefits from the use of the asset and can direct the use of the asset.

On May 10, 2021 and August 30, 2021, the Company and LCGM entered into the LCGM MSA and Statement of Work #3 ("SOW #3"), respectively, for the exclusive use of a manufacturing suite at the LCGM facility. Pursuant to the terms of SOW #3, LCGM agreed to provide the Company with certain dedicated space for the clinical manufacturing, release testing, and product release in the Company's Phase 1/2 CEDAR clinical trial to treat sickle cell disease. The Company concluded that the agreement contained an embedded lease as the Company controlled the use of a dedicated manufacturing suite and the equipment therein. The agreement included fixed lease payments of $5.6 million from inception of lease through April 30, 2023, the expiration date of SOW #3. As of December 31, 2023, the Company does not have any remaining obligations related to SOW #3.

The Company and Explora BioLabs, Inc. ("Explora") entered into a License Service Agreement and Master Services Agreement (together, the "Explora Agreements") on November 17, 2021 and December 16, 2021, respectively. Pursuant to the terms of the Explora Agreements, Explora agreed to provide a certain dedicated space to perform in vitro or in vivo studies, obtain or house research animals, and provide scientific or technical consultation to the Company. The Company concluded that the Explora Agreements contained an embedded lease as the Company controlled the use of a dedicated manufacturing suite and the equipment therein. The Explora Agreements contained fixed lease payments of $0.7 million from inception of lease through November 2023. As of December 31, 2023, the Company does not have any remaining obligations related to the Explora embedded lease.

As of December 31, 2023, the Company did not have any operating lease right-of-use assets and operating lease liabilities related to the embedded leases recorded on its balance sheet.

Operating Lease Obligations

As of December 31, 2023, the future minimum lease payments for the Company's operating leases for each of the years ending December 31 were as follows (in thousands):

	Amount
2024	304
2025	78
Total undiscounted lease payments	382
Present value adjustment	(20)
Total net lease liabilities	$ 362

Lease expense was $7.3 million and $6.7 million for the years ended December 31, 2023 and 2022, respectively.

Under the terms of the remaining lease agreements, the Company is also responsible for certain variable lease payments that are not included in the measurement of the lease liability. Variable lease payments for operating leases were $2.2 million and $1.3 million for the years ended December 31, 2023 and 2022, respectively, including non-lease components such as common area maintenance fees, taxes, and insurance.

The following information represents supplemental disclosure for the statement of cash flows related to the operating leases (in thousands):

	December 31, 2023
Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flows under operating leases	$ 44,123

9. Common Stock

As of December 31, 2023 and 2022, the Company was authorized to issue 300,000,000 shares of its common stock with $0.00001 par value per share. Each share of the Company's common stock is entitled to one vote. In connection with the IPO in June 2021, all outstanding shares of redeemable convertible preferred stock were converted into 30,761,676 shares of common stock. The IPO closed

on June 29, 2021, pursuant to which the Company issued and sold 14,000,000 shares of its common stock at a public offering price of $17.00 per share.

On June 29, 2021, the underwriters also exercised their option to purchase an additional 2,100,000 shares of common stock at the IPO price, less the underwriting discounts and commissions. The closing of the offering of the additional shares occurred on July 2, 2021. The Company issued and sold 2,100,000 shares of its common stock at a public offering price of $17.00 per share.

Shares Reserved for Future Issuance

As of December 31, 2023 and 2022, the Company reserved common stock for future issuances as follows:

	December 31, 2023	December 31, 2022
Outstanding stock option awards	5,376,373	7,755,303
Shares available for future stock option grants	10,798,817	5,382,907
ESPP shares available for future grants	1,253,729	754,951
Total shares reserved for future issuance	17,428,919	13,893,161

Founders' and Investor's Restricted Common Stock

In March 2020, the Board approved and in April 2020, the Company issued 6,081,413 shares of its common stock to its founders and 2,467,104 shares of its common stock to its investor at the purchase price of $0.00002 per share. As of December 31, 2020, the investor's shares were fully vested and a portion of the shares issued were subject to the Company's option to repurchase per the Stanford Adjustment Repurchase Right, as described below.

The shares of the Company's common stock issued to its founders for their services as an employee, advisor, or consultant vest monthly over four years with one year cliff from the vesting commencement date. The vesting commencement date was the date of the initial closing of the Series A preferred stock financing or June 24, 2020. Pursuant to the restricted stock purchase agreements with each of the founders, the vesting of the founders' common stock shares could be accelerated upon the occurrence of certain events, including signing of the term sheet for the license with Stanford, a change in control, or if the founder's service is terminated by the Company without cause. The Company signed the term sheet with Stanford in June 2020, and as a result, an aggregate of 912,212 shares of founders' common stock vested pursuant to the acceleration terms.

If a founder terminates the service relationship with the Company during the vesting period, the Company may repurchase any unvested restricted common stock at the price per share equal to the lower of (i) the original purchase price, subject to adjustment in the event of any reorganization, recapitalization, reclassification, stock dividend, stock split, reverse stock split, or (ii) the current fair market value as of the date the Company elects to exercise its Stanford Adjustment Repurchase Right, as described below. The repurchase right lapses in 180 days after the termination of the founder's service or employment. During the vesting term, holders of founders' common stock awards are deemed to be common stockholders and have the right to receive dividends and voting rights.

The founders' shares of common stock are also subject to the Company's option to repurchase per the Stanford Adjustment Repurchase Right, as described below.

The Company accounts for shares issued to founders as equity compensation awards and the estimated fair value at the grant date was minimal. During the year ended December 31, 2023, the Company repurchased 152,694 shares of founders' common stock awards. 431,863 and 1,938,430 shares of founders' common stock awards were unvested and expected to vest in 0.5 years and 1.5 years as of December 31, 2023 and 2022, respectively.

Stanford Adjustment Repurchase Right

Upon the issuance of shares of common stock to Stanford pursuant to the License Agreement, as discussed in Note 5, the Company has a right to repurchase from each founder and an investor a number of shares of common stock equal to the number of shares issued to Stanford multiplied by the applicable number of shares issued to the founder or investor, as applicable, divided by 7,273,848 shares (a fully diluted number of shares of the Company at the end of March 2020, after the founders' and the investors' shares were approved by the board of directors). The Stanford Adjustment Repurchase Right may be exercised by the Company within six months following the date of the issuance of the shares of common stock to Stanford. The repurchase price per share is equal to the lower of (i) the purchase

price, subject to adjustment in the event of any reorganization, recapitalization, reclassification, etc., or (ii) the current fair market value as of the date the Company elects to exercise its Stanford Adjustment Repurchase Right.

On May 7, 2021, the Company issued an aggregate of 640,861 shares of the Company's common stock to Stanford and certain individuals designated by Stanford in consideration for rights granted to the Company under the Company's exclusive license agreement.

On June 18, 2021, the Company exercised its right to repurchase an aggregate of 624,845 shares from each founder and investor under the Stanford Adjustment Repurchase Right. As of December 31, 2023, the Company has not exercised the right to purchase the remaining 16,016 shares.

The Company accounts for the founders and investors' shares of restricted common stock as equity share-based awards.

10. Equity Incentive Plans

2020 Stock Option and Grant Plan

Prior to the effectiveness of the registration statement on Form S-1 (File No. 333-256838) for its IPO, the Company granted share-based awards under the 2020 Stock Option and Grant Plan, as amended (the "2020 Plan"). The Company was authorized to grant under the 2020 Plan incentive stock options, nonqualified stock options, restricted stock awards, restricted stock units and other share-based awards to the Company's officers, employees, directors and consultants. Options under the 2020 Plan could be granted for periods of up to 10 years and at prices no less than 100.0% of the estimated fair value of the shares on the date of grant as determined by the Board, provided, however, that the exercise price of an incentive stock option granted to a 10.0% stockholder shall not be less than 110.0% of the estimated fair value of the shares on the date of grant and the option is not exercisable after the expiration of five years from the date of grant. Options generally vest monthly over four years with or without one year cliff vesting. Per the 2020 Plan, granted options may be early exercised prior to vesting and the Company will issue shares of restricted stock upon the early exercise with vesting terms consistent with the original grant. Upon completion of the Company's IPO, the remaining shares available for issuance under the 2020 Plan were retired, and the Company no longer grants awards pursuant to the 2020 Plan.

2021 Stock Option and Incentive Plan

In June 2021, the Company's board of directors approved the 2021 Stock Option and Incentive Plan (the "2021 Plan") that became effective immediately prior to the date when the Company's prospectus was declared effective by the SEC on June 24, 2021. The Company initially reserved 5,636,000 shares of common stock for issuance of awards under the 2021 Plan. The 2021 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by 5% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Company's compensation committee. On January 1, 2022 and 2023, the number of shares of common stock available under the 2021 Plan increased by 2,900,541 shares and 2,911,088 shares, respectively, pursuant to the evergreen provision of the 2021 Plan. The option exercise price of each option will be determined by the Company's compensation committee but generally may not be less than 100% of the fair market value of the Company's common stock on the date of grant. The term of each option will be fixed by the Company's compensation committee and may not exceed ten years from the date of grant. The grant date fair value of all awards made under the 2021 Plan and all other cash compensation paid by the Company to any non-employee director for services as a non-employee director in any calendar year may not exceed $1.0 million for the first year of service and $750.0 thousand for each year of service thereafter.

As of December 31, 2023, there were 10,798,817 shares available for future issuance under the 2021 Plan.

Restricted Stock Awards

During the year ended December 31, 2020, the Company issued 832,983 shares as restricted stock awards under the 2020 Plan. The purchase price of the restricted common stock awards was fair value as determined by the Board at the issuance date. The shares vest monthly over four years with the one-year cliff vesting from the grant date. Upon termination of employment, the Company has the right to repurchase any unvested restricted shares. The repurchase price for unvested shares of common stock will be the lower of (i) the fair market value on the date of repurchase or (ii) their original purchase price. There were no shares issued during the years ended December 31, 2023 and 2022.

The Company accounted for restricted stock awards as early exercised options and recognized a liability in other liabilities when cash was received for the purchase of shares of restricted stock awards. As shares of restricted stock awards vest, the Company reclassified

the liability to common stock and additional paid in capital. As of December 31, 2023 and 2022, the Company recorded a minimal liability for restricted stock awards included in accrued expenses and other current liabilities.

There were 163,830 and 5,140 shares of restricted stock award shares canceled and repurchased as of December 31, 2023 and 2022, respectively. There were 751,758 and 553,443 shares of restricted stock vested as of December 31, 2023 and 2022, respectively.

Employee Stock Purchase Plan

In June 2021, the Company's board of directors and stockholders approved the 2021 Employee Stock Purchase Plan (the "ESPP") which became effective upon the IPO. Pursuant to the ESPP, certain employees of the Company, excluding consultants and non-employee directors, are eligible to purchase common stock of the Company at a reduced rate during offering periods. The ESPP permits participants to purchase common stock using funds contributed through payroll deductions, subject to a calendar year limit of $25,000 and at a purchase price of 85% of the lower of the fair market value of the Company's common stock on the first trading day of the offering period or on the applicable purchase date, which will be the final trading day of the applicable purchase period. The ESPP has two annual purchase periods extending from June to November and December to May.

As of December 31, 2023, no employees were enrolled in the ESPP and the Company did not record a liability for ESPP in accrued liabilities as of December 31, 2023. The Company had $0.1 million in accrued liabilities as of December 31, 2022. The Company issued 65,222 shares and 333,155 shares under the ESPP during the years ended December 31, 2023 and 2022, respectively.

Effective January 1, 2022 and 2023, the number of shares of common stock available under the 2021 ESPP increased by 564,000 shares pursuant to the evergreen provision of the 2021 ESPP.

	Year Ended December 31,	
	2023	**2022**
Expected volatility	75.00% - 79.00%	73.00% - 75.00%
Expected dividend yield	0%	0%
Expected term (in years)	0.5	0.5
Risk-free interest rate	4.65% - 5.44%	0.10% - 4.65%

Incentive Stock Options and Nonqualified Stock Options

Stock options issued under the 2020 Plan and 2021 Plan, generally, vest over a four-year period and expire ten years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the individual award agreements.

The Company used the Black-Scholes option pricing model to estimate stock-based compensation expense for stock option awards granted during the periods presented, with the following assumptions.

	Year Ended December 31,	
	2023	**2022**
Expected volatility	77.00% - 79.00%	74.00% - 75.00%
Expected dividend yield	0%	0%
Expected term (in years)	6.04	5.97 - 6.01
Risk-free interest rate	3.50% - 4.12%	1.91% - 4.23%

A summary of option activity under the 2020 Plan and the 2021 Plan during the year ended December 31, 2023 is as follows:

	Number of Options	**Weighted-Average Exercise Price Per Share**	**Weighted-Average Remaining Contractual Term (in years)**	**Aggregate Intrinsic Value (in thousands)**
Outstanding as of December 31, 2022	7,755,303	$ 8.47	8.7	$ 794
Options granted - 2021 Plan	3,223,400	$ 2.22		
Options exercised	(101,900)	$ 0.98		
Options cancelled	(5,500,430)	$ 6.79		
Outstanding as of December 31, 2023	5,376,373	$ 6.58	6.1	$ 847
Exercisable	3,812,992	$ 6.42	5.2	$ 664
Vested and expected to vest as of December 31, 2023	5,376,373	$ 6.58	6.1	$ 847

Aggregate intrinsic value represents the difference between the fair value of the underlying common stock and the exercise price as of December 31, 2023. The weighted-average grant date fair value of options granted during the December 31, 2023 was $1.56 per share.

The intrinsic value of the stock options exercised was $0.1 and $0.2 million for the years ended December 31, 2023 and 2022, respectively.

Early Exercise of Stock Options

The terms of the 2020 Plan permit the exercise of options granted prior to vesting, subject to required approvals. The unvested shares are subject to the repurchase right upon termination of employment at the original purchase price. The repurchase right lapses in 180 days after the termination of the employee's employment. Shares purchased by employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be issued until those shares vest according to their respective vesting schedules. Cash received for early exercised stock options is recorded as other liabilities on the balance sheet and is reclassified to common stock and additional paid-in capital as such shares vest. During the years ended December 31, 2023 and 2022, the Company repurchased 227,792 and 189,414 shares that were previously early exercised.

At December 31, 2023 and 2022, 68,868 and 554,695 shares, respectively, remained subject to the right of repurchase as a result of the early exercised stock options. The remaining liability related to early exercised shares as of December 31, 2023 and 2022 was minimal and was recorded in accrued expenses and other current liabilities in the balance sheets.

Stock-Based Compensation Expense

The following table presents the components of stock-based compensation expense for the Company's stock-based awards for the periods presented (in thousands):

	Year Ended December 31,	
	2023	**2022**
Restricted stock awards and founders' common stock awards	$ 7	$ 11
ESPP	96	391
Stock options	10,471	13,132
Total stock-based compensation expense	$ 10,574	$ 13,534

The above stock-based compensation expense also includes the expenses of $2.6 million and $2.2 million related to stock options issued to non-employees during the years ended December 31, 2023 and 2022, respectively.

The following table presents the classification of stock-based compensation expense for the Company's stock-based awards for the periods presented (in thousands):

	Year Ended December 31,	
	2023	**2022**
Research and development expenses	$ 1,904	$ 5,317
General and administrative expenses	8,670	8,217
Total stock-based compensation expense	$ 10,574	$ 13,534

As of the years ended December 31, 2023 and 2022, there was $7.4 million and $31.0 million, respectively, of unrecognized stock-based compensation expense related to the employee and non-employee awards, which is expected to be recognized over a weighted-average period of 1.5 years and 2.6 years, respectively.

11. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders, which excludes shares which are legally outstanding, but subject to repurchase by the Company (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss	$ (124,651)	$ (101,052)
Denominator:		
Weighted-average common shares outstanding	58,046,553	58,111,437
Less: weighted-average unvested restricted shares and shares subject to repurchase	(1,031,394)	(3,237,762)
Weighted-average shares used to compute basic and diluted net loss per share attributable to common stockholders	57,015,159	54,873,675
Net loss per share attributable to common stockholders — basic and diluted:	$ (2.19)	$ (1.84)

Anti-dilutive Outstanding Shares or Equivalents

The following outstanding options, unvested shares, and ESPP shares were excluded (as common stock equivalents) from the computation of diluted net loss per common share for the periods presented as their effect would have been antidilutive (in thousands):

	Year Ended December 31,	
	2023	2022
Options to purchase common stock	5,376,373	7,755,303
Common stock subject to vesting or repurchase	565,667	2,767,526
Employee Stock Purchase Plan shares	—	168,080
Total	5,942,040	10,690,909

12. Income Taxes

No provision for income taxes was recorded for the years ended December 31, 2023 and 2022. The Company has incurred net operating losses only in the United States since its inception. The Company has not reflected any benefit of such net operating loss carryforwards in the financial statements.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate was as follows:

	Year Ended December 31,	
	2023	2022
Federal statutory income tax rate ate	21.00%	21.00%
State taxes	1.01	1.10
Others	(0.06)	(0.69)
Research and development credits	1.00	1.11
Transaction costs	(1.01)	—
Lease Modification	3.27	—
Interest expense	—	—
Stock-based compensation	(1.52)	(0.97)
Change in valuation allowance	(23.69)	(21.55)
Provision for taxes	0.00%	0.00%

Net deferred tax assets and liabilities consisted of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating losses - non-current	$ 30,820	$ 15,940
Capitalized R&D	14,493	13,815
General business credit - non-current	7,201	5,699
Operating lease right-of-use assets	88	1,220
Lease termination costs	6,621	—
Stock based compensation	2,017	1,703
Accruals and reserves	295	735
Fixed assets	6,161	170
Other	3	3
Gross deferred tax assets	67,699	39,285
Valuation allowance	(67,626)	(38,110)
Net deferred tax assets	73	1,175
Fixed asset basis	—	—
Operating lease liabilities	(73)	(1,175)
Other	—	—
Gross deferred tax liabilities	(73)	(1,175)
Valuation allowance	$ —	$ —

Net operating losses and tax credit carryforwards were as follows as of December 31, 2023 (dollars in thousands):

	Year Ended December 31, 2023	
	Amount	Expiration Years
Net operating losses, federal (starting from January 1, 2018)	$ 146,450	Do Not Expire
Net operating losses, state	29	2039 - 2043
Tax credits, federal	6,395	2041 - 2043
Tax credits, state	4,716	Do Not Expire

Utilization of the net operating loss carryforwards and research credit carryforwards may be subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code, as amended, ("IRC"), and similar state provisions. Annual limitations may result in the expiration of the net operating losses and tax credit carryforwards before they are utilized. The Company did not perform an IRC Section 382 analysis and any previous ownership changes may result in a limitation that will reduce the total amount of net operating loss and tax credit carryforwards disclosed that can be utilized. Subsequent ownership changes may affect the limitation in future years.

During the years ended December 31, 2023 and 2022, the Company recorded a full valuation allowance on federal and state deferred balances since management does not forecast the Company to be in a profitable position in the near future. Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2023 and 2022 related primarily to the increases in net operating loss carryforwards and research and development tax credit carryforwards and were as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Valuation allowance at the beginning of the year	$ 38,110	$ 16,332
Increases recorded to income tax provision	29,516	21,778
Valuation allowance at the end of the year	$ 67,626	$ 38,110

The Company's U.S. federal and state income tax returns are generally subject to tax examinations for the tax years from inception through December 31, 2022. There are currently no pending income tax examinations. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service and state tax authorities to the extent utilized in a future period.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2022	2022
Balance at beginning of year	$ 2,701	$ 1,407
Additions based on tax positions related to current year	899	1,862
Reduction for prior period positions	(42)	(568)
Unrecognized tax benefit-December 31	$ 3,558	$ 2,701

The entire amount of the unrecognized tax benefits would not impact the Company's effective tax rate if recognized. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. The Company has elected to include interest and penalties as a component of tax expense. During the years ended December 31, 2023 and 2022, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease during the next 12 months.

13. Restructuring Activities

In February 2023, the Company's board of directors approved a restructuring plan (the "First Restructuring Plan") to reduce the Company's operating costs and better align its workforce with the needs of its business. The First Restructuring Plan eliminated approximately 50% of the Company's workforce.

Employees affected by the First Restructuring Plan obtained involuntary termination benefits that are provided pursuant to a one-time benefit arrangement. For employees who were notified of their termination in February 2023 and had no requirements to provide future service, the Company recognized the liability for the termination benefits in full at fair value in February 2023. For employees who were required to render services beyond a minimum retention period to receive their one-time termination benefits, the Company recognized the termination benefits ratably over their future service periods. The service periods began in February 2023 and ended at various dates through June 2023. The Company has incurred approximately $3.4 million of employee termination benefits expense to implement the First Restructuring Plan and does not have any remaining obligations as of December 31, 2023.

In August 2023, the Company's board of directors approved a second restructuring plan (the "Second Restructuring Plan"; together with the First Restructuring Plan, the "Restructuring Plans") to further reduce the Company's operating costs and align its workforce with the needs of its business. The Second Restructuring Plan eliminated approximately an additional 33.1% of its total workforce, and in aggregate, 78.1% of its total workforce. Employees affected by the Second Restructuring Plan obtained involuntary termination benefits that are provided to an ongoing benefit arrangement. Accordingly, the Company recognized termination benefits upon announcement of termination to all employees. The Company has incurred approximately $3.5 million and has a remaining liability of $1.0 of employee termination benefits expense to implement the Second Restructuring Plan.

The Company determined that it had set a precedence for providing terminated employees with severance benefits, and accordingly, it had a de facto severance plan. In September 2023, the Company determined that it was reasonably likely to incur additional employee termination benefits expense for its remaining employees within the next twelve months. It recognized termination benefits for the remaining employees totaling $1.0 million, of which $0.6 million was paid during the year ended December 31, 2023.

The following table summarizes the Company's restructuring liability that is included in accrued expenses and other current liabilities in the accompanying balance sheet:

	Year Ended December 31, 2023
Accrued employee termination benefits beginning balance	$ —
Employee termination benefits charges incurred during the period	8,100
Amounts paid or otherwise settled during the period	(6,565)
Accrued employee termination benefits as of December 31, 2023	$ 1,535

In addition, the board of directors determined that it was in the best interests of the Company and its stockholders to put in place arrangements designed to provide that the Company will have the continued dedication and commitment of those employees, including executives, determined to be key to the Company's planned go-forward operations. In March 2023, the Board approved, and management implemented, a retention program for certain employees staying with the Company which includes cash retention bonuses totaling $4.2 million for certain retained employees provided that they remain within the Company through the requisite service period, which is the earlier of March 1, 2024 or the termination date upon a Restructuring Plan. As a result, these cash retention bonuses are being accrued over the requisite service period, with $3.7 million recognized during the year ended December 31, 2023 and included within general and administrative and research and development expenses in the statements of operations. During the year ended December 31, 2023, the Company paid $3.2 million in retention bonuses to employees for fulfilling their requisite service periods.

In June 2023, the Company committed to a plan to sell certain of its lab equipment associated with the Restructuring Plan. During the year ended December 31, 2023, the Company implemented a plan to sell its remaining lab equipment as well as other fixed assets not transferred to the Bayside lease. As of December 31, 2023, the Company disposed of all of its assets previously meeting the criteria of held for sale. These assets were recognized at the lower of cost or fair value less cost to sell using market approach. The fair value of these assets were classified as Level 3 in the fair value hierarchy due to a mix of unobservable inputs utilized such as independent research in the market as well as actual quotes from market participants. Subsequent changes to the estimated selling price of assets held for sale are recorded as gains or losses to the statements of operations and comprehensive loss wherein the recognition of subsequent gains is limited to the cumulative loss previously recognized. During the year ended December 31, 2023, the Company recorded

impairment charges and loss on disposal of assets, which was included in restructuring and impairment costs in the statements of operations and comprehensive loss, of $7.0 million.

In connection with the Restructuring Plans, the Company has determined that it will not utilize the Bayside and South San Francisco leases for purposes of its own operations. In August 2023, the Company subleased one of its office suites in the South San Francisco lease for 20 months starting from August 2023 for aggregate sublease payments of $0.5 million. In October 2023, the Company entered into a sublease agreement and amendment to the original master lease with the landlord to accelerate the termination date of the Bayside lease and in November 2023, the Company entered into an amendment to the original lease agreement to reassign the second suite of the South San Francisco lease (Note 8). The Company performed a recoverability test by comparing the future cash flows attributable to the asset group to the carrying value of the long-lived assets. Future cash flows were estimated using comparable laboratory and office facilities discounted at a market discount rate over the remaining term of the Company's lease. During the year ended December 31, 2023, the Company recorded a non-cash impairment of $46.9 million, to the right-of-use asset and related leasehold improvement, which was included in restructuring and impairment costs in the statements of operations and comprehensive loss.

The Company entered into an asset purchase agreement with Maro pursuant to which the Company sold to the counterparty, concurrently with the execution of the APA, certain assets related to the Company’s non-genotoxic conditioning technology in exchange for upfront consideration of $0.5 million. Additional consideration included certain contingent milestone payments totaling up to approximately $1.0 million in the aggregate, as well as royalties on net sales by Maro of certain products incorporating the acquired technology, and potential fees upon the completion of certain transactions by Maro. The APA also provided for reimbursement of certain research and development amounts incurred prior to closing of approximately $0.6 million.

In addition, the Company also entered into an LOA with Kamau Therapeutics, Inc. (“Kamau”) pursuant to which the Company exclusively licensed to Kamau, and granted the counterparty an option to acquire, certain intellectual property and materials related to the Company’s nulabeglogene autogedtemcel (nula-cel) program and related pre-clinical platform assets. Exercise of the option is contingent on Kamau timely achieving a financing milestone, and all rights to the intellectual property and materials will revert to the Company if the milestone is not achieved or if the counterparty elects not to exercise the option. In return for this license and option, the Company received an equity interest in the counterparty representing 20% of all outstanding shares on a fully diluted basis.

14. Subsequent Events

The Company has evaluated all subsequent events that occurred after the date of the accompanying financial statements and determined that there were no events or transactions during this subsequent event reporting period which require recognition or disclosure in our financial statements other than those disclosed elsewhere within this Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended (the "Exchange Act") as of the end of the period covered by this Form 10-K. Based upon that evaluation, our Chief Executive Officer has concluded that, as of December 31, 2023, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer, or persons performing similar functions, and effected by a company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of a company's assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that a company's receipts and expenditures are being made only in accordance with authorizations of the company's management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 framework). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2023.

This Form 10-K does not include an attestation report of the Company's independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three month period ending December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving

its stated goals under all potential future conditions, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information.

No Rule 10b5-1 plans or non-Rule 10b5-1 trading arrangements were adopted, modified, or terminated by our officers or directors, nor were there any material changes to the procedures by which securityholders may recommend nominees to the our board of directors, during the quarter ended December 31, 2023.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors

Our directors are elected to serve for three-year terms until the next annual meeting of stockholders and until his or her successor shall have been duly elected and qualified. The following table sets forth the name and age of each director, indicating all positions and offices with us currently held by the director.

Name	Positions and Offices Held with Graphite Bio, Inc.	Director Since	Class and Year in Which Term Will Expire	Age
Perry Karsen	Director and Board Chair	2020	Class I - 2025	69
Jerel Davis, Ph.D.	Director	2019	Class I - 2025	47
Joseph Jimenez	Director	2020	Class I - 2025	64
Abraham Bassan	Director	2020	Class II - 2026	39
Matthew Porteus, M.D., Ph.D.	Director	2020	Class II - 2026	59
Jo Viney, Ph.D.	Director	2021	Class II - 2026	58
Kimberlee C. Drapkin	Interim President and Chief Executive Officer and Director	2023	Class III - 2024	55
Kristen M. Hege, M.D.	Director	2021	Class III - 2024	60
Carlo Rizzuto, Ph.D.	Director	2020	Class III - 2024	53
Smital Shah	Director	2021	Class III - 2024	47

Perry Karsen has served as the chair of our board of directors since October 2020 and as a member of our board of directors since June 2020. From May 2013 to December 2015, Mr. Karsen was the Chief Executive Officer of Celgene Cellular Therapeutics, Inc., a division of Celgene Corporation (collectively, "Celgene"). Prior to that, Mr. Karsen served as Chief Operations Officer and Executive Vice President of Celgene from July 2010 to May 2013, and as Senior Vice President and Head of Worldwide Business Development of Celgene from 2004 to 2009. From February 2009 and July 2010, Mr. Karsen was Chief Executive Officer of Pearl Therapeutics Inc., subsequently acquired by AstraZeneca plc. (Nasdaq: AZN). Prior to that, Mr. Karsen held executive positions at Human Genome Sciences, Inc., a publicly traded biotechnology company (since acquired by GlaxoSmithKline plc (Swiss: GSK.SW)), Bristol-Myers Squibb Co., Genentech, Inc. (since acquired by Hoffmann-La Roche AG (Roche)), and Abbott Laboratories. In addition, Mr. Karsen served as a General Partner at Pequot Capital Management, Inc. He is currently a member of the boards of Jounce Therapeutics, Inc. (Nasdaq: JNCE) since January 2016 and Nitrase Therapeutics, Inc. since May 2020. Mr. Karsen formerly served on the boards of several public biotechnology companies, including Intellia Therapeutics, Inc. (Nasdaq: INTL) from April 2016 to December 2020, Oncomed Pharmaceuticals, Inc. (Nasdaq: OMED) (until it was acquired by Mereo BioPharma (Nasdaq: MREO)), from January 2016 to April 2019, Voyager Therapeutics, Inc. (Nasdaq: VYGR) from July 2015 to August 2019, Agios Pharmaceuticals, Inc. (Nasdaq: AGIO) from November 2011 to March 2016, and Alliqua Biomedical, Inc. (Nasdaq: ALQA) from December 2013 to February 2016. Mr. Karsen was also formerly a member of the boards of directors of the Biotechnology Innovation Organization (BIO) and the Alliance for Regenerative Medicine. Mr. Karsen received his B.S. in Biological Sciences from the University of Illinois, Urbana-Champaign, a Masters of Management from Northwestern University's Kellogg Graduate School of Management and an M.A.T. in Biology from Duke University. We believe that Mr. Karsen's executive leadership experience, including his experience as an executive at large and successful multi-national pharmaceutical companies and membership on boards of directors of various publicly traded biotechnology companies, qualifies him to serve as a member of our board of directors.

Jerel Davis, Ph.D. has served on our board of directors since our inception in October 2019. Dr. Davis is currently a Managing Director of Versant Venture Management, LLC, a healthcare investment firm which he joined in 2012 and has held his current role since 2015. Dr. Davis currently serves on the boards of public companies, Chinook Therapeutics, Inc. (Nasdaq: KDNY) since December 2018 and Repare Therapeutics, Inc. (Nasdaq: RPTX) since September 2016. Dr. Davis also serves on the boards of a number of private companies including Nested Therapeutics, Inc., RayzeBio, Inc., Tentarix Biotherapeutics, Inc., Ventus Therapeutics Inc., and Turnstone Biologics Corp., among others. Prior to joining Versant Venture Management, LLC, Dr. Davis worked at McKinsey & Company, Inc., where he serviced various healthcare markets including the United States, Europe and China. Dr. Davis received a B.S. in Mathematics and Biology from Pepperdine University and a Ph.D. in Population Genetics from Stanford University. We believe that Dr. Davis's broad and extensive experience in the life sciences industry, both investing in and launching numerous life sciences companies, qualifies him to serve as a member of our board of directors.

Joseph Jimenez has served on our board of directors since June 2020. Mr. Jimenez is currently the Co-Founder and Managing Partner of Aditum Bio Management Company LLC, a biotechnology venture fund, where he has served since August 2019. He was formerly the Chief Executive Officer of Novartis AG, a position he held from February 2010 to January 2018. Prior to that, Mr. Jimenez held several senior positions at Novartis AG from April 2007 to January 2010, including Division Head of Novartis Pharmaceuticals and leadership of the company's Consumer Health Division. Prior to that, Mr. Jimenez was advisor to the Blackstone Group L.P. from July

2006 to March 2007. Additionally, Mr. Jimenez has held various leadership roles at H. J. Heinz Company, L.P. in Europe and North America from 1999 to 2006 and at ConAgra Foods Inc. from 1993 to 1998. Mr. Jimenez is currently a member of the board of directors of General Motors Company (NYSE: GM) since June 2015, Procter & Gamble Co. (NYSE: PG) since March 2018 and Century Therapeutics, Inc. (Nasdaq: IPSC) since August 2019. Mr. Jimenez received a B.A. in Economics from Stanford University and an M.B.A. from University of California, Berkeley's Haas School of Business. We believe that Mr. Jimenez's extensive leadership experience and executive leadership at various technology companies qualify him to serve on our board of directors.

Abraham Bassan has served on our board of directors since June 2020. Mr. Bassan is currently a Principal at Samsara BioCapital, L.P., a life science investment firm that takes a long-term view to company building in the biotech space. Since 2017, Mr. Bassan has been part of the investment team at Samsara Biocapital, L.P., where he plays a central role in sourcing new investments and overseeing operations at current portfolio companies in his capacity as a director or board observer. Mr. Bassan currently serves on the boards of directors of CARGO Therapeutics, Inc. (formerly Syncopation Life Sciences, Inc.), since February, 2021, Septerna, Inc., since November, 2021, Vedere Bio II, Inc., since April, 2021, and Link Cell Therapies Inc., since May, 2022. From February 2021 to May 2022, Mr. Bassan was President of CARGO Therapeutics, Inc. (formerly Syncopation Life Sciences, Inc.). From December 2014 to July 2017, Mr. Bassan held various leadership roles at Revolution Medicines, Inc. (Nasdaq: RVMD), including Director of Program Biology and Director of Project Management, where he co-led the initial stages of RVMD's 4EBP1/mTORC1 cancer program. From May 2010 to August 2012, Mr. Bassan was an Associate Director at bluebird bio, Inc. (Nasdaq: BLUE), where he was also the Project Manager for the company's β-Thalassemia, Sickle Cell Anemia, and ALD gene therapy programs. Mr. Bassan received his A.B. in Molecular Biology from Princeton University and a Master of Sciences in Development Biology from Stanford University. We believe that Mr. Bassan's significant knowledge of the life sciences industry and experience and expertise in evaluating and investing in life sciences companies qualify him to serve as a member of our board of directors.

Matthew Porteus, M.D., Ph.D. has served on our board of directors since March 2020. Dr. Porteus is an Associate Professor of Pediatrics of the Department of Pediatrics, Divisions of Hematology/Oncology and Human Gene Therapy, at Stanford School of Medicine, where he has served in various leadership roles since October 2010. Prior to joining the Stanford School of Medicine, Dr. Porteus served as an Assistant Professor at the University of Texas Southwestern Medical Center from February 2003 to August 2010. His research focuses on developing homologous recombination-based therapies for genetic and other diseases. Dr. Porteus also maintains a clinical practice at the Lucille Packard Children's Hospital, where he is an Attending Physician for the Pediatric Bone Marrow Transplant Service. Dr. Porteus completed his residency training in Pediatrics at Boston Children's Hospital and fellowship training in Pediatric Hematology/Oncology at Boston Children's Hospital and the Dana Farber Cancer Institute. For his post-doctoral work, Dr. Porteus trained at the Massachusetts Institute of Technology and the California Institute of Technology. During this time, he began studying gene editing and was the first to show that engineered nucleases could be used to precisely modify human cells by homologous recombination. Dr. Porteus graduated Magna Cum Laude with an A.B. in History and Science from Harvard University and completed his M.D. and Ph.D. degrees at Stanford University. We believe that Dr. Porteus's medical background and extensive knowledge surrounding genetic diseases, gene therapy and gene editing qualify him to serve as a member of our board of directors.

Jo Viney, Ph.D. has served on our board of directors since March 2021. Since October 2021, Dr. Viney has been a Co-Founder, President and Chief Executive Officer of Seismic Therapeutic, Inc., a biotechnology company. From July 2019 to October 2021, Dr. Viney was the Co-Founder and President of Pandion Therapeutics Inc. (Nasdaq: PAND), subsequently acquired by Merck & Co Inc. (NYSE: MRK), after serving as its Chief Scientific Officer since April 2017. From November 2015 to November 2016, Dr. Viney served as Senior Vice President, Drug Discovery at Biogen Inc. (Nasdaq: BIIB), after serving as Vice President, Immunology Research from July 2011 to October 2015. From September 2003 to April 2011, Dr. Viney served as Executive Director of Inflammation Research at Amgen, Inc. (Nasdaq: AMGN), after serving as Director of Inflammation Research from July 2002 to August 2003. Dr. Viney currently serves on the boards of public biotechnology companies, Harpoon Therapeutics, Inc. (Nasdaq: HARP) and Finch Therapeutics Group, Inc. (Nasdaq: FNCH). Dr. Viney holds a BSc in Biophysical Science from the University of East London and a Ph.D. in Immunology from the University of London, St. Bartholomew's Hospital Medical School. We believe that Dr. Viney's substantial leadership experience in the biotechnology industry qualifies her to serve as a member of our board of directors.

Kimberlee C. Drapkin has served as a member of our board of directors since July 2023 and as our interim President and Chief Executive Officer since August 2023. Ms. Drapkin has over 25 years of experience working with private and publicly traded biotechnology and pharmaceutical companies, including building and leading finance functions, raising capital, and leading strategic financial planning. Most recently, Ms. Drapkin was the Chief Financial Officer at Jounce Therapeutics, Inc., a position she held from August 2015 until the company's acquisition by Concentra Biosciences, LLC in May 2023, playing a key role in building Jounce's financial infrastructure. Prior to joining Jounce, Ms. Drapkin owned a financial consulting firm where she served as the interim chief financial officer for numerous early-stage biotechnology companies. Previously, she was the Chief Financial Officer at EPIX Pharmaceuticals, Inc. and also spent ten years in roles of increasing responsibility within the finance organization at Millennium Pharmaceuticals, Inc. Her career began in the technology and life sciences practice at PricewaterhouseCoopers LLP. Ms. Drapkin served as a member of the board of directors of Proteostasis Therapeutics, Inc. until the completion of the merger of Proteostasis and Yumanity Therapeutics, Inc., at which point she became a member of the Yumanity board of directors. Ms. Drapkin then served on the board of directors of Yumanity through the completion of its reverse merger with Kineta, Inc. She currently serves on the board of directors of Acumen Pharmaceuticals, Inc. (Nasdaq: ABOS), Imugene Limited (ASX: IMU) and Kineta, Inc. (Nasdaq: KA), where she is a member of audit committee at all three

companies. Ms. Drapkin holds a B.S. in accounting from Babson College. We believe that Ms. Drapkin's role as our interim president and chief executive officer qualifies her to serve on our board of directors.

Kristen M. Hege, M.D. has served as a member of our board of directors since April 2021. Dr. Hege joined Celgene Corporation in 2010 as Vice President, Translational Development and is currently Senior Vice President, Early Clinical Development, Hematology/Oncology & Cell Therapy at Bristol Myers Squibb Company (NYSE: BMY) (following its acquisition of Celgene Corporation in 2019). Prior to Celgene Corporation, she served as Chief Medical Officer at Cellerant Therapeutics, Inc. and Acting Chief Medical Officer at Aragon Pharmaceuticals, Inc. and Theraclone Sciences, Inc. Dr. Hege was also Vice President, Clinical Research and Development at Cell Genesys. She currently serves as a member of the board of directors at Mersana Therapeutics, Inc. (Nasdaq: MRSN) since 2016 and has previously served as a member of the board of directors at Arcus Biosciences, Inc. (NYSE: RCUS) from 2018 to 2019 and as a Board Observer for Flexus Biosciences from 2014 to 2015. She also previously served as a Volunteer-at-Large Director for the Society for Immunotherapy of Cancer from 2016 to 2019 and the BayBio/California Life Sciences Association from 2014 to 2016. Dr. Hege is currently a volunteer Clinical Professor of Medicine, Hematology/Oncology at the University of California, San Francisco Medical Center, where she was previously an active faculty member since 1996. Dr. Hege received a B.A. in Biochemistry from Dartmouth College summa cum laude, an M.D. from University of California, San Francisco, Internal Medicine training at Harvard's Brigham & Women's Hospital, and Board certification in Hematology and Medical Oncology from the University of California, San Francisco. We believe that Dr. Hege's medical background and experience in the biotechnology industry qualify her to serve on our board of directors.

Carlo Rizzuto, Ph.D. has served as a member of our board of directors since March 2020. Dr. Rizzuto is currently a Managing Director at Versant Venture Management, LLC, a healthcare investment firm. He has been with the firm since November 2012 where he has served in a variety of roles including operating principal, venture partner and partner. Prior to that, Dr. Rizzuto worked at Novartis AG, where he was a Global Program Team Director from 2010 to 2012. Dr. Rizzuto currently serves on the board of directors of Century Therapeutics, Inc. (Nasdaq: IPSC) since March 2018 and previously served on the board of directors of Pandion Therapeutics, Inc., from January 2018 until its acquisition by Merck (NYSE: MRK) in March 2021. Dr. Rizzuto received a B.A. in Biology from the University of Virginia and a Ph.D. in Virology from Harvard University. We believe that Dr. Rizzuto's experience as an investor in the life sciences industry qualifies him to serve on our board of directors.

Smital Shah has served as a member of our board of directors since April 2021. Ms. Shah currently serves on the board of directors of Pliant Therapeutics, Inc. (Nasdaq: PLRX) since March 2019. From December 2018 to December 2022, Ms. Shah was the Chief Business and Financial Officer at ProQR Therapeutics NV (Nasdaq: PRQR) and prior to that, she was the company's Chief Financial Officer from October 2014 to December 2018. From August 2012 to September 2014, Ms. Shah was in Corporate Treasury at Gilead Sciences, Inc. (Nasdaq: GILD). Prior to Gilead Sciences, Inc., she was an investment banker at Leerink Partners LLC and JP Morgan Chase and Co., where she focused on capital raising and strategic transactions in the biotechnology space. Ms. Shah also held various research and development roles at Johnson & Johnson Company. Ms. Shah holds a B.S. in Chemical Engineering from the University of Mumbai, a M.S. in Chemical Engineering from Virginia Tech and an M.B.A. from the University of California, Berkeley Haas School of Business. We believe that Ms. Shah's extensive experience in the life sciences industry and her leadership experience as a senior financial executive qualify her to serve as a member of our board of directors.

Board Diversity

Our Corporate Governance Guidelines provide that diversity of background and experience should be considered in determining director candidates as well as other factors such as a candidate's character, judgment, skills, education, expertise and absence of conflicts of interest. However, we do not have a formal policy concerning the diversity of the board of directors. Our priority in selection of board members is identification of members who will further the interests of our stockholders through their established records of professional accomplishment, their ability to contribute positively to the collaborative culture among board members, and their knowledge of our business and understanding of the competitive landscape in which we operate and adherence to high ethical standards. Although the nominating and corporate governance committee does not have a formal diversity policy and does not follow any ratio or formula with respect to diversity in order to determine the appropriate composition of the board of directors, the nominating and corporate governance committee and the full board of directors are committed to creating a board of directors that promotes our strategic objectives and fulfills its responsibilities to our stockholders, and considers diversity of gender, race, national origin, education, professional experience, and differences in viewpoints and skills when evaluating proposed director candidates.

We comply with Nasdaq Rule 5605 by having four diverse directors (40%), including two from underrepresented minorities. As required by Nasdaq Rule 5606 as approved by the SEC in August 2021, we are providing additional information about the gender and demographic diversity of our directors in the format required by such rule. The information in the matrix below is based solely on information provided by our directors about their gender and demographic self-identification.

Board Diversity Matrix (As of February 1, 2024)				
Total Number of Directors	10			
	Female	Male	Non-Binary	Did Not Disclose Gender
Part I: Gender Identity				
Directors	4	6		
Part II: Demographic Background				
African American or Black				
Alaskan Native or Native American				
Asian	1			
Hispanic or Latinx		1		
Native Hawaiian or Pacific Islander				
White	3	4		
Two or More Races or Ethnicities				
LGBTQ+				
Did Not Disclose Demographic Background	1			

Executive Officers

The following table identifies our sole current executive officer, and her current positions at Graphite Bio and her age as of February 1, 2024. You should refer to "*Directors*" above for biographical information about her.

Name	Position Held with Graphite Bio, Inc.	Since	Age
Executive Officers			
Kimberlee C. Drapkin	Interim President and Chief Executive Officer and Director	2023	55

Board Committees

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which operate pursuant to a charter adopted by our board of directors. We believe that the composition and functioning of all of our committees comply with the applicable requirements of Nasdaq, the Sarbanes-Oxley Act of 2002 and SEC rules and regulations that are applicable to us. We intend to comply with future requirements to the extent they become applicable to us.

The full text of our audit committee charter, compensation committee charter and nominating and corporate governance charter is posted on the investor relations portion of our website at *https://ir.graphitebio.com/corporate-governance*.

The Board of Directors also has a standing science and technology committee, which is an advisory committee. Matthew Porteus, M.D., Ph.D., and Carlo Rizzuto, Ph.D., serve on the science and technology committee, which is chaired by both Kristen Hege, M.D., and Jo Viney, Ph.D.

Audit Committee

Smital Shah, Perry Karsen and Joseph Jimenez serve on the audit committee, which is chaired by Ms. Shah. Our board of directors has determined that each member of the audit committee is "independent" for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and that each member of the audit committee has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Ms. Shah as an "audit committee financial expert," as defined under the applicable rules of the SEC. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;

- recommending based upon the audit committee's review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

Compensation Committee

Abraham Bassan, Perry Karsen and Carlo Rizzuto, Ph.D. serve on the compensation committee, which is chaired by Mr. Bassan. Our board of directors has determined that each member of the compensation committee is "independent" as defined in the applicable Nasdaq rules. The compensation committee's responsibilities include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our principal executive officer;
- evaluating the performance of our principal executive officer in light of such corporate goals and objectives and based on such evaluation: (i) determining, or recommending to the board of directors, cash compensation of our principal executive officer; and (ii) reviewing and approving, or recommending to the board of directors, grants and awards to our principal executive officer under equity-based plans;
- reviewing and approving the cash compensation (including severance), incentive compensation plans, equity-based plans, perquisites and other benefits of our other executive officers;
- reviewing management's aggregate decision regarding the compensation of all employees of the Company;
- reviewing and establishing our overall management compensation philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- reviewing and approving, or, at the request of the board of directors, recommending to the board of directors, our policies and procedures for the grant of equity-based awards;
- evaluating and determining, or recommending for determination by the board of directors, the achievement of milestones under any inventive or equity-based awards to officers, consultants and other employees;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention, termination or compensation of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

Nominating and Corporate Governance Committee

Perry Karsen, Jerel Davis, Ph.D., and Joseph Jimenez serve on the nominating and corporate governance committee, which is chaired by Mr. Karsen. Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as defined in the applicable Nasdaq rules. The nominating and corporate governance committee's responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;

- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

The nominating and corporate governance committee considers candidates for our board of directors membership suggested by its members and the Chief Executive Officer. Additionally, in selecting nominees for directors, the nominating and corporate governance committee will review candidates recommended by stockholders in the same manner and using the same general criteria as candidates recruited by the committee and/or recommended by our board of directors.

Identifying and Evaluating Director Nominees. Our nominating and corporate governance committee is responsible for filling vacancies on our board of directors and for nominating candidates for election by our stockholders each year in the class of directors whose term expires at the relevant annual meeting. Our board of directors delegates the selection and nomination process to the nominating and corporate governance committee, with the expectation that other members of our board of directors, and of management, will be requested to take part in the process as appropriate.

In identifying and recommending nominees for directors, the nominating and corporate governance committee may consider, among other factors that it considers appropriate, character, integrity, judgment, diversity, independence, skills, education, expertise, business acumen, business experience, length of service, understanding of our business and industry, conflicts of interest, and other commitments.

Board and Committee Meetings

During 2023, the full board of directors met thirteen times, the audit committee met four times, and the compensation committee met four times. There were no nominating and corporate governance meetings during 2023. During 2023, each member of the board of directors attended in person or participated in 75% or more of the aggregate of (i) the total number of meetings of the board of directors (held during the period for which such person has been a director) and (ii) the total number of meetings held by all committees of the board of directors on which such person served (during the periods that such person served).

Code of Business Conduct and Ethics

Our board of directors adopted a Code of Business Conduct and Ethics in connection with our IPO in June 2021. The Code of Business Conduct and Ethics applies to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), agents and representatives, including directors and consultants. The full text of our Code of Business Conduct and Ethics is posted on our website at *https://ir.graphitebio.com/corporate-governance/documents-charters*. If we make any substantive amendments to, or grant any waivers from, the Code of Business Conduct and Ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Policy on Trading, Pledging and Hedging of Company Stock

Our Insider Trading Policy prohibits our executive officers, the non-employee members of our board of directors and certain other employees from engaging in the following transactions:

- selling any of our securities that they do not own at the time of the sale (referred to as a "short sale");
- buying or selling puts, calls, other derivative securities of the Company or any derivative securities that provide the economic equivalent of ownership of any of our securities or an opportunity, direct or indirect, to profit from any change in the value of our securities or engaging in any other hedging transaction with respect to our securities;
- using our securities as collateral in a margin account; and
- pledging our securities as collateral for a loan (or modifying an existing pledge).

As of the date of this Form 10-K, none of our executive officers or non-employee directors have previously engaged in any hedging or pledging transaction involving our securities.

Board Leadership Structure and Board's Role in Risk Oversight

The roles of chairperson and of President and Chief Executive Officer are currently separated. Perry Karsen is our current chair of the board and Kimberlee Drapkin is our current interim President and Chief Executive Officer. We believe that separating these positions allows our President and Chief Executive Officer to focus on setting our overall strategic direction, expanding the organization to deliver

on our strategy and overseeing our day-to-day business, while allowing the chair of the board to lead the board of directors in its fundamental role of providing strategic advice to and independent oversight of management.

Our board of directors recognizes the time, effort and energy that the President and Chief Executive Officer is required to devote to her position in the current business environment, as well as the commitment required to serve as our chair of the board, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated bylaws and corporate governance guidelines do not require that our chair of the board and president positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction and intellectual property. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of our board of directors in overseeing the management of our risks is conducted primarily through committees of our board of directors, as disclosed in the descriptions of each of the committees above and in the charters of each of the committees. Our full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables our board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Compensation Risk Assessment

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking. This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to remain focused on both short-term and long-term strategic goals, in particular in connection with our pay-for-performance compensation philosophy. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

Item 11. Executive Compensation.

Non-Employee Director Compensation

Non-Employee Director Advisor Agreement

We have entered into an advisor agreement with Dr. Porteus as one of our founders. The material terms of his advisor agreement are summarized below.

Matthew Porteus, M.D., Ph.D.

On March 24, 2020, we entered into an advisory agreement with Dr. Porteus (the "Porteus Agreement"), pursuant to which he serves on our Scientific & Clinical Advisory Board and among other things, provides consulting services to us involving the development of techniques and improvements in the field of clustered regularly interspaced short palindromic repeats or CRISPR, cell and gene therapy and derivatives technologies for the prevention and treatment of human disease, assists us in reviewing goals and developing strategies for achieving such goals, advises on scientific research and supports the recruitment of personnel in our research and product development activities. As consideration for such services, Dr. Porteus is entitled to receive an annual retainer of $70,000, subject to his performance of services for nine (9) days per quarter. Furthermore, Dr. Porteus received a restricted stock grant of up to 3,819,901 shares, subject to reduction based on our issuance of common stock to Stanford University, as set forth in the applicable restricted stock purchase agreement. The shares of restricted stock are subject to a four (4) year vesting schedule (up to 25% of the total amount of shares granted (to the extent not previously vested) will vest on June 24, 2021, the first anniversary of the date on which we sold preferred stock with aggregate proceeds of at least $10 million, and the remaining 75% vests in equal monthly installments thereafter, subject to continued service through each such date); provided, that 364,884 shares vested on June 10, 2020 upon our execution of a term sheet for a license with Stanford and 100% of the then-unvested shares will vest upon a "change in control" (as defined in the Porteus Agreement) subject to Dr. Porteus remaining in continued service through such date. The Porteus Agreement also provides for reimbursement of travel and out-of-pocket expenses incurred by Dr. Porteus in providing services at our request, with any expense in excess of $500 per month requiring pre-approval by us. Pursuant to the Porteus Agreement, Dr. Porteus is subject to certain standard assignment of intellectual property and confidentiality covenants, as well as twenty-four (24) month post-termination non-solicitation of employees, consultants and customers restrictive covenants.

Non-Employee Director Compensation Policy

We have adopted a non-employee director compensation policy to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, our non-employee directors are eligible to receive cash retainers (which are payable quarterly in arrears and prorated for partial years of service) and equity awards as set forth below:

Annual Retainer for Board Membership		
$35,000 for general availability and participation in meetings and conference calls of our board of directors		
Additional Annual Retainer for Committee Membership		
Audit Committee Chairperson:	$	15,000
Audit Committee member (other than Chairperson):	$	7,500
Compensation Committee Chairperson:	$	10,000
Compensation Committee member (other than Chairperson):	$	5,000
Nominating and Corporate Governance Committee Chairperson:	$	8,000
Nominating and Corporate Governance Committee member (other than Chairperson):	$	4,000
Science & Technology Committee Chairperson:	$	10,000
Science & Technology Committee member (other than Chairperson):	$	5,000
Additional Retainer for Non-Executive Chairperson of the Board:	$	30,000

In addition, our policy provides that, upon initial election or appointment to our board of directors, each new non-employee director will be granted a one-time grant of a non-statutory stock option to purchase 40,000 shares of our common stock on the date of such director's election or appointment to the board of directors (the "Director Initial Grant"). The Director Initial Grant will vest in substantially equal monthly installments over three years, subject to the non-employee director's continued services to us. On the date of each annual meeting of our stockholders, each non-employee director who will continue as a non-employee director following such meeting will be granted an annual award of a non-statutory stock option to purchase 20,000 shares of common stock (the "Director Annual Grant"). The Director Annual Grant will vest in full on the earlier of the one-year anniversary of the grant date or on the date of our next annual meeting of stockholders, subject to the non-employee director's continued services to us. If a new non-employee director joins our board of directors on a date other than the date of our annual meeting of stockholders, then in lieu of the Director Annual Grant above, such non-employee director will be granted a pro-rata portion of the Director Annual Grant at the next annual meeting of stockholders based on the time between such non-employee director's appointment and such next annual meeting of stockholders. The Director Initial Grant and Director Annual Grant are subject to full acceleration vesting upon the sale of our company.

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any non-employee director for service as a non-employee director in a calendar year period will not exceed $1,000,000 in the first calendar year such individual becomes a non-employee director and $750,000 in any other calendar year.

We will reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of our board of directors or any committee thereof.

Employee directors will receive no additional compensation for their service as a director.

Director Compensation Table

The following table presents the total compensation for each of our non-employee directors who served as a member of our board of directors during the fiscal year ended December 31, 2023. Dr. Lehrer and Ms. Drapkin, who each served as a director and our President and Chief Executive Officer for a portion of 2023, did not receive any additional compensation for their services as a director. The compensation received by Ms. Drapkin and Dr. Lehrer, as our named executive officers, is presented in the "2023 Summary Compensation Table" in the "Executive Compensation" section below. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity or awards to or reimburse any expenses of, any of our non-employee directors in 2023.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Abraham Bassan[2]	$ 45,000	$ 38,398	$ —	$ 83,398
Jerel Davis, Ph.D.[3]	$ 46,500	$ 38,398	$ —	$ 84,898
Kristen M. Hege, M.D.[4]	$ 45,000	$ 38,398	$ —	$ 83,398
Joseph Jimenez[5]	$ 46,500	$ 38,398	$ —	$ 84,898
Perry Karsen[6]	$ 78,000	$ 38,398	$ —	$ 116,398
Matthew Porteus, M.D., Ph.D.[7]	$ 40,000	$ 38,398	$ 70,000 (8)	$ 148,398
Carlo Rizzuto, Ph.D.[9]	$ 45,000	$ 38,398	$ —	$ 83,398
Smital Shah[10]	$ 50,000	$ 38,398	$ —	$ 88,398
Jo Viney, Ph. D.[11]	$ 45,000	$ 38,398	$ —	$ 83,398

(1) The amounts reported represent the aggregate grant date fair value of the stock options granted to our directors during the 2023 fiscal year, calculated in accordance with Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC"), Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in notes 2 and 11 to our financial statements. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by our directors upon the exercise of the stock options or any sale of the underlying shares of common stock.
(2) As of December 31, 2023, Mr. Bassan held options to purchase an aggregate of 80,000 shares of common stock.
(3) As of December 31, 2023, Dr. Davis held options to purchase an aggregate of 80,000 shares of common stock.
(4) As of December 31, 2023, Dr. Hege held options to purchase an aggregate of 133,585 shares of common stock.
(5) As of December 31, 2023, Mr. Jimenez held (i) 153,815 shares of restricted stock from the early exercise of his options and (ii) options to purchase an aggregate of 52,469 shares of common stock.
(6) As of December 31, 2023, Mr. Karsen held (i) 155,908 shares of restricted stock from the early exercise of his options and (ii) options to purchase an aggregate of 133,492 shares of common stock
(7) As of December 31, 2023, Dr. Porteus held (i) 3,528,529 shares of founder restricted stock and (ii) options to purchase an aggregate of 40,000 shares of common stock.
(8) Amount represents the advisor fees earned by Dr. Porteus during the fiscal year ended December 31, 2023.
(9) As of December 31, 2023, Dr. Rizzuto held options to purchase an aggregate of 80,000 shares of common stock.
(10) As of December 31, 2023, Ms. Shah held options to purchase an aggregate of 133,585 shares of common stock.
(11) As of December 31, 2023, Dr. Viney held options to purchase an aggregate of 133,585 shares of common stock.

Executive Officer Compensation

Our named executive officers for the year ended December 31, 2023 are:

- Kimberlee C. Drapkin, who has served as our interim President and Chief Executive Officer since August 21, 2023;
- Josh Lehrer, M.D., our former President and Chief Executive Officer, who served as our President and Chief Executive Officer through August 21, 2023; and
- Alethia Young, our former Chief Financial Officer, who served as our Chief Financial Officer through June 30, 2023.

2023 Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for the years indicated:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)[1]	Non-equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Kimberlee C. Drapkin[2]	2023	200,521	—	71,148	—	—	271,669
Interim President and Chief Executive Officer and Director							
Josh Lehrer, M.D.[3]	2023	361,778	—	1,050,446 [4]	—	491,253 [5]	1,903,477
Former President, Chief Executive Officer and Director	2022	550,000	—	4,705,285	233,750	1,500	5,490,535
Alethia R. Young[6]	2023	232,950	—	385,164 [7]	—	50,000 [8]	668,114
Former Chief Financial Officer	2022	337,500	170,000	1,212,715	115,274	151,350	1,986,839

(1) The amounts reported represent the aggregate grant date fair value of the stock options granted to Graphite's named executive officers during the applicable fiscal year, calculated in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the stock options reported in this column are set forth in notes 2 and 11 to Graphite's financial statements included herein for the year ended December 31, 2023. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by Graphite's named executive officers upon the exercise of the stock options or any sale of the underlying shares of common stock.
(2) Ms. Drapkin commenced employment with Graphite on August 21, 2023. Her 2023 annual base salary is pro-rated based on her employment commencement date.
(3) Dr. Lehrer resigned as Chief Executive Officer on August 21, 2023 and transitioned to serve as a consultant to Graphite on such date. His 2023 annual base salary is pro-rated based on his resignation date. Dr. Lehrer did not receive any cash compensation for his services as a consultant to Graphite.
(4) Includes an aggregate grant date fair value of $918,480 for Dr. Lehrer's 2023 option grants as well as an incremental fair value of $131,966, in each case calculated in accordance with FASB ASC Topic 718, related to the modification of the Dr. Lehrer's outstanding options to provide for the extension of their post-termination exercise periods.
(5) Includes a payment equal to $286,000 pursuant to the Lehrer Retention Agreement, as well as severance payments in the amount of $190,667 in base salary continuation and $14,586 in COBRA premium reimbursements, made to Dr. Lehrer pursuant to the Lehrer Separation Agreement.
(6) Ms. Young resigned as Chief Financial Officer, effective June 30, 2023.
(7) Includes an aggregate grant date fair value of $336,776 for Ms. Young's 2023 option grants as well as an incremental fair value of $48,388, in each case calculated in accordance with FASB ASC Topic 718, related to the modification of Ms. Young's outstanding options to provide for the extension of their post-termination exercise periods.
(8) Includes reimbursements for relocation housing assistance paid to Ms. Young for the first quarter of the fiscal year ended December 31, 2023.

Narrative to 2023 Summary Compensation Table

Our compensation committee reviews compensation annually for all employees, including our executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, the compensation committee considers compensation for comparable positions in the market, the historical compensation levels of our executive officers, individual performance as compared to our expectations and objectives, internal equity, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to us. We target a general competitive position, based on independent third-party benchmark analytics to inform the mix of compensation of base salary, bonus and long-term incentives.

Our compensation committee is primarily responsible for determining the compensation for our executive officers. Our compensation committee typically reviews and discusses management's proposed compensation with our Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, taking into account the factors noted above, the compensation committee then sets the compensation for each executive officer other than the Chief Executive Officer. For the Chief Executive Officer, our compensation committee determines and approves the compensation, or upon request of the board of directors, recommends our Chief Executive Officer's compensation for approval by our board of directors. Our compensation committee may delegate certain authorities to an officer of the company and has delegated to our Chief Executive Officer the authority to make certain equity award grants to employees (other than our executive officers), within specified limits approved by the compensation committee. Our compensation committee has the authority to engage the services of a consulting firm or other outside advisor to assist it in designing our executive compensation programs and in making compensation decisions. During 2023, the compensation committee retained the services of Aon plc ("Aon"), formerly known as Radford, as its external compensation consultant to advise on executive compensation matters including our overall compensation program design and collection of market data to inform our compensation programs for our executive officers and members of our board of directors. Aon reports directly to our compensation committee. Our compensation committee annually assesses its independence consistent with Nasdaq's listing standards and concluded that the engagement of such consultant did not raise any conflict of interest.

Base Salaries

The annual base salary for each of Ms. Drapkin, Dr. Lehrer and Ms. Young for the fiscal year ended December 31, 2023 was $550,000, $572,000, and $468,000, respectively. The pro-rated annual base salary for Ms. Drapkin from her hiring on August 21, 2023 to December 31, 2023 was $200,521. The pro-rated annual base salaries for Dr. Lehrer and Ms. Young from January 1, 2023 to their respective employment termination dates were $361,778 and $232,950, respectively. Graphite's compensation committee reviews the base salaries of Graphite's executive officers, including Graphite's named executive officers, from time to time and makes adjustments (or, in the case of our Chief Executive Officer, may recommend adjustments for approval by the Graphite board of directors) as it determines to be reasonable and necessary to reflect the scope of the executive officer's performance, contributions, responsibilities, experience, prior salary level, position (in the case of a promotion) and market conditions, including base salary amounts relative to similarly situated executive officers at peer group companies.

Bonuses

Ms. Drapkin does not have a target annual bonus and does not participate in any of our incentive compensation plans. The target annual bonuses for Dr. Lehrer and Ms. Young from January 1, 2023 through the termination of their respective employments were 50%, and 40%, respectively, of the applicable named executive officer's annual base salary. Both Dr. Lehrer and Ms. Young terminated employment with us prior to December 31, 2023 and, as such, did not receive an annual bonus (or any portion thereof) for 2023.

Equity Compensation

During the fiscal year ended December 31, 2023, we granted stock option awards to each of our named executive officers, as described in more detail in the "Outstanding Equity Awards at Fiscal 2023 Year-End" table.

Perquisites or Personal Benefits

We generally do not provide significant perquisites or personal benefits to our employees with an aggregate equal to or greater than $10,000, other than reimbursements for relocation expenses for Ms. Young.

401(k) Plan

We maintained a tax-qualified retirement plan (the "401(k) Plan") through December 31, 2023 that provided eligible U.S. employees with an opportunity to save for retirement on a tax-advantaged basis. Plan participants were able to defer eligible compensation subject to applicable annual Code limits. We were able to provide matching contributions under the 401(k) Plan, but did not provide any such contributions during the 2023 fiscal year. The 401(k) Plan was intended to be qualified under Section 401(a) of the Code with the 401(k) Plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) Plan and earnings on those contributions were not taxable to the employees until distributed from the 401(k) Plan. We terminated the 401(k) Plan on December 31, 2023.

Executive Employment Arrangements

We have entered into an offer letter with each of the named executive officers in connection with his or her employment with us, which set forth the terms and conditions of his or her employment. Each named executive officer has also entered into our standard proprietary information and inventions agreement.

Employment and Severance Agreements in Place During the Fiscal Year Ended December 31, 2023 for Our Named Executive Officers

Kimberlee C. Drapkin

On August 21, 2023, we entered into an offer letter with Ms. Drapkin (the "Drapkin Letter"), for the position of interim Chief Executive Officer. The Drapkin Letter provides for Ms. Drapkin's at-will employment. Ms. Drapkin's current base salary is $550,000, which is subject to periodic review and adjustment. Ms. Drapkin is eligible to participate in the employee benefit plans generally available to our employees. The Drapkin Letter also provides that Ms. Drapkin will be entitled to cash severance payments in the amount of (i) $400,000 in the event of a termination of her employment other than for cause or death upon or within 12 months after the closing of a Strategic Transaction (as defined in the Drapkin Letter and which includes the merger), plus an additional $200,000 if the definitive agreement for such Strategic Transaction is executed within three (3) months after the Start Date or (ii) $350,000 in the event of a termination of her employment other than for cause or death upon or within 12 months after our board of directors' approval of our plan of dissolution under Delaware law, in each case subject to Ms. Drapkin's execution and non-revocation of a separation agreement and release, as further provided in the Drapkin Letter.

In addition, in connection with Ms. Drapkin's appointment as a member of our board of directors, on July 28, 2023, Ms. Drapkin received an initial equity grant in the amount of 40,000 shares of Graphite common stock, which vests in substantial equal monthly installments over a period of three years, subject to Ms. Drapkin's continued services to us. Such initial grant is subject to full accelerated vesting upon our sale, including the merger. Ms. Drapkin did not receive any additional compensation, including cash retainers, for her services as a director.

Josh Lehrer, M.D.

On March 21, 2023, we entered into a retention agreement with Dr. Lehrer (the "Lehrer Retention Agreement"), which provided for a lump sum cash payment equal to 50% of Dr. Lehrer's then-current annualized base salary, payable upon the earliest of (A) a termination by us other than for "cause," as defined in the Lehrer Retention Agreement, death or disability, (B) a resignation for "good reason," as defined in the Lehrer Retention Agreement, and (C) February 22, 2024, provided that clauses (A) and (B) above shall be subject to the execution and delivery of an effective release of claims in our favor. In addition, the Lehrer Retention Agreement provided for (i) the full acceleration of vesting of 50% of any outstanding and unvested equity awards granted in 2023 to Dr. Lehrer in the event he is terminated by us other than for cause or due to death or disability, or he resigns after June 30, 2023, and (ii) an extension of the exercise period for all stock options held by Dr. Lehrer at the time his employment is terminated until the earlier of (i) 12 months following such termination and (ii) the applicable expiration date of the stock option.

On September 7, 2023, we and Dr. Lehrer entered into a separation and release agreement (the "Lehrer Separation Agreement"), pursuant to which Dr. Lehrer is entitled to, in addition to the retention entitlements included in the Lehrer Retention Agreement, (i) a separation payment in the amount of $47,666.67 per month for a period of twelve (12) months and (ii) COBRA continuation coverage for twelve (12) months following August 21, 2023 (the "Termination Date"), or until he has commenced other employment and is eligible for healthcare coverage under the new employer's plan, whichever comes first.

Pursuant to the Lehrer Separation Agreement, Dr. Lehrer will continue to serve as a consultant to us until the earlier of (i) twelve (12) months from the Termination Date or (ii) the date of completion of a Strategic Transaction (as defined in the Lehrer Separation Agreement and which includes the merger) (the "Post- Employment Consulting Period"). During the Post-Employment Consulting Period, Dr. Lehrer's outstanding equity awards in us will continue to vest in accordance with their existing terms as in effect as of the Termination Date; provided, that in the event the Post-Employment Consulting Period ends upon the consummation of a Strategic Transaction prior to February 21, 2024, we shall accelerate the vesting of a number of shares equal to the number of shares subject to Dr. Lehrer's equity awards that would otherwise have vested through February 21, 2024 had his service relationship with us continued through such period (or such lesser amount then remaining unvested thereunder).

Alethia Young

Ms. Young resigned as our Chief Financial Officer, effective June 30, 2023. Although she did not enter into a separation agreement with us upon her resignation, fifty percent (50%) of the outstanding and unvested equity awards granted in 2023 to Ms. Young were immediately vested and the post termination exercise period for all options was extended from three (3) months to twelve (12) months.

Executive Severance Plan

Our board of directors has adopted an Executive Severance Plan (the "Severance Plan"), in which our named executive officers, and certain other executives, participate. The benefits provided in the Severance Plan replace any severance for which our named executive officers may be eligible under their existing offer letters or other agreements or arrangements.

The Severance Plan provides that upon a termination by us for any reason other than for "cause," as defined in the Severance Plan, death or "disability," as defined in the Severance Plan, or resignation for "good reason", as defined in the Severance Plan, in each case outside of the change in control period (i.e., the period of one year after a "change in control," as defined in the Severance Plan), an eligible participant will be entitled to receive, subject to the execution and delivery of an effective release of claims in favor of the Company and continued compliance with all applicable restrictive covenants, (i) 12 months of "base salary" (i.e., the higher of the annual base salary in effect immediately prior to the date of termination or the annual base salary in effect for the year immediately prior to the year in which the date of termination occurs) for our Chief Executive Officer, 9 months for Tier 2 officers (which is determined by the plan administrator and includes the named executive officers other than the Chief Executive Officer) and 6 months for Tier 3 officers (which is determined by the plan administrator) and (ii) an amount equal to the monthly employer contribution, based on the premiums as of the date of termination, that we would have made to provide health insurance for the named executive officer if he or she had remained employed by us for up to 12 months for our Chief Executive Officer, 9 months for Tier 2 officers and 6 months for Tier 3 officers. The payments under (i) and (ii) will be paid in substantially equal installments in accordance with our payroll practice over 12 months for our Chief Executive Officer, 9 months for Tier 2 officers and 6 months for Tier 3 officers.

The Severance Plan also provides that upon a (A) termination by us other than for cause, death or disability or (B) resignation for good reason, in each case within the change in control period, an eligible participant will be entitled to receive, in lieu of the payments and benefits above and subject to the execution and delivery of an effective release of claims in favor of the company and continued compliance with all applicable restrictive covenants, (I) a lump sum amount equal to 150% of the base salary and 150% of the target annual bonus in effect immediately prior to the date of termination (or immediately prior to the change in control, if higher) for our Chief Executive Officer, 100% of the base salary and 100% of the target annual bonus in effect immediately prior to the date of termination (or immediately prior to the change in control, if higher) for our Tier 2 officers and 75% of the base salary for our Tier 3 officers, (II) a lump sum amount equal to the eligible participant's annual target bonus in effect immediately prior to such termination, pro-rated for the number of days of service provided by the participant during the year of the termination, (III) a lump sum amount equal to the monthly employer contribution, based on the premiums as of the date of termination, that we would have made to provide health insurance for the participant if the applicable named executive officer had remained employed by us for 18 months for our Chief Executive Officer, 12 months for our Tier 2 officers and 9 months for our Tier 3 officers, and (IV) for all outstanding and unvested equity awards that are subject to time-based vesting held by the participant, full accelerated vesting of such awards; provided, that the performance conditions applicable to any outstanding and unvested equity awards subject to performance-based vesting will be deemed satisfied at the target level specified in the terms of the applicable award agreement.

The payments and benefits provided under the Severance Plan in connection with a change in control may not be eligible for a federal income tax deduction by us pursuant to Section 280G of the Code. These payments and benefits may also subject an eligible participant, including the named executive officers, to an excise tax under Section 4999 of the Code. If the payments or benefits payable in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to the participant.

Outstanding Equity Awards at Fiscal 2023 Year-End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2023:

			Option Awards[1]						Stock Awards[1]		
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable		Number of Securities Underlying Unexercised Options (#) Unexercisable		Option Exercise Price	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)		Market Value of Shares or Units of Stock That Have Not Vested ($)[2]
Kimberlee C. Drapkin	7/28/2023	7/28/2023	5,555	(3)	34,445	$	2.52	7/27/2033			—
Josh Lehrer, M.D.	4/20/2020	4/20/2020	—		—	$	—	—	55,867	(4)	146,372
	5/20/2020	4/20/2020	—		—	$	—	—	9,095	(4)	23,829
	1/13/2021	4/20/2020	—		—	$	—	—	31,168	(4)(5)	81,660
	3/17/2021	3/17/2021	546,697	(6)	248,499	$	6.11	3/16/2031	—		—
	3/17/2021	3/17/2021	234,298	(6)(7)	106,500	$	6.11	3/16/2031	—		—
	2/16/2022	1/1/2022	311,458	(6)	338,542	$	11.02	2/15/2032	—		—
	2/21/2023	1/1/2023	450,000	(8)	150,000	$	2.18	2/20/2033	—		—
Alethia R. Young	4/1/2022	4/1/2022	109,375		350,000	$	5.23	7/3/2024	—		—
	2/21/2023	1/1/2023	110,000	(9)	110,000	$	5.23	7/3/2024	—		—

(1) Each equity award is subject to the terms of Graphite's 2020 Stock Option Plan, as amended (the "2020 Plan"), or Graphite's 2021 Stock Option Plan, as amended

(the "2021 Plan"). Grants made subsequent to June 24, 2021 are subject to the terms of the 2021 Plan.

(2) Based on the closing price of a share of the Graphite common stock on December 29, 2023, the last business day of the most recently completed fiscal year, which was $2.62.

(3) The shares of common stock underlying the option vest in 36 equal monthly installments following the vesting commencement date, subject to the named executive officer's continuous service relationship with Graphite through each applicable vesting date. Notwithstanding the foregoing, in connection with (and contingent on) the consummation of the merger, all unvested shares shall immediately vest and become exercisable.

(4) The shares of restricted stock vest as follows: 25% of the shares on the first anniversary of the vesting commencement date and the remaining 75% in 36 equal monthly installments thereafter, subject to the named executive officer's continuous service relationship with Graphite through each applicable vesting date, including his continuous service relationship as a consultant to Graphite. During his post-employment consulting period, Dr. Lehrer's outstanding equity awards will continue to vest in accordance with the foregoing terms; provided, that in the event the consummation of the merger occurs prior to February 21, 2024, Graphite shall accelerate the vesting of a number of shares equal to the number of shares subject to Dr. Lehrer's equity awards that would otherwise have vested through February 21, 2024 had Dr. Lehrer's service relationship with Graphite continued through such period (or such lesser amount then remaining unvested thereunder). The foregoing vesting schedule is discussed further in the section of this Form 10-K titled *"Graphite Executive Compensation—Narrative to 2023 Summary Compensation Table—Executive Employment Arrangements—Josh Lehrer, M.D."* above.

(5) The named executive officer received an early exercisable stock option award, which the named executive officer early exercised in its entirety.

(6) The shares of Graphite common stock underlying the option vest in 48 equal monthly installments following the vesting commencement date, subject to the named executive officer's continuous service relationship with Graphite through each applicable vesting date. Notwithstanding the foregoing, during his post-employment consulting period, Dr. Lehrer's outstanding equity awards shall continue to vest in accordance with the foregoing terms; provided, that in the event the consummation of the merger occurs prior to February 21, 2024, Graphite shall accelerate the vesting of a number of shares equal to the number of shares subject to Dr. Lehrer's equity awards that would otherwise have vested through February 21, 2024 had Dr. Lehrer's service relationship with Graphite continued through such period (or such lesser amount then remaining unvested thereunder. The foregoing vesting schedule is discussed further in the section of this Form 10-K titled *"Graphite Executive Compensation—Narrative to 2023 Summary Compensation Table—Executive Employment Arrangements—Josh Lehrer, M.D."* above.

(7) The option was granted subject to the achievement by Graphite of performance vesting criteria. On June 29, 2021, the performance vesting criteria was met such that the option became subject to time-based vesting in accordance with the vesting schedule described in footnote (6) above.

(8) The shares of common stock underlying the option vest in 48 equal monthly installments following the vesting commencement date, subject to the named executive officer's continuous service relationship with the Company through each applicable vesting date. Notwithstanding the foregoing, pursuant to the Lehrer Separation Agreement, 50% of the unvested shares underlying such option accelerated upon his termination with Graphite (i.e., August 21, 2023), and the remaining unvested shares shall continue to vest during his post-employment consulting period in accordance with the foregoing vesting terms; provided, that in the event the consummation of the merger occurs prior February 21, 2024, Graphite shall accelerate the vesting of a number of shares equal to the number of shares subject to Dr. Lehrer's equity awards that would otherwise have vested through February 21, 2024 had Dr. Lehrer's service relationship with Graphite continued through such period (or such lesser amount then remaining unvested thereunder). The foregoing vesting schedule is discussed further in the section of this Form 10-K titled *"Graphite Executive Compensation—Narrative to 2023 Summary Compensation Table—Executive Employment Arrangements—Josh Lehrer, M.D."* above.

(9) The shares of common stock underlying the option vest in 48 equal monthly installments following the vesting commencement date, subject to Ms. Young's continuous service relationship with the Company through each applicable vesting date. Notwithstanding the foregoing, upon Ms. Young's resignation, fifty percent (50%) of the unvested shares underlying such option accelerated and the remaining unvested shares of Graphite common stock were forfeited.

Securities Authorized for Issuance under Equity Compensation Plans

Equity Compensation Plan Information

The following table provides information as of December 31, 2023 with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights[1]	Number of securities remaining available for future issuance under equity compensation plans (excluding securities in first column)
Equity compensation plans approved by security holders[2]	5,376,373	$ 6.58	10,798,817 [3]
Equity compensation plans not approved by security holders	—	$ —	—
Total	5,376,373	$ 6.58	10,798,817

(1) The weighted average exercise price is calculated based solely on outstanding stock options.
(2) Includes the following plans: our 2021 Plan, our 2020 Plan, and our 2021 Employee Stock Purchase Plan (the "2021 ESPP").
(3) As of December 31, 2023, a total of 10,798,817 shares of Graphite common stock have been reserved for issuance pursuant to the 2021 Plan, which number excludes the 2,900,419 shares that were added to the plan as a result of the automatic annual increase on January 1, 2024. The number of shares of Graphite common stock reserved and available for issuance under the 2021 Plan is subject to an automatic annual increase on each January 1, beginning January 1, 2022, by an amount equal to the lesser of: (i) 5% of the number of shares of Graphite common stock issued and outstanding on the immediately preceding December 31, and (ii) such lesser number of shares of Graphite common stock as determined by the Graphite board of directors or its compensation committee. This number will be subject to adjustment in the event of a stock split, stock dividend or other change in Graphite's capitalization. The shares of Graphite common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by Graphite prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated, other than by exercise, under the 2021 Plan and the 2020 Plan will be added back to the shares of Graphite common stock available for issuance under the 2021 Plan. Graphite no longer makes grants under the 2020 Plan. As of December 31, 2023, a total of 1,253,729 shares of Graphite common stock have been reserved for issuance pursuant to the 2021 ESPP, which number excludes the 564,000 shares that were added to the plan as a result of the automatic annual increase on January 1, 2024. The number of shares of Graphite common stock reserved and available for issuance under the 2021 ESPP is subject to an automatic annual increase on each January 1, beginning January 1, 2022, by an amount equal to the least of: (i) 564,000 shares of common stock, (ii) 1% of the number of shares of Graphite common stock issued and outstanding on the immediately preceding December 31, and (iii) such lesser number of shares of Graphite common stock as determined by the Graphite board of directors or its compensation committee. This number will be subject to adjustment in the event of a stock split, stock dividend or other change in Graphite's capitalization.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information, to the extent known by us or ascertainable from public filings, with respect to the beneficial ownership of our common stock as of February 1, 2024 by:

- each of our directors;
- each of our named executive officers;
- all of our directors and executive officers as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own greater than 5.0% of our outstanding common stock.

The column entitled "Shares Beneficially Owned" is based on a total of 58,232,864 shares of our common stock outstanding as of February 1, 2024.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock subject to options that are currently exercisable or exercisable within 60 days of February 1, 2024 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of Graphite Bio, Inc., 611 Gateway Blvd, Suite 120, South San Francisco, CA, 94080.

Name	Shares beneficially owned	
	Number	Percentage
5% or Greater Stockholders:		
Entities Affiliated with Versant Ventures[(1)]	16,416,117	28.19 %
Entities Affiliated with Samsara BioCapital[(2)]	8,497,067	14.59 %
Entities Affiliated with EcoR1 Capital LLC[(3)]	8,538,446	14.66 %
Matthew Porteus, M.D., Ph.D.[(4)]	3,548,529	6.09 %
Named Executive Officers and Directors:		
Kimberlee C. Drapkin[(5)]	8,888	*
Josh Lehrer, M.D.[(6)]	2,899,270	4.83 %
Alethia Young[(7)]	219,375	*
Perry Karsen[(8)]	272,851	*
Abraham Bassan[(9)]	56,666	*
Jerel Davis, Ph.D.[(10)]	56,666	*
Kristen M. Hege, M.D.[(11)]	113,585	*
Joseph Jimenez[(12)]	191,292	*
Matthew Porteus, M.D., Ph.D.[(4)]	3,548,529	6.09 %
Carlo Rizzuto, Ph.D.[(13)]	56,666	*
Smital Shah[(14)]	119,467	*
Jo Viney, Ph.D.[(15)]	113,585	*
All executive officers and directors as a group (12 persons) [(16)]	7,656,840	12.58 %

* Represents beneficial ownership of less than one percent.

(1) Based on Amendment No. 1 to Schedule 13D filed on November 17, 2023. Consists of (i) 14,708,398 shares of common stock held by Versant Venture Capital VI, L.P., ("Versant VI"), and (ii) 1,707,719 shares of common stock held by Versant Vantage II, L.P. ("Versant Vantage II", and together with Versant IV, the "Versant Funds"). Versant Ventures VI GP-GP, LLC ("Versant Ventures VI GP-GP") is the general partner of Versant Ventures VI GP, L.P. ("Versant Ventures VI GP"), which is the general partner of Versant VI. Each of Versant Ventures VI GP-GP and Versant Ventures VI GP share voting and dispositive power with respect to the shares held by Versant VI. Versant Vantage II GP-GP, LLC ("Versant Vantage II GP-GP") is the general partner of Versant Vantage II GP, L.P. ("Versant Vantage II GP"), which is the general partner of Versant Vantage II. Each of Versant Vantage II GP and Versant Vantage II GP-GP share voting and dispositive power with respect to the shares held by Versant Vantage II. The address for the Versant Funds is One Sansome Street, Suite 1650, San Francisco, CA 94104.

(2) Based on a Schedule 13G/A filed on February 14, 2023. Consists of (i) 8,459,314 shares of common stock held by Samsara BioCapital, L.P. ("Samsara LP") and (ii) 37,753 shares of common stock held by 436, L.P. The general partner of Samsara LP is Samsara BioCapital GP, LLC, or Samsara LLC. The general partner of 436, L.P. is 436, LLC. Voting and dispositive decisions with respect to the shares held by Samsara LP and 436, L.P. are made by Dr. Srinivas Akkaraju, MD, Ph.D., a manager of Samsara GP LLC and 436, LLC, and, accordingly, Dr. Akkaraju may be deemed to beneficially own the shares held by Samsara LP. And 436, L.P. The address of the principal business and office of Samsara LP and 436, L.P. is 628 Middlefield Road, Palo Alto, CA 94301.

(3) Based on a Schedule 13G/A filed on January 9, 2023. Consists of 8,538,446 shares of common stock held by EcoR1 Capital, LLC ("EcoR1"), EcoR1 Capital Fund Qualified, L.P. ("Qualified Fund") and Oleg Nodelman. The general partner and investment adviser of investment funds, including Qualified Fund, is EcoR1. Mr. Nodelman is the control person of EcoR1. The principal business office of EcoR1, Qualified Fund, and Oleg Nodelman is 357 Tehama Street #3, San Francisco, CA 94103.

(4) Consists of (i) 3,528,529 shares of common stock held by Dr. Porteus, and (ii) 20,000 shares of common stock underlying options directly held by Dr. Porteus exercisable within 60 days of February 1, 2024.

(5) Consists of 8,888 shares of common stock underlying options held by Ms. Drapkin exercisable within 60 days of February 1, 2024.

(6) Consists of (i) 1,161,670 shares of common stock held by Dr. Lehrer, and (ii) 1,737,600 shares of common stock underlying options directly held by Dr. Lehrer exercisable within 60 days of February 1, 2024.

(7) Consists of 219,375 shares of common stock underlying options held by Ms. Young exercisable within 60 days of February 1, 2024.

(8) Consists of (i) 164,034 shares of common stock held by Mr. Karsen, and (ii) 108,817 shares of common stock underlying options directly held by Mr. Karsen exercisable within 60 days of February 1, 2024.

(9) Consists of 56,666 shares of common stock underlying options directly held by Mr. Bassan exercisable within 60 days of February 1, 2024. Mr. Bassan, a member of our board of directors, is a vice president at Samsara BioCapital. Mr. Bassan has no voting or dispositive power over the shares held by the Samsara BioCapital entities referred to in Footnote 2 above.

(10) Consists of 56,666 shares of common stock underlying options directly held by Dr. Davis exercisable within 60 days of February 1, 2024. Dr. Davis, a member of our board of directors, is a Managing Director at Versant Ventures. Dr. Davis has no voting or dispositive power over the shares held by the Versant Ventures entities referred to in Footnote 1 above.

(11) Consists of 113,585 shares of common stock underlying options held by Dr. Hege exercisable within 60 days of February 1, 2024.

(12) Consists of (i) 161,941 shares of common stock held by Mr. Jimenez, and (ii) 29,351 shares of common stock underlying options held by Mr. Jimenez exercisable within 60 days of February 1, 2024.

(13) Consists of 56,666 shares of common stock underlying options directly held by Dr. Rizzuto exercisable within 60 days of February 1, 2024. Dr. Rizzuto, a member of our board of directors, is a Partner at Versant Ventures. Dr. Rizzuto has no voting or dispositive power over the shares held by the Versant Ventures entities referred to in Footnote 1 above.

(14) Consists of (i) 5,882 shares of common stock held by Ms. Shah, and (ii) 113,585 shares of common stock underlying options held by Ms. Shah exercisable within 60 days of February 1, 2024.

(15) Consists of 113,585 shares of common stock underlying options held by Dr. Viney exercisable within 60 days of February 1, 2024.

(16) Includes the number of shares beneficially owned by our current executive officers and directors listed in the table above.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Certain Relationships and Transactions

Other than the compensation agreements and other arrangements described under "Executive Compensation" and "Non-Employee Director Compensation" in this Form 10-K, and the transactions described below, since January 1, 2023, there has not been and there is not currently proposed, any transaction or series of similar transactions to which we were, or will be, a party in which the amount involved exceeded, or will exceed, $120,000 (or, if less, 1% of the average of our total assets amounts at December 31, 2021 and 2022) and in which any director, executive officer, holder of five percent or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

License and Option to Acquire Nula-Cel Assets

On August 4, 2023, we entered into a license and option agreement with Kamau (the "LOA") pursuant to which we exclusively licensed to Kamau, and granted Kamau, an option to acquire, certain intellectual property and materials related to our nula-cel program and related pre-clinical platform assets. The option includes rights to assume the License Agreement and the First Option Agreement with Stanford, as well as the IDT License Agreement, among other agreements. Exercise of the option is contingent on Kamau raising a minimum of $10 million in funds no later than August 4, 2024 (the "Financing Milestone"), which contingency may be waived by us. All rights to the intellectual property and materials will revert to us if the milestone is not achieved or if Kamau elects not to exercise the option. In return for this license and option, we received an equity interest in Kamau representing 20% of all outstanding shares on a fully diluted basis subject to dilution protection until the Financing Milestone. The LOA includes customary representations and warranties, limitations of liability and indemnification obligations for a transaction of this nature. The LOA automatically expires upon the first to occur of: (1) Kamau's exercise of the option, (2) Kamau's failure to exercise the option within a specified exercise period following achievement of the financing milestone, or (3) Kamau's failure to achieve the financing milestone by the pre-agreed deadline. In addition, either party has the right to terminate the LOA for the uncured material breach or insolvency of the other party, and we have the right to terminate the LOA if Kamau challenges any of the patent rights that are subject to the option. As a result of the 20% equity interest, we have the ability to exert significant influence over Kamau and accounts for the interest as an equity method investment. We record our proportionate share of investee's equity in earnings or losses based on the most recently available financial information. Dr. Porteus is a director and stockholder of us and is the founder and chief executive officer of Kamau.

On September 12, 2023, we entered into an amendment to the LOA with Kamau, under which we agreed to assign certain contracts to Kamau prior to exercise of the option.

As of December 31, 2023, Kamau has not achieved the financial milestone and does not have the right to exercise the option.

Sale of Non-Genotoxic Targeted Conditioning Technology Assets

On August 1, 2023, we entered into an asset purchase agreement with Maro pursuant to which we sold to Maro, concurrently with the execution of the asset purchase agreement, certain assets related to our non-genotoxic conditioning technology in exchange for upfront consideration of $0.5 million. Maro is formed by Samsara BioCapital and funds affiliated with Versant Ventures, both of which are greater than 5% stockholders of us. Additional consideration included certain contingent milestone payments totaling up to approximately $1.0 million in the aggregate, and potential fees upon the completion of certain transactions by the acquirer. The asset purchase agreement also provided for reimbursement of certain research and development amounts incurred prior to closing of approximately $0.6 million as well as certain transition services to be provided by Graphite or Maro. Under the asset purchase agreement, Maro will also pay us a sub single digit percentage cash royalty of worldwide net sales of certain products incorporating the acquired technology. The royalty term will terminate on a product-by-product and country-by-country basis on the latest of (i) the ten (10) year anniversary of the first commercial sale of such product in such country, (ii) the expiration of the last-to-expire valid claim of a transferred patent that covers such product in such country, and (iii) the expiration of regulatory exclusivity with respect to such product in such country. The asset purchase agreement also includes customary representations and warranties, covenants and indemnification obligations for a transaction of this nature.

Support Agreements Under the Merger Agreement with LENZ

Concurrently with the execution of the Merger Agreement, certain of our stockholders, owning in the aggregate approximately 52% of the outstanding shares of our common stock, entered into support agreements to vote all of their shares of our common stock in favor of each proposal as set forth in the Registration Statement on Form S-4, as filed with the SEC on December 6, 2023, as amended (the "Graphite Stockholder Proposals"). In the event our board changes its recommendation, then the aggregate number of shares of our common stock subject to the support agreements will automatically be reduced on a pro rata basis so that the aggregate number of such shares of our common stock shall collectively only constitute the greater of (a) 20% of the outstanding shares of our capital stock or (b) 30% of the votes cast in support of the Graphite Stockholder Proposals.

Lock-Up Agreements

Concurrently with the execution of the Merger Agreement, certain of our executive officers, directors and stockholders have entered into lock-up agreements with our company, pursuant to which such parties have agreed not to, except in limited circumstances, sell or transfer their shares of our common stock, for the 90-day period following the closing. The stockholders who have executed lock-up agreements as of November 14, 2023 owned in the aggregate approximately 43% of the shares of our outstanding capital stock.

Policies for Approval of Related Party Transactions

Prior to our IPO, we did not have a formal policy regarding approval of transactions with related parties. We have adopted a written related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were, or will be participants and in which the amount involved exceeds $120,000 or one percent of our total assets at year-end for the last two completed fiscal years. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director, or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration, and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction, and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer, and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related person transactions and to effectuate the terms of the policy.

In addition, under our Code of Business Conduct and Ethics, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest.

In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs, and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director, or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify, or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion. All of the transactions described above were entered into prior to the adoption of the written policy, but all were approved by our board of directors considering similar factors to those described above.

Director Independence

Our common stock is listed on The Nasdaq Global Market. Under the Nasdaq listing rules, independent directors must comprise a majority of a listed company's board of directors within twelve months from the date of listing. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under Nasdaq listing rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (2) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a

director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that all members of the board of directors, except Ms. Drapkin and Dr. Porteus, are independent directors, including for purposes of Nasdaq and the SEC rules. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock and with licensors and service providers of our Company. We expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of Nasdaq and the rules and regulations of the SEC. Ms. Drapkin is not an independent director under these rules because she is currently employed as the interim chief executive officer of our Company, and Dr. Porteus is not an independent director under these rules because he is currently providing services to us as a paid consultant and has an affiliation with our licensor and service provider.

Item 14. Principal Accountant Fees and Services.

Our independent public accounting firm is Deloitte & Touche LLP, San Francisco, CA, PCAOB Auditor ID 34.

Graphite Bio incurred the following fees from Deloitte & Touche LLP for the audit of the financial statements and for other services provided during the years ended December 31, 2023 and 2022.

	2023	2022
Audit Fees[(1)]	$ 2,648,839	$ 1,118,341
Audit-Related Fees[(2)]	—	—
Tax Fees[(3)]	—	—
All Other Fees[(4)]	—	—
	$ 2,648,839	$ 1,118,341

(1) Audit fees for the fiscal years ended December 31, 2023 and 2022 consist of fees for professional services rendered for the audit, quarterly review of our financial statements filed with the SEC on Form 10-K, 10-Q and services provided in connection with SEC filings, including consents and comfort letters, and matters related to the Merger including required filings
(2) Audit-related fees consist of services that are reasonably related to the performance of the audit or review of our financial statements. There were no such fees incurred in 2023 or 2022.
(3) Tax Fees consist of fees for tax compliance, advice and tax planning and includes fees for tax return preparation.
(4) There were no other fees incurred in 2023 or 2022.

Audit Committee Pre-approval Policy and Procedures

Our audit committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our independent registered public accounting firm. This policy provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our audit committee or the engagement is entered into pursuant to the pre-approval procedure described below.

From time to time, our audit committee may pre-approve specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next twelve (12) months. Any such pre-approval details the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

During our 2023 and 2022 fiscal years, no services were provided to us by Deloitte & Touche LLP other than in accordance with the pre-approval policies and procedures described above.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of November 14, 2023, by and among Graphite Bio, Inc., Generate Merger Sub, Inc. and LENZ Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on November 15, 2023).
3.1	Amended and Restated Certificate of Incorporation, as currently in effect (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on June 30, 2021).
3.2	Amended and Restated Bylaws, as currently in effect (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on June 30, 2021).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 11, 2021).
4.2	Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated March 11, 2021 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 4, 2021).
4.3	Description of Registrant's Securities (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K (File No. 001-40532) filed on March 21, 2022).
10.1#	2020 Stock Option and Grant Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 4, 2021).
10.2#	2021 Stock Option and Incentive Plan and forms of award agreements thereunder (incorporated by reference to Exhibit 10.2 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021).
10.3#	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021).
10.4#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.4 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021).
10.5#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.5 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021).
10.6	Forms of Indemnification Agreement by and between the Registrant and each of its directors and officers (incorporated by reference to Exhibit 10.9 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021).
10.7	Office Lease, by and between the Registrant and ARE-San Francisco No. 12, LLC, dated April 24, 2020, as amended by the First Amendment to Lease dated March 3, 2021 (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 4, 2021).
10.8	Laboratory Lease, by and between the Registrant and ARE-San Francisco No. 65, LLC, dated February 26, 2021 (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 4, 2021).
10.9	Exclusive License Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University, dated December 7, 2020 (incorporated by reference to Exhibit 10.12 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021).
10.10†	Amendment No. 1 to the Exclusive License Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University, dated March 4, 2021 (incorporated by reference to Exhibit 10.13 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021)
10.11†	Amendment No. 2 to the Exclusive License Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University, dated April 7, 2021 (incorporated by reference to Exhibit 10.14 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021)
10.12†	Exclusive Option Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University, dated January 22, 2021 (incorporated by reference to Exhibit 10.15 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021)

10.13†	Exclusive Option Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University, dated April 12, 2021 (incorporated by reference to Exhibit 10.16 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021)
10.14#	Executive Severance Plan (incorporated by reference to Exhibit 10.17 to Amendment No. 2 the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 21, 2021).
10.15#	Advisor Agreement by and between the Registrant and Matthew Porteus, dated March 24, 2020 (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 4, 2021).
10.16†	License Agreement by and between the Registrant and Integrated DNA Technologies, Inc., dated June 7, 2021 (incorporated by reference to Exhibit 10.20 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-256838) filed on June 11, 2021).
10.17	Sublease Agreement between the Registrant and Annexon, Inc. dated November 10, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on November 16, 2021).
10.18	Lease Agreement between the Registrant and Bayside Area Development, LLC dated December 16, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on December 20, 2021).
10.19#	Employment Offer Letter, by and between Graphite Bio, Inc. and Kimberlee C. Drapkin, dated August 21, 2023 (incorporated by reference to Exhibit 10.1 to Graphite Bio, Inc.'s Quarterly Report on Form 10-Q (File No. 001-40532) filed on November 13, 2023).
10.20#	Separation and Release Agreement, by and between Graphite Bio, Inc. and Josh Lehrer, dated September 7, 2023 (incorporated by reference to Exhibit 10.2 to Graphite Bio, Inc.'s Quarterly Report on Form 10-Q (File No. 001-40532) filed on November 13, 2023).
10.21	Subscription Agreement, dated November 14, 2023, by and among the Registrant, certain existing LENZ stockholders and new investors and certain parties thereto (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on November 15, 2023).
10.22	Form of Graphite Bio, Inc. Stockholder Support Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on November 15, 2023).
10.23	Form of Lock-up Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on November 15, 2023).
10.24	Sublease Agreement, dated October 26, 2023, by and between the Registrant and Soleil Labs, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on October 30, 2023).
10.25	First Amendment to Lease, dated October 26, 2023, by and between the Registrant and Bayside Area Development, LLC (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on October 30, 2023).
10.26	Form of Retention and Severance Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-40532) filed on March 16, 2023).
10.27	Compensation Recovery Policy
21.1	Subsidiaries of the Registrant.
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on signature page to this Annual Report on Form 10-K)
31.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document

101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

_____
† Portions of this exhibit (indicated by "[***]") have been omitted pursuant to Item 601(b)(10) of Regulation S-K.
# Indicates a management contract or any compensatory plan, contract or arrangement.
* This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

(b) Financial Statements:

The financial statements of the Registrant are included in Item 8 of this Form 10-K.

(c) Financial Statements Schedules:

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 16. Form 10-K Summary.

Not applicable.

Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

GRAPHITE BIO, INC.

Date: February 27, 2024

By: /s/ Kimberlee C. Drapkin

Kimberlee C. Drapkin
Interim President and Chief Executive Officer and Director

Power of Attorney

Each person whose individual signature appears below hereby constitutes and appoints Kimberlee C. Drapkin and Perry Karsen and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Kimberlee C. Drapkin Kimberlee C. Drapkin	Interim President and Chief Executive Officer and Director (Principal Executive Officer and Principal Accounting and Financial Officer)	February 27, 2024
/s/ Perry Karsen Perry Karsen	Chairman of the Board and Director	February 27, 2024
/s/ Abraham Bassan Abraham Bassan	Director	February 27, 2024
/s/ Jerel Davis, Ph.D. Jerel Davis, Ph.D.	Director	February 27, 2024
/s/ Kristen M. Hege, M.D. Kristen M. Hege, M.D.	Director	February 27, 2024
/s/ Joseph Jimenez Joseph Jimenez	Director	February 27, 2024
/s/ Matthew Porteus, M.D., Ph.D. Matthew Porteus, M.D., Ph.D.	Director	February 27, 2024
/s/ Carlo Rizzuto, Ph.D. Carlo Rizzuto, Ph.D.	Director	February 27, 2024
/s/ Smital Shah Smital Shah	Director	February 27, 2024
/s/ Jo Viney, Ph.D. Jo Viney, Ph.D.	Director	February 27, 2024

Exhibit 10.27

GRAPHITE BIO, INC.

COMPENSATION RECOVERY POLICY

Adopted as of November 14, 2023

Graphite Bio, Inc., a Delaware corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any Executive Officer. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded

Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means October 2, 2023.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs.

h. "Exchange" means the Nasdaq Stock Market LLC.

i. An "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation and received Incentive-Based Compensation after beginning service in any such role (regardless of whether such Incentive-Based Compensation was received during or after such person's service in such role): the president, principal financial officer, principal accounting officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure.

l. A "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

m. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee; provided, however, that the Board shall have exclusive authority to authorize the Company to prepare a Financial Restatement. In doing so, the Board may rely on a recommendation of the Audit Committee of the Board. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.

Exhibit 21.1

SUBSIDIARIES OF GRAPHITE BIO, INC.

None.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-263747, 333-257486, and 333-270694 on Form S-8, No. 333-266262 on Form S-3, and No. 333-275919 on Form S-4 of our report dated February 27, 2024, relating to the financial statements of Graphite Bio, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2023.

/s/ Deloitte & Touche LLP

San Francisco, California
February 27, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kimberlee C. Drapkin, certify that:

1. I have reviewed this Annual Report on Form 10-K of Graphite Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2024

By: /s/ Kimberlee C. Drapkin

Kimberlee C. Drapkin
Chief Executive Officer
(Principal Executive Officer and Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with this Annual Report of Graphite Bio, Inc. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2024

By: /s/ Kimberlee C. Drapkin

Kimberlee C. Drapkin
Chief Executive Officer
(Principal Executive Officer and Principal Accounting and Financial Officer)