2023 ANNUAL REPORT OF CALCIMEDICA, INC.

Note to Stockholders Regarding Company Name Change

As previously disclosed in the Company's Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 22, 2023, Graybug Vision, Inc. ("Graybug") changed its name to CalciMedica, Inc. (the "Company"), effective March 20, 2023, following the completion of its previously announced merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated as of November 21, 2022, as amended on February 10, 2023 (the "Merger Agreement"), by and among Graybug, Camaro Merger Sub, Inc., a wholly owned subsidiary of Graybug ("Merger Sub"), and CalciMedica, Inc. ("legacy CalciMedica"), pursuant to which Merger Sub merged with and into legacy CalciMedica, with legacy CalciMedica surviving the merger as a wholly owned subsidiary of Graybug. The Company's common stock, par value $0.0001 per share, is listed on The Nasdaq Capital Market and its CUSIP is 38942Q202. In connection with the name change, the Company also changed its Nasdaq ticker symbol from "GRAY" to "CALC". The below Annual Report on Form 10-K was filed with the SEC on March 9, 2023, prior to the Company's name change, and refers to the Company's former name.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2022

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 001-39538

GRAYBUG VISION, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**45-2120079**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

274 Redwood Shores Parkway, P.O. Box 144
Redwood City, CA 94065

(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (650) 487-2805

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 $0.0001 per share	GRAY	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 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, a 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, 2022, the last business day of the Registrant's most recently completed second fiscal quarter the aggregate market value of common stock held by non-affiliates of the Registrant computed by reference to the closing price of the Registrant's common stock on June 30, 2022 was approximately $13.0 million. Shares of common stock held by each executive officer, director and their affiliated holders have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the Registrant's common stock outstanding as of March 3, 2023 was 21,997,030.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement relating to the 2022 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein. The Definitive Proxy Statement will be filed within 120 days of the Registrant's fiscal year ended December 31, 2022. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as part of this Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements, other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our proposed merger, divestiture of assets, future financial condition, and objectives of management for future operations, are forward-looking statements. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" or the negative or plural of these words or similar expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- the timing and consummation of our proposed merger;
- the potential of divesting or licensing our remaining technologies and product candidates; and
- our ability to fund our working capital needs in the event that we do not consummate our proposed merger.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. You should not rely upon forward-looking statements as predictions of future events. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, after the date of this report, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

Item 1. Business.

To conserve our cash resources, we have substantially reduced our workforce and have reduced our research and development activities. On June 28, 2022 we announced that our board of directors would conduct a comprehensive review of strategic alternatives focused on maximizing shareholder value. Prior to this announcement, we had devoted substantially all our resources to conducting research and development on our product candidates and raising capital.

Prior to the completion of that strategic review, our most advanced programs were GB-102 for the treatment of wet age-related macular degeneration, which had completed Phase 2 clinical trials, and GB-401 for the treatment of glaucoma, which had not yet been studied in humans. On August 11, 2022, we announced that all clinical development of GB-102, GB-401, and GB-501, a gene therapy program that we acquired in March 2022, had been put on hold to conserve capital pending the outcome of our strategic review. On August 18, 2022, our board of directors approved certain strategic, operational and organizational steps for the Company including both the termination of all activities relating to our GB-102 and GB-401 programs and certain cost-reduction initiatives, including a reduction in our workforce by 71%. While clinical development of GB-501 remains on hold, preclinical work is still proceeding.

On October 3, 2022, we provided written notification to Johns Hopkins University ("JHU") of our decision to terminate our exclusive license agreement to all licensed patent rights owned by JHU that were relevant to our GB-102 program. On November 10, 2022, we entered into an agreement with Mireca Medicines GmbH ("Mireca") to assign certain intellectual property and revert all rights to our GB-601 preclinical program for retinitis pigmentosa, Stargardt Disease, and Leber congenital amaurosis back to Mireca, thereby terminating our involvement in that program.

To assist with evaluating strategic alternatives to maximize stockholder value, our board of directors engaged Piper Sandler & Co.to help explore the available strategic alternatives, including possible mergers and business combinations, a sale of part or all of our assets, and collaboration and licensing arrangements. On November 21, 2022, we and CalciMedica, Inc. ("CalciMedica") announced the signing of an Agreement and Plan of Merger and Reorganization, dated November 21, 2022, as may be amended from time to time (the "Merger Agreement"). Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by our stockholders, our wholly owned subsidiary will be merged with and into CalciMedica, with CalciMedica surviving the Merger as a wholly-owned subsidiary of Graybug Vision (the "Merger").

Although we have entered into the Merger Agreement and intend to consummate the Merger, there is no assurance that we will be able to successfully consummate the proposed Merger on a timely basis, or at all. If, for any reason, the Merger is not completed, we will reconsider our strategic alternatives and could pursue one or more of the following courses of action to reduce our current expenditures:

- ***Pursue potential collaborative, partnering or other strategic arrangements for our assets, including a sale or other divestiture of our assets.*** Even though our prior efforts were largely unsuccessful, we may again elect to seek potential collaborative, partnering or other strategic arrangements for our programs, including a sale or other divestiture of our assets, which could allow our technology to continue being developed. We may be unable to divest our assets in a timely manner, or at all, and therefore may not receive any return on our investment in our program assets.

- ***Pursue another strategic transaction like the proposed Merger.*** The board of directors may elect to pursue an alternative strategy, one of which may be a strategic transaction similar to the Merger.

- ***Dissolve and liquidate our assets.*** If, for any reason, the Merger is not consummated and we are unable to identify and complete an alternative strategic transaction like the Merger or potential collaborative, partnering or other strategic arrangements for our assets, or to continue to operate our business due to our inability to raise additional funding, we may be required to dissolve and liquidate our assets. In such case, we would be required to pay all of our debts and contractual obligations, and to set aside certain but potentially significant reserves for potential future claims, and there can be no assurances as to the amount or timing of available cash left to distribute to our stockholders after paying our debts and other obligations and setting aside funds for reserves for future or currently unknown liabilities.

We are continuing the preclinical development of our two remaining programs: GB-501, a gene therapy delivered via a recombinant adeno-associated virus ("AAV") vector to treat corneal clouding caused by mucopolysaccharidosis type 1 ("MPS1"), and GB-701, a novel and potent small-molecule complement factor B inhibitor being developed to target the complement pathway as a potential treatment for geographic atrophy ("GA"). As GB-501 is a biologic, it will not require, nor benefit from, our drug delivery technologies as it is administered via an intrastromal injection into the cornea. GB-701 is a new chemical entity currently being developed in collaboration with Insilico Medicine, a clinical-stage, end-to-end artificial intelligence ("AI")-drug discovery company. As a small molecule that is targeted to treat a chronic disease, GB-701 will likely require a sustained delivery technology.

Overview

We have historically been a clinical-stage biopharmaceutical company focused on developing transformative medicines for the treatment of diseases of the retina and optic nerve. On June 28, 2022, we announced that our board of directors would conduct a comprehensive review of strategic alternatives focused on maximizing shareholder value. As part of this review of strategic alternatives,

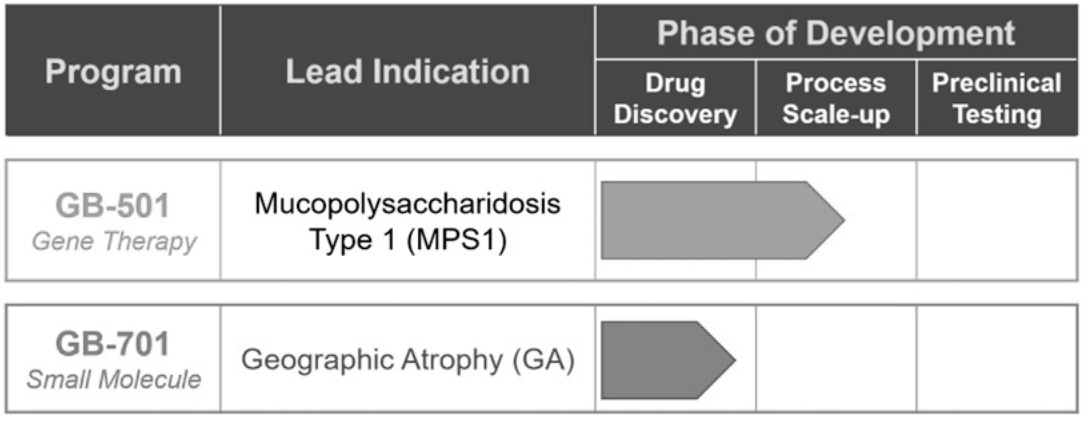
we explored the potential for an acquisition, company sale, merger, divestiture of assets, private placement of equity securities, and other strategic transactions. Prior to this announcement, we had devoted substantially all our resources to conducting research and development and raising capital.

After conducting a broad and rigorous search for strategic partners who could fund the clinical development of our most advanced programs, GB-102 for the treatment of wet age-related macular degeneration and GB-401 for glaucoma, we concluded that we did not have sufficient capital to pursue further clinical development of either program on our own, nor did we believe that we had the ability to raise sufficient additional capital to do so. Between October 2021 and August 2022, we contacted 38 parties to solicit interest in licensing or partnering GB-102, and 11 parties to solicit interest in licensing GB-401, but received only one proposal, and it was on terms that were not acceptable to us. As a result, on August 18, 2022, our board of directors approved a restructuring plan, which included the termination of all activities related to GB-102 and GB-401, as well as certain cost-reduction initiatives, including a 71% reduction in our workforce. On October 3, 2022, we provided written notification to Johns Hopkins University ("JHU") of our decision to terminate our exclusive license agreement to all licensed patent rights owned by JHU that were relevant to our GB-102 program. On November 10, 2022, we entered into an agreement with Mireca Medicines GmbH ("Mireca") to assign certain intellectual property and revert all rights to our GB-601 preclinical program for retinitis pigmentosa, Stargardt Disease, and Leber congenital amaurosis back to Mireca, thereby terminating our involvement in that program. On November 21, 2022, we announced that we had entered into a definitive merger agreement with CalciMedica, Inc. ("CalciMedica") to combine our companies in an all-stock transaction, subject to shareholder approval.

We are continuing the preclinical development of our two remaining programs: GB-501, a gene therapy delivered via a recombinant adeno-associated virus ("AAV") vector to treat corneal clouding caused by mucopolysaccharidosis type 1 ("MPS1"), and GB-701, a novel and potent small-molecule complement factor B inhibitor being developed to target the complement pathway as a potential treatment for geographic atrophy ("GA"). As GB-501 is a biologic, it will not require, nor benefit from, our drug delivery technologies as it is administered via an intrastromal injection into the cornea. GB-701 is a new chemical entity currently being developed in collaboration with Insilico Medicine, a clinical-stage, end-to-end artificial intelligence ("AI")-drug discovery company. As a small molecule that is targeted to treat a chronic disease, GB-701 will likely require a sustained delivery technology.

Our pipeline

The following chart summarizes the status and development plan for the two product candidates remaining in our pipeline. We own worldwide rights to each of these programs.



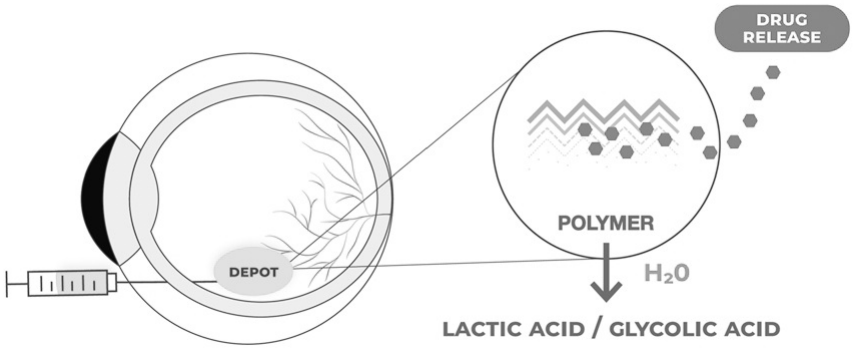
Our proprietary technologies

Our proprietary technologies are designed to allow sustained delivery of pharmacologic agents to the eye in a well-tolerated and controlled manner to achieve extended duration of effectiveness. Our proprietary technologies utilize microparticle depot and implant formulations each containing biodegradable polymers such as poly (lactic-co-glycolic acid) ("PLGA").

The microparticles are engineered to carry a hydrophilic coating such as polyethylene glycol ("PEG") that helps eliminate or minimize inflammation typically associated with intraocular administration of conventional PLGA microparticles. Our preclinical studies and Phase 1, 2a, and 2b clinical trials provided preliminary evidence that our microparticles are well-tolerated in the eye.

Furthermore, our microparticles are designed to aggregate after intravitreal injection upon exposure to the vitreous fluid at body temperature to form a depot near the bottom of the eye, outside of the visual axis. Our biodegradable microparticles then gradually

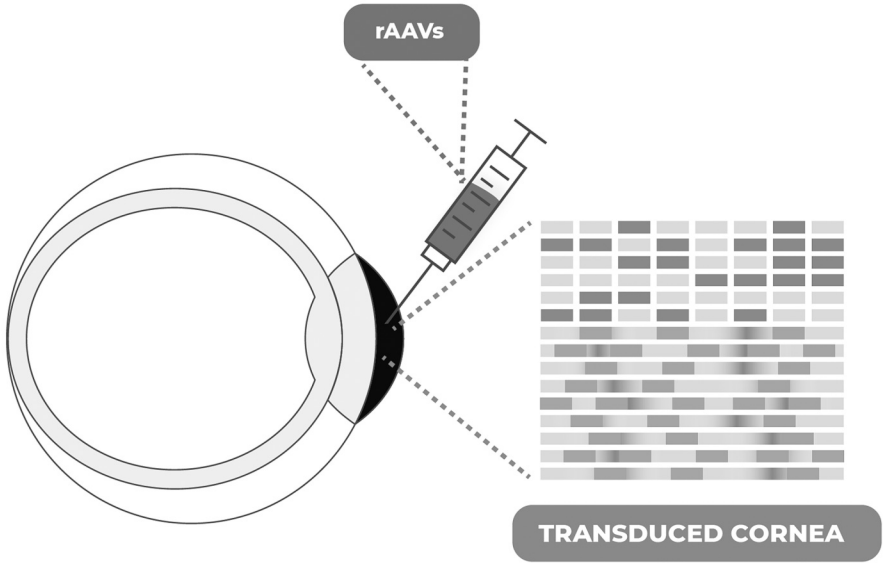
release the active ingredient at a rate dependent on the composition of the polymers and biodegrade into lactic acid, glycolic acid and PEG that are naturally cleared from the body.



Some molecules, due to their physicochemical properties, are difficult to integrate into polymer formulations and deliver in a controlled manner. For that purpose, we have developed a proprietary prodrug technology to enable sustained delivery of these therapeutics. Our research and development team has developed our product candidates with different pharmacologic agents using this prodrug technology. For example, we had been developing GB-401 using this approach until that program was terminated in August 2022.

We have also developed intravitreally-injected implant formulations containing biodegradable polymers such as poly (lactic-co-glycolic acid) ("PLGA") in the form of a rod. Our implants are designed to be injected near the bottom of the eye and are expected to remain in place due to their geometry and the structure of the vitreous humor.

With the acquisition of RainBio, Inc. in March 2022, we acquired exclusive rights to a gene therapy technology for our GB-501 program that is based on a recombinant adeno-associated virus ("rAAV") vector and is designed to deliver a functional copy of the gene that encodes alpha-L-iduronidase ("IDUA"). IDUA is an enzyme that breaks down intracellular and extracellular glycosaminoglycans ("GAGs") and can be administered directly to the cornea of Mucopolysaccharidosis Type 1 patients ("MPS1") with a single injection.



Our remaining programs, GB-501 and GB-701

Our most advanced product candidate, GB-501, is a gene therapy delivered via an adeno-associated virus ("AAV") vector to treat corneal clouding caused by mucopolysaccharidosis type 1 ("MPS1") a rare genetic disorder characterized by an abnormal build-up of glycosaminoglycans ("GAGs") in the body's cells. We acquired all rights to this product candidate in March 2022, including an exclusive license from the University of North Carolina ("UNC") to the gene sequence required to produce an enzyme called alpha-L-iduronidase ("IDUA") which is essential for the breakdown of GAGs. In patients suffering from MPS1, IDUA production in the cornea is insufficient to eliminate naturally occurring GAGs, which accumulate over time to the point that the cornea becomes opaque, rendering the patient

functionally blind. We anticipate that the direct injection of GB-501 into the cornea of MPS1 patients may result in the production of IDUA and the corresponding reduction of GAGs within the cornea, thereby mitigating or resolving the loss of vision caused by GAG accumulation.

In studies using a canine model of MPS1 with early and advanced corneal disease, a single intrastromal injection of research-grade GB-501 was well-tolerated at all administered doses. The eyes with advanced disease demonstrated resolution of corneal clouding as early as one week post-injection, followed by sustained corneal transparency until the experimental endpoint. We have engaged a leading contract development and manufacturing organization ("CDMO") to produce Good Manufacturing Practices ("GMP") material, with the goal of being ready for human clinical trials in 2024.

Our other remaining program, GB-701, is a discovery-stage small molecule program targeting the treatment of geographic atrophy ("GA"). In 2021, we formed a strategic partnership with Insilico Medicine, a clinical-stage, end-to-end artificial intelligence ("AI")-drug discovery company to develop a family of novel and potent small-molecule complement factor B inhibitors targeting the complement pathway as a potential treatment for GA. Discovery work is progressing, but we do not anticipate having a product candidate ready for preclinical development until after 2023. We anticipate that one or more of our drug delivery technologies will be required to deliver such a factor B inhibitor on a sustained basis to effectively treat GA.

Our executive leadership team

We are led by a team of experienced pharmaceutical industry executives with significant experience in ophthalmology:

- Frederic Guerard, Pharm.D., our Chief Executive Officer, has 20 years of leadership, strategic and commercial pharmaceutical experience, including as Worldwide Business Franchise Head of Ophthalmology at Novartis AG and Global Franchise Head of Pharmaceuticals at Alcon Laboratories, Inc.
- Parisa Zamiri, M.D., Ph.D., our Chief Medical Officer, is an ophthalmologist and was previously Vice President, Global Head of Clinical Development and Therapeutic Area Head for Ophthalmology at Novartis AG.
- Robert S. Breuil, our Chief Financial Officer, has over 20 years of experience in the biopharmaceutical and drug delivery industries, and previously served as Chief Financial Officer of Corium, Inc. and Codexis, Inc.
- Bettina Maunz, our Chief People Officer, has over 20 years of experience across the pharmaceutical, biotechnology, and medical device industries, and previously served as VP, Group Head of Enterprise Communications at Novartis AG.
- Ming Yang, Ph.D., our Senior Vice President of R&D, has over 20 years of R&D experience in developing novel therapeutics and drug delivery systems, including past experience at Genentech focused on ocular drug delivery.

Commercialization

We currently have no sales, marketing, or commercial product distribution capabilities. We intend to secure a partner to fund and complete development of all our remaining programs and, if approved, commercialize them.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technologies, knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, generic drug companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial and human resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These organizations compete with us and our potential strategic partners for recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring products, product candidates, or other technologies complementary to our programs.

The key competitive factors affecting the success of GB-501, if approved, are likely to be its efficacy, safety, and availability of coverage and reimbursement from government and other third-party payors. The method of administration of GB-501, intrastromal injection, is commonly used to administer ophthalmic drugs for the treatment of fungal diseases and is generally accepted by patients facing the prospect of severe visual loss or blindness. However, a therapy that offers a less invasive method of administration might have a competitive advantage over one administered by intrastromal injection, depending on the relative efficacy, safety, and durability

of the other method of administration. There are currently several systemic treatments for MPS1, but none of them are reported to effectively resolve the corneal clouding that GB-501 is intended to treat. If a new systemic treatment that also resolves corneal clouding is developed and approved, the market opportunity for GB-501 could be greatly reduced or even eliminated.

Manufacturing

We have neither large-scale manufacturing facilities nor personnel, other than personnel who manage our CDMO relationship. We currently rely, and expect to continue to rely, for the next few years, on third parties for the manufacture of all components of our product candidates undergoing preclinical and clinical testing. We are relying on a leading CDMO to establish small-volume GMP manufacturing capability to support a future clinical trial of GB-501.

Our GB-701 drug candidate is a family of small molecules that are manufactured in synthetic processes from base materials. We expect to continue to develop product candidates that can be produced cost-effectively at CDMO facilities. We anticipate that these arrangements will be sufficient for the manufacture of our product candidates until such time that a future strategic partner, if any, decides that it should establish its own large-scale manufacturing facility and it becomes operational.

We anticipate that we will continue to rely on CDMOs for all aspects of the drug manufacturing process, such as filling and labelling of our products for commercial sale and the manufacture of material. While we believe that having control over the whole manufacturing process would allow us to reduce cycle times, increase the robustness and consistency of the process and reduce cost of goods for commercial production, we also believe that we are unlikely to have or gain access to sufficient capital to invest in a dedicated manufacturing facility.

Intellectual property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our therapeutic products for ocular diseases, which include our novel microparticle aggregation technologies, to deliver therapeutically active agents. We also seek to protect our proprietary methods of treatment using our delivery technologies for ocular diseases, alone and in combination with other therapeutic agents. In addition, we seek protection on manufacturing processes for our aggregating microparticles, and dosing regimens and formulations for the ocular administration of our products. Our success also depends on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights.

Our policy is to seek to protect our proprietary position by filing, purchasing, or exclusively in-licensing U.S. and foreign patent applications covering our proprietary technologies, active pharmaceutical ingredients, inventions, and improvements that are important to the development and implementation of our business. If our proposed Merger fails to close, we may need to seek patent term adjustments, restorations, and/or patent term extensions where applicable in the United States, Europe and other jurisdictions. We also rely on trade secrets, know-how, continuing technological innovation, and potential in-licensing opportunities to develop and maintain our proprietary position. Additionally, we expect to benefit, where appropriate, from statutory frameworks in the United States, Europe, and other countries that provide a period of regulatory data exclusivity to compensate for the time required for regulatory approval of our drug products.

As part of our comprehensive review of strategic alternatives announced in June 2022, we began the process of reducing our patent filing footprint that covers our GB-102 and GB-401 programs outside the U.S., including the abandonment of certain patents and patent applications in certain non-U.S. jurisdictions. Following this reduction, we are the sole owner of eleven patent families covering our products, active pharmaceutical ingredients, and proprietary aggregating microparticle technology, which include composition of matter, methods of use, and processes of manufacture, as described in more detail below. Our owned patent estate as of December 31, 2022, on a worldwide basis, includes over 60 granted or pending patent applications with nine granted U.S. patents, one allowed U.S. patent application, 11 pending U.S. non-provisional applications, one pending international patent application filed under the Patent Cooperation Treaty and more than 40 pending patent applications that have entered the national phase of prosecution in countries outside the United States.

We have exclusively licensed one patent family from the University of North Carolina relating to our GB-501 product candidate. The patent family contains one granted U.S. patent, one pending U.S. patent application, and 13 pending or allowed applications in countries outside the United States.

We had previously licensed five patent families on an exclusive basis from Johns Hopkins University ("JHU") described below, and had granted an exclusive sublicense to Kala Pharmaceuticals, Inc. ("Kala") solely in the area of delivery through a mucosal barrier for the five families licensed from JHU only. On October 3, 2022, we terminated all of our exclusive licenses from JHU.

We had previously acquired two patent families and licensed one patent family from Mireca Medicines GmbH ("Mireca") a private company, for the treatment of disorders of the ear and eye, including retinitis pigmentosa, Stargardt Disease, and Leber congenital amaurosis. The two patent families that we acquired had also been licensed back to the private company for their use in non-overlapping therapeutic areas. On November 10, 2022, we entered into a termination and assignment agreement with Mireca that terminated our rights to their patent and assigned to Mireca the two patent families that we had previously acquired as well as additional intellectual property that we had developed in exchange for a release of all future financial obligations.

We continually assess and refine our intellectual property strategies as we develop new technologies and product candidates. We plan to file additional patent applications based on our intellectual property strategies where appropriate, including where we seek to adapt to competition or to improve business opportunities. Further, we plan to file patent applications, as we consider appropriate under the circumstances, to protect new technologies that we develop. Our patent filing strategy generally includes seeking patent protection in the United States, the European Union and China (which may include Macau and Hong Kong) and may in addition seek protection in countries where we believe such protection is likely to be useful, including one or more of Argentina, Australia, Brazil, Canada, countries of the Gulf Cooperation Council, India, Israel, Japan, Mexico, Russia and Taiwan.

The exclusivity terms of our patents depend upon the laws of the countries in which they are obtained. In the countries in which we currently file, the patent term is 20 years from the earliest date of filing of a non-provisional patent application. The term of a U.S. patent may be extended to compensate for the time required to obtain regulatory approval to sell a drug, which is referred to as a patent term extension, or by delays encountered during patent prosecution that are caused by the United States Patent and Trademark Office ("USPTO") which is referred to as patent term adjustment. For example, the Hatch-Waxman Act permits a patent term extension for new chemical entity drugs approved by the United States Food and Drug Administration ("FDA") of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review and diligence during the review process. Patent term extensions in the United States cannot extend the term of a patent beyond a total of 14 years from the date of product approval, and only one patent covering an approved drug or its method of use may be extended. A similar kind of patent extension, referred to as a Supplementary Protection Certificate, is available in Europe. Legal frameworks are also available in certain other jurisdictions to extend the term of a patent. We currently do not intend to seek patent term extensions on any of our issued patents in jurisdictions in which we have a qualifying patent and the extension is available, as they all relate to programs that we have terminated.

Our pending applications on additional methods of use of our former clinical candidates, should we find a buyer and such patents issue, will expire in 2039. If we are able to find one or more buyers for our patent estate covering our terminated programs, or if our planned Merger fails to close, we may need to file additional applications on aspects of our innovations that may have patent terms that extend beyond these dates. However, any of our patents, including patents that we or our assignees may rely on to protect the market for approved products, may be held invalid or unenforceable by a court of final jurisdiction. Alternatively, we or our assignees may decide that it is in our interest to settle a litigation in a manner that affects the term or enforceability of our patent. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish our or our assignees' ability to protect our inventions and enforce such intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that have been or may be granted on our patents or on third-party patents. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to obtain and maintain our proprietary position for our technologies and novel therapeutic agents will depend on our success in enforcing the claims that have been granted or may be granted. We do not know whether any of the pending patent applications that we have filed or may file or license from third parties will result in the issuance of any additional patents. The issued patents that we own or may receive in the future may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize drugs with similar mechanisms of action and/or duplicate our methods of treatments or strategies without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent.

Government regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA approval process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA") and other federal and state statutes and regulations. The failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending New Drug Applications ("NDAs") or Biologics License Applications ("BLA") warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices ("GLP"). The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls ("CMC") and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans.

If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice ("GCP"), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board ("IRB") for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial may be sufficient in rare instances, including (1) where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome, and confirmation of the result in a second trial would be practically or ethically impossible, (2) when in conjunction with other confirmatory evidence, or (3) in the case of ultra-rare diseases, such as MPS1, with a sufficiently clear clinical trial result.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to disclose, such as by posting on its website, its policy on evaluating and responding to requests for expanded access to such investigational drug.

After completion of the required clinical testing, an NDA (or BLA, if it pertains to a biologic such as GB-501) is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. Furthermore, under the Prescription Drug User Fee Act ("PDUFA") the submission of most NDAs is additionally subject to a substantial application user fee, and the

applicant under an approved NDA is also subject to an annual program fee for each prescription product. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. Under PDUFA, the FDA has agreed to certain performance goals in the review of NDAs to encourage timeliness. NDAs for most standard review drug products are reviewed within twelve months from submission of NDAs for new molecular entities ("NMEs") and within ten months from submission of NDAs for non-NMEs. Priority review can be applied to drugs that FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. NDAs for most priority review drug products are reviewed within eight months from submission of NDAs for NMEs and within six months from submission of NDAs for non-NMEs. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices ("cGMP") is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. The applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved application, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Disclosure of clinical trial information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information in the ClinicalTrials.gov database. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric information

Under the Pediatric Research Equity Act ("PREA") NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for

submission of data. With certain exceptions, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act ("BPCA") provides NDA holders a six-month extension of any exclusivity—patent or nonpatent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

The target population for our GB-501 product candidate is primarily children.

Post-approval requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements, including, among other things, record-keeping requirements, providing the FDA with updated safety information, product sampling and distribution requirements, and promotion and advertising requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed or promoted only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product (the "FDA") may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to current good manufacturing practices after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the Agency inspects manufacturing facilities to assess compliance with current good manufacturing practices. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with current good manufacturing practices. Regulatory authorities may withdraw product approvals, request product recalls or take other administrative or judicial enforcement actions if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be referenced by potential generic competitors in support of approval of an abbreviated new drug application ("ANDA"). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug pursuant to each state's laws on drug substitution.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. A recent opinion from the United States Court of Appeals for the Federal Circuit, however, held that a generic manufacturer launching a product with a patented method-of-use carve out may, nonetheless, still be liable for patent infringement by inducement based on certain information in the label and external information such as press releases and product catalogues. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021) *reh'g denied, en banc, GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 2022 U.S. App. LEXIS 3812 (Fed. Cir., Feb. 11, 2022).

If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents,

or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity ("NCE") which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which the FDA may not receive any ANDA seeking approval of a generic version of that drug. An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period. Certain changes to a drug, such as the addition of a new indication to the package insert, can be the subject of a three-year period of exclusivity if the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. The FDA cannot approve an ANDA for a generic drug that includes the change during the period of exclusivity.

Patent term extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval up to a maximum of five years). The time can be shortened if the FDA determines that the applicant did not pursue development or approval with due diligence. The total patent term after the extension may not exceed 14 years, and only one patent can be extended. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Hatch-Waxman patent certification and the 30-month stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the application will not be approved until all the listed patents claiming the referenced product have expired (other than method of use patents involving indications for which the applicant is not seeking approval).

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent

infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the ANDA applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical studies which must contain substantial evidence of the safety and efficacy of the proposed new product for the proposed use. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application enables the applicant in certain circumstances to rely, in part, on the FDA's prior findings in approving a similar product or published literature in support of its application. A Section 505(b)(2) NDA may provide an alternate path to FDA approval for a new or improved formulation, a new route of administration or a new use of a previously approved product.

Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the applicant for approval of the application "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted." If the Section 505(b)(2) applicant can establish that reliance on the FDA's prior findings of safety and/or effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Thus, Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the applicant. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, the applicant may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new drug candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on the FDA's prior findings of safety or effectiveness for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Neither of our remaining product candidates are likely to be eligible for approval via the 505(b)(2) regulatory pathway.

Biologics License Application

The FDA regulates biological products, including but not limited to, gene therapies, differently than it does small molecule drug therapies. The assessment of biological products is performed through the Center for Biologics Evaluation and Research ("CBER") at the FDA. For GB-501 to receive marketing approval from the FDA, a Biologics License Application ("BLA") will be required. The BLA concentrates on the unique characteristics and manufacturing processes of the biological products as biological products are much more complex than small molecule drug compounds. Biological products comprise large and complex protein structures that are primarily derived from living material, including human, animal, and microorganisms. An NDA for a small molecule needs to show that the drug is "safe and effective," while the BLA is required to ensure that the licensed biological product has demonstrated "safety, purity, and potency." The clinical trial requirements to demonstrate safety, tolerability and efficacy of the drug product are similar for both the NDA and BLA.

Other U.S. healthcare laws and compliance requirements

In the United States, pharmaceutical company activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services ("CMS") other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the federal false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act ("HIPAA") and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, recommending or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and/or formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act ("ACA") to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Federal false claims laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the civil 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. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus generally non-reimbursable, uses and purportedly concealing price concessions in the pricing information submitted to the government for government priced reporting purposes.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the 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.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Data privacy and security regulations by both the federal government and the states in which business is conducted may also be applicable. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, imposes requirements on certain types of people and entities relating to the privacy, security and transmission of individually identifiable health information. HIPAA requires covered entities to limit the use and transmission of individually

identifiable health information. HIPAA requires covered entities to limit the use and disclosure of protected health information to specifically authorized situations and requires covered entities to implement security measures to protect health information that they maintain in electronic form. Among other things, HITECH made HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, 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 attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. The reported information is made publicly available on a searchable website. Failure to submit required information may result in civil monetary penalties.

Commercial distribution of products requires compliance with state laws that require the registration of manufacturers and wholesale distributors of drug products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. 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 and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, 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 and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. Sales and marketing activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Violation of any of the federal and state healthcare laws described above or any other governmental regulations may result in penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, refusal to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings.

Pharmaceutical insurance coverage and health care reform

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated health care costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

MPS1 is a rare disease, which we believe has fewer than 1,500 patients currently in the United States, with fewer than 50 new patients diagnosed every year. In order to substantiate the significant investment that will be required to conduct human clinical trials and gain approval in the United States, the price of this therapy may need to exceed $250,000 per patient in 2022 dollars. Even though the total cost to treat all patients would be fraction of the total cost of treating many other diseases, the cost per therapy may be judged to be prohibitive by individual payors.

The containment of health care costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. 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 a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The Department of Health and Human Services ("HHS") plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. Many similar proposals, including the plans to give Medicare Part D authority to negotiate drug prices, require drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation, and cap out-of-pocket costs, have already been included in policy statements and legislation currently being considered by Congress. It is unclear to what extent these and other statutory, regulatory, and administrative initiatives will be enacted and implemented.

In March 2010, the United States Congress enacted the ACA, which, among other things, include changes to the coverage and payment for drug products under government health care programs.

There have been executive, legislative and judicial efforts to modify, repeal, replace, or otherwise invalidate all, or certain aspects, of the ACA. For example, the Tax Cuts and Jobs Act of 2017 included, among other things, a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In June 2021, the U.S. Supreme Court held that plaintiffs did not have standing to challenge constitutionality of the individual mandate. It is unclear whether there may be other efforts to challenge, repeal or replace the ACA. Further, prior to the Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and closed on August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or other healthcare measures on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures, including aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. The Medicare reductions phase back in starting with a 1% reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2% reduction. Moreover, the American Taxpayer Relief Act of 2012, among other things, 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.

Recently 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 and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products. By way of example, in December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. On September 9, 2021, the Biden Administration published a wide-ranging list of policy proposals, most of which would need to be carried

out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to (1) give Medicare authority to directly negotiate drug prices with manufacturers, (2) authorize HHS to negotiate Medicaid supplemental rebates on behalf of states, (3) allow employer-based, ACA marketplace and commercial health insurance plans to access Medicare negotiated drug prices, (4) place a cap on out-of-pocket costs for Medicare Part D beneficiaries and redistribute a higher proportion of drug costs to Part D and manufacturers, (5) mandate purchase of the least costly-alternative and to institute value-based or outcomes-based pricing arrangements, (6) disincentivize drug price increases, (7) facilitate approval and prescription of biosimilar and generic drugs, (8) increase drug pricing transparency, (9) prohibit certain types of rebates to pharmacy benefit managers, and (10) develop drug pricing models by tying price to outcomes. Many similar proposals, including the plans to give Medicare authority to negotiate drug prices and cap out-of-pocket costs, have already been included in policy statements and legislation currently being considered by Congress. It is unclear to what extent new statutory, regulatory, and administrative initiatives will be enacted and implemented. Additional state and federal healthcare reform measures will likely be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for such product candidates or additional pricing pressures.

Finally, in the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings.

Employees and Human Capital Resources

As of December 31, 2022, we had 8 full time employees, all in the United States, 3 of whom have an M.D. or Ph.D. None of our employees are represented by a labor union or covered by collective bargaining agreements, and we believe our relationship with our employees is good.

Our current human capital resources objectives include retaining and incentivizing our existing employees. The principal purposes of our equity incentive and cash-based performance bonus plans have been to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Properties and Facilities

Our principal executive office was located in Redwood City, California, and consisted of 2,560 square feet of office space under a lease which expired in January 2023. We had used this facility for operations and administrative purposes, but now all of our employees work remotely. We also have a facility located in Baltimore, Maryland, which consists of 15,649 square feet of office and laboratory space under a lease which expires in June 2023. We used the Maryland facility for our internal research and development activities until it was decommissioned in October 2022. We rely on third-party contract development and manufacturing organizations for both of our remaining product candidates and believe that their facilities and capabilities are adequate to meet our needs for the foreseeable future.

Corporate Information

We were incorporated in Delaware in May 2011. Our website is www.graybug.vision. We are subject to the informational requirements of the Securities and Exchange Act of 1934, as amended (the "Exchange Act") and file or furnish reports, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act, proxy statements and other information with the SEC. We make copies of these reports and other information available free of charge through our website as soon as reasonably practicable after we file or furnish them with the SEC. The SEC maintains a website that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. The information contained on the websites referenced in this Annual Report is not incorporated by reference into this filing, and the website addresses are provided only as inactive textual references.

Item 1A. Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially. Additionally, to the extent the ongoing COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks incorporated by reference or set forth below. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Summary of Risk Factors

An investment in our common stock involves various risks, and prospective investors are urged to carefully consider the matters discussed in the section titled "Risk Factors" prior to making an investment in our common stock. These risks include, but are not limited to, the following:

- If the proposed merger with CalciMedica is not consummated, our business could suffer materially and our stock price could decline.
- If we do not successfully consummate the merger or another strategic transaction, then our Board may decide to pursue a dissolution and liquidation under Delaware law. 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, and it is possible that shareholders would receive significantly less than the current market value of their shares.
- Our net cash may be less than $18 million at the closing of the merger, which would cause a condition to CalciMedica's obligation to consummate the merger to fail to be satisfied and may result in the termination of the merger agreement.
- Some of our officers and directors have conflicts of interest that may influence them to support or approve the merger.
- The merger may be completed even though material adverse changes may result from the announcement of the merger, industry-wide changes and other causes.
- We are a clinical-stage biopharmaceutical company with no products approved. We have incurred significant losses since inception, and we expect to incur continued and increasing losses over the next several years and may never achieve or maintain profitability.
- We will need substantial additional funding to support our operations and pursue our growth strategy. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- Our approach to the treatment of retinal diseases is unproven, and we do not know whether we will be able to successfully develop any products.
- If we do not successfully consummate the merger or another strategic transaction, we will depend heavily on the success of our product candidates. Clinical trials of our product candidates may not be successful. If we are unable to successfully complete clinical development of, and obtain marketing approvals for, our product candidates, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize these product candidates, our business will be materially harmed.
- We have not yet successfully initiated or completed any Phase 3 clinical trials nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.
- If clinical trials of GB-501 or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other regulatory authorities or do not otherwise produce favorable results, we may

incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of such product candidate.

- The ongoing COVID-19 pandemic may, directly or indirectly, adversely affect our business, results of operations and financial condition.
- Gene therapy is an emerging field of drug development that poses many scientific and other risks, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval.
- We have no prior experience with gene therapy, the sourcing or manufacturing of gene therapy products and components, or the conduct of clinical trials of such products.
- Our business and operations would suffer in the event of computer system failures or security breaches.
- We could potentially contract with third parties for the production of our product candidates. This could increase the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- The manufacture of our product development candidates requires outsourced, custom manufacturing and we may encounter difficulties in production, particularly with respect to formulation, process development or scaling up of our manufacturing capabilities. If we, or our contract manufacturing organizations ("CMOs") encounter such difficulties, our ability to provide supply of our product candidates for preclinical studies, clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.
- Gene therapies are novel, complex and difficult to manufacture. We could experience manufacturing problems that result in delays in our development or commercialization programs or otherwise harm our business.
- We have no experience manufacturing any of our product candidates at a commercial scale. We, or our CMOs, may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.
- Our products 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, and the market opportunity for these products may be smaller than we estimate.
- If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business.
- Patents filed by our licensor, University of North Carolina at Chapel Hill ("UNC") may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.
- We may be required, or choose, to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, the trials are not well-designed, or research participants experience adverse safety outcomes.
- If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate significant revenue will be materially impaired. The regulatory approval process is expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain regulatory approval to commercialize our product candidates.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- The market price of our stock has been and may continue to be volatile, and you could lose all or part of your investment.
- If our stock price does not meet Nasdaq's minimum bid requirement, it could become subject to delisting.
- 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.

Risks Related to the Proposed Merger with CalciMedica, Inc.

If the proposed merger with CalciMedica is not consummated, our business could suffer materially and our stock price could decline.

The consummation of the proposed merger with CalciMedica is subject to a number of closing conditions, including the approval by our stockholders, approval by Nasdaq of our application for initial listing of our common stock in connection with the merger, and other customary closing conditions. We are targeting a closing of the transaction in the first quarter of 2023.

If the proposed merger is not consummated, we may be subject to a number of material risks, and our business and stock price could be adversely affected, as follows:

- We have incurred and expect to continue to incur significant expenses related to the proposed merger with CalciMedica even if the merger is not consummated.
- The merger agreement contains covenants relating to our solicitation of competing acquisition proposals and the conduct of our business between the date of signing the merger agreement and the closing of the merger. As a result, significant business decisions and transactions before the closing of the merger are restricted or prohibited. Accordingly, we may be unable to pursue business opportunities that would otherwise be in our best interest as a standalone company. If the merger agreement is terminated after we have invested significant time and resources in the transaction process, we will have a limited ability to continue our current operations without obtaining additional financing to fund our operations.
- We could be obligated to pay CalciMedica a $1 million or $1.5 million termination fee in connection with the termination of the merger agreement, depending on the reason for the termination.
- We could be obligated to pay CalciMedica $250,000 or $1 million for expense reimbursement in connection with the termination of the merger agreement, depending on the reason for the termination.
- Our collaborators and other business partners and investors in general may view a failure to consummate the merger as a poor reflection on our business or prospects.
- Some of our suppliers, collaborators and other business partners may seek to change or terminate their relationships with us as a result of the proposed merger.
- As a result of the proposed merger, current and prospective employees could experience uncertainty about their future roles within the combined company. This uncertainty may adversely affect our ability to retain our key employees, who may seek other employment opportunities. Additionally, pursuant to the merger agreement, all Graybug employees will be terminated effective as of the closing.
- Our management team may be distracted from day-to-day operations as a result of the proposed merger.
- The market price of our common stock may decline to the extent that the current market price reflects a market assumption that the proposed merger will be completed.

In addition, if the merger agreement is terminated and our Board determines to seek another business combination, we may not be able to find a third party willing to provide equivalent or more attractive consideration than the value to be provided by each party in the merger. In such circumstances, our Board may elect to, among other things, divest all or a portion of our business, or take the steps necessary to liquidate all of our business and assets, and in either such case, the consideration that we receive may be less attractive than the consideration to be received by us pursuant to the merger agreement.

If the proposed merger with CalciMedica is not consummated, CalciMedica may not be able to repay amounts we have loaned to them.

Our loans to CalciMedica are in the form of unsecured promissory notes (the "Notes"), so we have no preference ahead of CalciMedica's other lenders and creditors. In the event that the Merger Agreement is terminated, whether as a result of our shareholders voting against the Merger, the acceptance by our Board of a Superior Offer, the passage of the End Date before the Merger closes, or other reasons, CalciMedica may not be able to repay the Notes in a timely fashion, if at all.

If we do not successfully consummate the merger or another strategic transaction, then 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 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 of Graybug. In such an event, the amount of cash available for distribution to Graybug's 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. The amount of cash available for distribution would also be reduced if we are required to pay a termination fee to CalciMedica pursuant to the merger agreement. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of Graybug, 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 our 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 of Graybug.

Our net cash may be less than $18 million at the closing of the merger, which would cause a condition to CalciMedica's obligation to consummate the merger to fail to be satisfied and may result in the termination of the merger agreement.

We are required to have a net cash balance of at least $18 million at the closing of the merger as a condition to CalciMedica's obligation to consummate the merger. For purposes of the merger agreement, net cash is subject to certain reductions, including, without limitation, short- and long-term liabilities accrued and any unpaid change of control payments or severance, termination, accrued paid time off, retention or similar payments at closing. In the event that our net cash falls below this threshold, a condition to the CalciMedica's obligation to consummate the merger will fail to be satisfied and CalciMedica will have the right to terminate the merger agreement at an outside date of May 21, 2023 (subject to extension as provided in the merger agreement) if our net cash continues to be lower than the $18 million threshold.

Some of our officers and directors have conflicts of interest that may influence them to support or approve the merger.

Our officers and directors participate in arrangements that provide them with interests in the merger that are different from yours, including, among others, their continued service as a director of the combined company, retention and severance benefits, the acceleration of option and restricted stock unit vesting, and continued indemnification. These interests, among others, may influence the officers and directors of Graybug to support or approve the merger.

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

In general, either CalciMedica or us can refuse to complete the merger if there is a material adverse change affecting the other party between November 21, 2022, the date of the merger agreement, and the closing. However, some types of changes do not permit either party to refuse to complete the merger, even if such changes would have a material adverse effect on us or CalciMedica, to the extent they resulted from the following:

- general business or economic conditions generally affecting the industry in which either company or their subsidiaries operate;
- acts of war, the outbreak or escalation of armed hostilities, acts of terrorism, earthquakes, wildfires, hurricanes or other natural disasters, health emergencies, including pandemics (including COVID-19 and any evolutions or mutations thereof) and related or associated epidemics, disease outbreaks or quarantine restrictions;
- changes in financial, banking or securities markets;
- any change in, or any compliance with or action taken for the purpose of complying with, any law or GAAP (or interpretations of any law or GAAP);
- the announcement of the merger agreement or the pendency of the contemplated transactions;
- the taking of any action required to be taken by the merger agreement, except in each case with respect to the first three bullets above, to the extent disproportionately affecting either company and its subsidiaries, taken as a whole, relative to other similarly situated companies in the industries in which either company or its subsidiaries operate, as applicable;
- our potential asset dispositions under the merger agreement;
- any reduction in the amount of our or our subsidiaries' cash and cash equivalents as a result of expenditures made by us or our subsidiaries related to our wind-down activities or our subsidiaries associated with the termination of our research and development activities (including the termination of ongoing contractual obligations relating to our or our subsidiaries' current products or product candidates);
- our or our subsidiaries' failure, taken as a whole, to meet internal or analysts' expectations or projections or the results of operations of us and our subsidiaries, taken as a whole; or
- any change in the stock price or trading volume of our common stock (it being understood, however, that any effect causing or contributing to any change in stock price or trading volume of our common stock may be taken into account in determining whether a material adverse effect has occurred, unless such effects are otherwise excepted from this definition).

If adverse changes occur but CalciMedica and we must still complete the merger, the combined company's stock price may suffer.

The market price of the combined company's common stock may decline as a result of the merger.

The market price of the combined company's common stock may decline as a result of the merger for a number of reasons including if:

- the combined company does not achieve the perceived benefits of the merger as rapidly or to the extent anticipated by financial or industry analysts;

- the effect of the merger on the combined company's business and prospects is not consistent with the expectations of financial or industry analysts; or
- investors react negatively to the effect on the combined company's business and prospects from the merger.

Our stockholders may not realize a benefit from the merger commensurate with the ownership dilution they will experience in connection with the merger.

If the combined company is unable to realize the strategic and financial benefits currently anticipated from the merger, our stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Significant management attention and resources will be required to integrate the two companies. Delays in this process could adversely affect the combined company's business, financial results, financial condition and stock price following the merger.

During the pendency of the merger, we may not be able to enter into a business combination with another party and will be subject to contractual limitations on certain actions because of restrictions in the merger agreement.

Covenants in the merger agreement impede our ability and the ability of CalciMedica to make acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the merger. As a result, if the merger is not completed, the parties may be at a disadvantage to their competitors. In addition, while the merger agreement is in effect and subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging, inducing or facilitating the communication, making, submission or announcement of certain acquisition inquiries or acquisition proposals or taking any action that could reasonably be expected to lead to certain acquisition inquiries or acquisition proposal, such as certain acquisitions of our common stock, a tender offers for our common stock, and mergers or other business combinations. Such prohibited transactions could otherwise be favorable to our stockholders.

Because the lack of a public market for CalciMedica common stock makes it difficult to evaluate the fairness of the merger, CalciMedica's stockholders may receive consideration in the merger that is greater than or less than the fair market value of CalciMedica common stock.

The outstanding share capital of CalciMedica is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of CalciMedica. Since the percentage of our equity to be issued to CalciMedica's stockholders was determined based on negotiations between the parties, it is possible that the value of our common stock to be issued in connection with the merger will be greater than the fair market value of CalciMedica. Alternatively, it is possible that the value of the shares of our common stock to be issued in connection with the merger will be less than the fair market value of CalciMedica.

The combined company will incur significant transaction costs as a result of the merger, including investment banking, legal and accounting fees. In addition, the combined company will incur significant consolidation and integration expenses which cannot be accurately estimated at this time. These costs could include the possible relocation of certain operations from Redwood, California to other offices of the combined company as well as costs associated with terminating existing office leases and the loss of benefits of certain favorable office leases. Actual transaction costs may substantially exceed CalciMedica's estimates and may have an adverse effect on the combined company's financial condition and operating results.

CalciMedica may not consummate its private placement or may fail to receive the minimum private placement proceeds of $10.0 million, which could put financial strain on CalciMedica's ability to consummate the merger as planned.

The closing of the private placement is expected to occur immediately prior to the closing of the merger and is subject to certain closing conditions, including the requirement that the private placement investors purchase at least $10.0 million shares of CalciMedica common stock, as specified in CalciMedica's securities purchase agreement. While the private placement investors have agreed to purchase an aggregate of $10.3 million shares of CalciMedica common stock, there can be no assurances that such purchases will occur. In the event that the private placement is not consummated, CalciMedica may have to look for alternative sources of funding to consummate the merger, including additional capital raising or credit financing transactions that may delay or derail the planned timeline of the merger and entail further transaction costs.

Failure of the merger to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code could harm the combined company.

The parties intend for the merger to qualify as a reorganization within the meaning of Section 368(a) of the Internal Revenue Code, as amended. Certain requirements must be met for the merger to qualify as a Section 368(a) reorganization. If such requirements are not satisfied, CalciMedica's stockholders could be subject to tax liability.

The merger is expected to result in a limitation on our ability to utilize our net operating loss carryforwards.

Under Section 382 of the Internal Revenue Code, use of our net operating loss carryforwards ("NOLs") will be limited if we experience an "ownership change." For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who own at least 5% of a corporation's stock increases by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We expect to experience an ownership change as a result of the merger, and therefore our ability to utilize our NOLs and certain credit carryforwards remaining at the effective time will be

limited. The annual limitation will be determined by the fair market value of our common stock outstanding prior to the ownership change, multiplied by the applicable federal rate. Limitations imposed on our ability to utilize NOLs could cause U.S. federal and state income taxes to be paid earlier than they would be paid if such limitations were not in effect and could cause such NOLs to expire unused, in each case reducing or eliminating the benefit of such NOLs.

Certain of our stockholders could attempt to influence changes which could adversely affect our operations, financial condition and the value of our common stock.

Our stockholders may from time to time seek to acquire a controlling stake in Graybug, engage in proxy solicitations, advance stockholder proposals or otherwise attempt to effect changes. Campaigns by stockholders to effect changes at publicly-traded companies are sometimes led by investors seeking to increase short-term stockholder value through actions such as financial restructuring, increased debt, special dividends, stock repurchases or sales of assets or the entire company. Responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, and could disrupt our operations and divert the attention of our Board and senior management from the pursuit of the proposed merger transaction. These actions could adversely affect our operations, financial condition, our ability to consummate the merger and the value of our common stock.

We and CalciMedica may become involved in securities litigation or stockholder derivative litigation in connection with the merger, and this could divert the attention of CalciMedica's or our management and harm the combined company's business, and insurance coverage may not be sufficient to cover all related costs and damages.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. Since the filing of our proxy statement on form PREM 14A on December 14, 2022, four lawsuits have been filed in federal courts against Graybug and the Graybug Board: *Bushansky v. Graybug Vision, Inc., et al*., 3:22-cv-09131 (N.D. Cal.), *Connelly v. Graybug Vision, Inc., et al*., 3:23-cv-00028 (N.D. Cal.), *Plumly v. Graybug Vision, Inc., et al*., 1:23-cv-00169 (D. Del.), and *Franchi v. Graybug Vision, Inc., et al.*, 1:23-cv-1390 (S.D.N.Y) (collectively, the "Stockholder Litigation"). In addition, nine purported stockholders of Graybug sent demand letters regarding the proxy statement (the "Demand Letters"). Further details regarding the Stockholder Litigation and the Demand Letters are set forth below in Item 3 "*Legal Proceedings*". We and CalciMedica may become involved in this type of litigation in connection with the merger again in the future, and the combined company may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect the business of us, CalciMedica and the combined company.

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

If the merger is not completed and the merger agreement is terminated under certain circumstances, we may be required to pay CalciMedica a termination fee of either $1 million or $1.5 million and/or an expense reimbursement of up to $1 million. Even if a termination fee or expense reimbursement is not payable in connection with a termination of the merger agreement, we will have incurred significant fees and expenses, which must be paid whether or not the merger is completed. Further, if the merger is not completed, it could significantly harm the market price of our common stock.

The exchange ratio is not adjustable based on the market price of our common stock so the merger consideration at the closing may have greater or lesser value than the market price at the time the merger agreement was signed.

Under the terms of the merger agreement, at the effective time of the merger, each share of CalciMedica capital stock (excluding shares held as treasury stock by CalciMedica or held or owned by us, the merger subsidiary or any subsidiary of us or CalciMedica and dissenting shares), after giving effect to (i) CalciMedica's preferred stock conversion, (ii) CalciMedica warrant exercises and (iii) the conversion of CalciMedica's convertible notes, will be converted solely into the right to receive a number of validly issued, fully paid and nonassessable shares of our common stock equal to the exchange ratio, which will be calculated based on the total number of shares outstanding of our common stock and CalciMedica common stock immediately prior to the effective time of the merger, in each case, on a fully-diluted basis using the treasury stock method and excluding out-of-the-money options and warrants, and based on our net cash as of the closing of the merger. Immediately following the effective time of the merger, CalciMedica's equity holders are expected to own or hold rights to acquire 71.4% of the combined company and our equity holders are expected to own or hold rights to acquire 28.6% of the combined company, in each case, on a fully-diluted basis using the treasury stock method and excluding out-of-the-money options and warrants, and subject to certain assumptions, including, but not limited to, (a) our net cash as of the closing of the merger being $25 million, (b) a closing date of February 15, 2023, and (c) CalciMedica issuing approximately 20.5 million shares of common stock in the private placement. The post-closing equity split is subject to certain adjustments including based on our net cash at closing, the closing date, the number of shares of CalciMedica's common stock issued in the private placement and to account for the effect of a reverse stock split. As a result, these ownership percentages may be adjusted upward or downward due to such adjustments and as a result, our stockholders could own less of the combined company than expected.

Any changes in the market price of our common stock before the completion of the merger will not affect the number of shares of our common stock issuable to CalciMedica's stockholders pursuant to the merger agreement. Therefore, if before the completion of the merger the market price of our common stock declines from the market price on the date of the merger agreement, then CalciMedica's stockholders could receive merger consideration with substantially lower value than the value of such merger consideration on the date

of the merger agreement. Similarly, if before the completion of the merger the market price of our common stock increases from the market price of our common stock on the date of the merger agreement, then CalciMedica's stockholders could receive merger consideration with substantially greater value than the value of such merger consideration on the date of the merger agreement. The merger agreement does not include a price-based termination right. Because the exchange ratio does not adjust as a result of changes in the market price of our common stock, for each one percentage point change in the market price of our common stock, there is a corresponding one percentage point rise or decline, respectively, in the value of the total merger consideration payable to CalciMedica's stockholders pursuant to the merger agreement.

Certain provisions of the merger agreement may discourage third parties from submitting alternative takeover proposals, including proposals that may be superior to the arrangements contemplated by the merger agreement.

The terms of the merger agreement prohibit each of us and CalciMedica from soliciting alternative takeover proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances when, among other things, our Board determines in good faith after consultation with outside financial advisors and outside legal counsel that an unsolicited alternative takeover proposal is or is reasonably likely to result in a superior takeover proposal, and that failure to cooperate with the proponent of the proposal could be reasonably likely to be inconsistent with our Board's fiduciary duties.

If the conditions to the merger are not met, the merger may not occur.

Even if the share issuances and amended and restated certificate of incorporation to effect the reverse stock split are approved by our stockholders, specified conditions must be satisfied or waived to complete the merger. These conditions are set forth in the merger agreement. We cannot assure you that all of the conditions will be satisfied or waived. If the conditions are not satisfied or waived, the merger will not occur or will be delayed, and we and CalciMedica each may lose some or all of the intended benefits of the merger.

Risks Related to Our Financial Position and Need for Additional Capital

We have historically been a clinical-stage biopharmaceutical company with no products approved. We have incurred significant losses since inception, and, if the merger fails to close, we would expect to incur continued and increasing losses over the next several years and may never achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $35.6 million and $35.8 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $204.8 million. To date, we have financed our operations primarily through private placements of convertible preferred stock and convertible promissory notes and the issuance of common stock upon our initial public offering ("IPO"). We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical trials and general and administrative costs to support such efforts. If the merger fails to close, we expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses 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. We expect to continue to incur substantial and increasing losses before we can consummate the merger.

Based on our current operating plan, which would be superseded if the merger closes, we would expect to continue to incur significant and increasingly higher expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- conduct pre-clinical activities in connection with the clinical development of our most advanced product candidate, GB-501;
- commence clinical trials of our product candidate GB-501;
- continue the research and development of GB-701;
- seek to identify and develop, or enter into strategic partnerships or collaborations to develop, additional product candidates;
- seek marketing approvals for any of our product candidates that successfully complete clinical development;
- develop and expand our sales, marketing and distribution capabilities for any of our product candidates for which we obtain marketing approval;
- scale up our manufacturing processes and capabilities or, in the future, establish and operate a manufacturing facility, to support sales of our product candidates, our ongoing clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- expand our operational, financial and management systems and personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;

- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts; and
- explore and review a range of strategic alternatives for our company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase if:

- we are required by the FDA, the European Medicines Agency (the "EMA") or any additional international regulatory agency to perform trials or studies in addition to those currently expected;
- there are any delays in receipt of regulatory clearances or approvals to begin our planned clinical programs; or
- there are any delays in enrollment of patients in or completing our clinical trials or the development of our product candidates.

We have no product sales. We do not expect sales of any product candidate for several years. For us to become profitable, we will need to succeed in developing and commercializing products. This will require us to be successful in a range of challenging activities, including:

- successfully completing clinical development of our product candidates, which may require establishing one or more strategic partnerships;
- obtaining marketing approval for these product candidates;
- manufacturing at commercial scale and selling and distributing those products for which we obtain marketing approval;
- achieving an adequate level of market acceptance of and obtaining and maintaining coverage and adequate reimbursement from third-party payors for our products, which may require establishing a strategic partnership; and
- protecting our rights to our intellectual property portfolio.

We may never succeed in these activities and may never generate revenue that is sufficient or great enough to achieve profitability. Even 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 reduce the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funding to support our operations. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs.

We incurred losses from operations and had negative cash flows from operating activities for the years ended December 31, 2022 and 2021, and our accumulated deficit as of December 31, 2022 is $204.8 million. Based on our current operating plan, we would expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct pre-clinical studies or clinical trials for GB-501, preclinical studies or clinical trials for GB-701, and seek marketing approval for any such product candidate for which we obtain favorable clinical results. Significant financial resources would be required to conduct research and development and to potentially seek regulatory approval for our current product candidates. In addition, substantial financial resources would be required to commercialize our products, if approved, including product manufacturing, sales, marketing and distribution for any of our product candidates for which marketing approval is obtained. Accordingly, substantial additional funding would be required to support our continuing and planned operations. If we are unable to raise or otherwise access capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

As of December 31, 2022, we had cash, cash equivalents and short-term investments of $39.1 million, which, based on our current operating plan, we believe is sufficient to fund our operations beyond the next 12 months. Our future funding requirements will depend on many factors, including:

- the scope, progress, costs and outcome of the clinical trials of our product candidates, in particular GB-501;
- the scope, progress, costs and outcome of preclinical development and clinical trials of GB-701;
- the costs, timing and outcome of regulatory review of our product candidates by the FDA, the EMA or other regulatory authorities;
- the costs of manufacturing, sales, marketing, distribution and other commercialization efforts with respect to any products for which we obtain marketing approval;
- subject to receipt of marketing approval, revenue received from product sales;

- our headcount growth and associated costs as we would need to expand our research and development and establish a commercial infrastructure;
- the extent to which we choose to establish collaboration, distribution or other marketing arrangements for our products and product candidates;
- the effect of competing technological and market developments;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or invest in other businesses, products and technologies; and
- the impact of the COVID-19 pandemic.

Conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain regulatory approval of products with the market potential sufficient to enable us to achieve profitability. We would not expect to generate sales of any commercial product for several years, if at all. Accordingly, we believe that we would need to obtain substantial additional financing to achieve our current 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.

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

We are an early-stage company. Our operations to date have been limited to organizing and staffing our company, acquiring rights to intellectual property, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and clinical trials and manufacturing initial quantities of our products and product candidates. Consequently, any predictions you make about our future success or viability in the absence of the merger may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If the merger fails to close, we would need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual period as an indication of future operating performance.

Risks Related to Product Development, Regulatory Approval and Commercialization

Our approaches to the treatment of retinal and corneal diseases are unproven, and we do not know whether we will be able to successfully develop any products.

GB-501 is a gene therapy that has never been tested in humans and is designed to be a single intrastromal injection. There are currently no FDA-approved therapies that treat corneal diseases with a single gene therapy treatment. If the merger fails to close, our future success currently depends on the successful development of product candidates, primarily GB-501, based on this novel therapeutic approach. We have not yet demonstrated efficacy and safety for GB-501 or GB-701 in a pivotal trial or obtained marketing approval of any product candidate. GB-501 may not demonstrate in patients any or all of the therapeutic benefits we believe it may possess. If we are unsuccessful in our development efforts, we may not be able to advance the development of GB-501 or any other product candidate, commercialize products, raise capital, expand our business or continue our operations.

If the merger fails to close, we would depend heavily on the success of our product candidates. Clinical trials of our product candidates may not be successful. If we are unable to successfully complete clinical development of, and obtain marketing approvals for, our product candidates, or experience significant delays in doing so, or if after obtaining marketing approvals, we fail to commercialize these product candidates, our business will be materially harmed.

We have devoted a significant portion of our financial resources and business efforts to the development of our product candidates for diseases and conditions of the eye. In particular, we have historically invested substantial resources to complete the development of GB-102 for wet AMD, a program that we terminated in August 2022. We cannot accurately predict when or if any of our ocular disease product candidates will prove effective or safe in humans or whether these product candidates will receive marketing approval. Our ability to generate product revenues sufficient to achieve profitability will depend heavily on obtaining marketing approval for, and commercialization of, GB-501.

The success of GB-501 and GB-701 will depend on many factors, including:

- successful completion of preclinical studies and clinical trials that demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- our ability to raise additional capital to fund future clinical trials for GB-501;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- applying for and receiving marketing approvals from applicable regulatory authorities for our product candidates;
- scaling up our manufacturing processes and capabilities to support additional or larger clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- developing, validating and maintaining a commercially viable manufacturing process that is compliant with current good manufacturing practices;
- maintaining a continued acceptable safety profile of our products following approval;
- obtaining and maintaining coverage and adequate reimbursement from third-party payors;
- developing and expanding our sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- minimizing and managing any delay or disruption to our ongoing or planned clinical trials, and any adverse impacts to the U.S. and global market for pharmaceutical products, including as a result of the ongoing COVID-19 pandemic;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting our rights in our intellectual property portfolio.

If the merger fails to close and we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business.

We have not yet initiated or completed any Phase 3 clinical trials nor commercialized any pharmaceutical products, which may make it difficult to evaluate our future prospects.

Our operations to date have been limited to financing and staffing our company, developing our technology and conducting preclinical research and Phase 1 and Phase 2 clinical trials for our product candidates. We have not yet demonstrated an ability to initiate or complete Phase 3 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 product commercialization. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by clinical-stage biopharmaceutical companies such as ours. Any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

If the merger fails to close, we may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We would eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

If clinical trials of GB-501 or any other product candidate that we develop fail to demonstrate safety and efficacy to the satisfaction of the FDA, the EMA or other regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of such product candidate.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, including GB-501, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing.

GB-501 has not yet been tested in humans, and because it is a gene therapy, it cannot be tested in healthy volunteers, so the first time it will be tested on humans will be in a Phase 3 clinical trial. In addition, because mucopolysaccharidosis type 1 ("MPS1") is a rare disease, the number of patients enrolled in the Phase 3 clinical trial will be very small, making it difficult to predict whether the favorable results from such a trial will be repeatable in the larger patient population. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

Even if the results of future Phase 3 clinical trials are positive, we may have to commit substantial time and additional resources to conducting further preclinical studies and clinical trials before obtaining FDA approval for any of our drug candidates.

If serious adverse or unacceptable side effects are identified during the development of GB-501 or any other product candidates that we may develop, we may need to abandon or limit our development of such product candidates.

If GB-501 or any of our other product candidates are associated with serious adverse events ("SAEs") or other undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the SAEs, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

There are potential side effects that are related to ocular injection procedures, including intrastromal injections. These side effects are shared by any treatment that uses injection as a means of delivering medication. These can include conjunctival hemorrhage, punctate keratitis, eye pain, conjunctival hyperemia, intraocular pressure rise, intraocular inflammation, retinal detachment and endophthalmitis.

Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients are exposed to the product. If safety problems occur or are identified after one of our products reaches the market, the FDA, the EMA or other regulatory authorities may require that we amend the labeling of our product, recall our product or even withdraw approval for our product.

Moreover, with regard to GB-501, additional or unexpected adverse side effects could develop, as gene therapy is still a relatively new approach to disease treatment. There also is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material. Possible adverse side effects that could occur with treatment with gene therapy products include an immunologic reaction early after administration which, while not necessarily adverse to the patient's health, could substantially limit the effectiveness of the treatment.

Gene therapy is an emerging field of drug development, which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval. Currently, only a limited number of gene therapy products have been approved in the United States and in foreign countries.

The future success of GB-501, a recombinant AAV gene therapy designed to treat corneal clouding caused by MPS1, depends on the successful development of this novel therapeutic approach. The regulatory requirements that govern any novel gene therapy product candidates we develop are not entirely clear and are subject to change. The clinical study requirements of the FDA and the criteria regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours may be more expensive and take longer than for other, better known or extensively studied product candidates. Further, as we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. To date, only a limited number of gene therapy products have been approved in the United States and foreign countries, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States or other jurisdictions. Further, approvals by any ex-U.S. regulatory agency may not be indicative of what the FDA may require for approval, or vice versa.

Gene therapy is an emerging field of drug development that poses many scientific and other risks. Our lack of experience with gene therapy and the limited patient populations for our newly acquired gene therapy programs may limit our ability to be successful or may delay our development efforts.

Gene therapy is an emerging field of drug development with only a small number of gene replacement therapies having received FDA approval to date. GB-501 is our first gene therapy program, and it is based entirely on technology that we acquired in March 2022 through our purchase of RainBio, Inc. ("RainBio"). We did not acquire any employees or manufacturing assets from RainBio, only the intellectual property rights that RainBio had in-licensed as well as the preclinical data that they had generated. We did not acquire any raw materials or finished drug product. We will need to rely entirely on third-party providers for all aspects of process development, manufacturing, and analytical methods for GB-501. We have no prior experience with any of these specialty providers, so we may not be able to negotiate acceptable supply terms, including pricing or timing of delivery, if at all.

As a result, there are several areas of drug development risk, including translational science, manufacturing processes and materials, safety concerns, regulatory pathway and clinical trial design and execution, which pose particular uncertainty for our gene therapy program given the relatively limited development history of, and our limited prior experience with, gene therapies. Furthermore, the medical community's understanding of the genetic causes of many diseases continues to evolve and further research may change the medical community's views on what therapies and approaches are most effective for addressing certain diseases.

As we pursue our first gene therapy research program and any subsequent programs, we expect we may need to grow our own gene therapy scientific and technical capabilities through hiring internally and seeking assistance from outside service providers. We believe that gene therapy is an area of significant investment by biotechnology and pharmaceutical companies and that there may be a

scarcity of talent available to us in these areas. If we are not able to expand our gene therapy capabilities, we may not be able to develop, in the way that we intend or desire, any of our gene therapy research programs into product candidates.

We have not previously conducted any clinical development involving gene therapies and, if and when we are ready to conduct our first gene therapy clinical trial, we will need to build our internal and external capabilities in designing and executing a gene therapy clinical trial. There are many known and unknown risks involved in translating preclinical development of gene therapies to clinical development, including selecting appropriate endpoints and dosage levels for dosing humans based on preclinical data. Many of the indications for which we are pursuing our gene therapy programs have limited natural history data and a limited number of therapies in clinical development, which may make selecting an appropriate endpoint difficult. Furthermore, our gene therapy programs are targeting orphan diseases with relatively small populations, which limits the pool of potential patients for our gene therapy clinical trials. Because gene therapy trials generally require patients who have not previously received any other therapy for the same indication, we will also need to compete for the same group of potential clinical trial patients with our competitors who are also developing therapies for these same indications. If we are unable to initiate and conduct our gene therapy clinical trials in a manner that satisfies our expectations or regulatory requirements, the value of our gene therapy programs may be diminished.

Adverse public perception of genetic medicines may negatively impact regulatory approval of, and/or demand for, our potential products.

Regulatory approval of and/or demand for our potential products will depend in part on public acceptance of the use of genetic medicine for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that genetic medicines are unsafe, unethical or immoral, and consequently, our products may not gain the acceptance of the public or the medical community. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop.

There have been several significant adverse side effects reported in genetic medicine treatments in the past. SAEs in our clinical trials, or other clinical trials involving gene therapy by us or our competitors, even if not ultimately attributable to the relevant product candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception and potential regulatory delays in the clinical testing or approval of our product candidates.

The COVID-19 pandemic may, directly or indirectly, adversely affect our business, results of operations and financial condition.

Our business could be materially adversely affected, directly or indirectly, by the widespread outbreak of contagious disease, including the ongoing COVID-19 pandemic.

The COVID-19 pandemic caused us to modify our business practices (including but not limited to curtailing or modifying employee travel, moving to full remote work for many employees, and cancelling physical participation in meetings, events and conferences). The majority of our office-based employees have been working from home since March 2020. Further, we decommissioned our laboratories in Baltimore, MD in October 2022 and the lease for our administrative offices in Redwood City, California expired on January 31, 2023, resulting in the need for all of our employees to work remotely, which exposes us to greater risks related to cybersecurity and our information technologies systems. In addition, we have experienced and will continue to experience disruptions to our business operations resulting from quarantines, self-isolations and other restrictions on the ability of our employees to perform their jobs.

The COVID-19 pandemic has disrupted business operations. The extent and severity of the impact on our business and clinical trials will be determined largely by the extent of future disruptions in the supply chains for GB-501 and our future product candidates and delays in the conduct of current and future clinical trials. Further, our ability to conduct our future clinical trials may be adversely affected, directly or indirectly, by the COVID-19 pandemic, which has been known to cause disruptions in the ability to monitor patients in person due to clinics and hospitals closing sites or diverting the resources that are necessary to conduct clinical trials to care for COVID-19 patients. Further, our suppliers, vendors and manufacturing and clinical trial partners have been adversely affected by the COVID-19 pandemic, including by adversely impacting the ability of their employees to get to their places of work and maintain the continuity of their on-site operations. In addition, the impact of the COVID-19 pandemic on the operations of the FDA and other health authorities may delay potential approvals of GB-501 and our future product candidates.

The COVID-19 pandemic has also impacted and may further impact the global economic and capital markets, including by negatively impacting capital markets, which may adversely affect our business, liquidity and access to capital.

We could experience any of a number of possible unforeseen events in connection with our future clinical trials, potential marketing approval or commercialization of our product candidates could be delayed or prevented.

If the merger fails to close, we may experience numerous unforeseen events in connection with our future clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our ocular disease product candidates or any other product candidates that we may develop, including:

- clinical trials of our product candidates may not produce statistically significant, positive results, and we may decide, or regulators may require us, to conduct additional clinical trials or amend product development programs, or abandon product development programs entirely;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our contractors may fail to comply with regulatory requirements or meet their obligations to us in a timely manner, or at all;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- we may decide, or regulators or institutional review boards may require us, to suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our clinical trial material or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently foresee, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not favorable or are only modestly favorable or if there are safety concerns, we may:

- be delayed in obtaining or unable to obtain marketing approval for our product candidates;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs would also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials would begin as expected, would need to be restructured or would be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

We could experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate clinical trials for GB-501 or our other product candidates that we may develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, the EMA or similar regulatory authorities outside the United States. Although there is a significant prevalence of disease in the areas of ophthalmology in which we are focused, we may nonetheless experience unanticipated difficulty with patient enrollment.

A variety of factors affect patient enrollment, including:

- the prevalence and severity of the ophthalmic disease or condition under investigation;
- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate under study;
- the perceived risks and benefits of switching patients from treatment with eye drops to intravitreal therapy, in the case of certain glaucoma patients;
- the efforts to facilitate timely enrollment in clinical trials;
- any delay or disruption to enrollment or attendance for injections, including as a result of the ongoing COVID-19 pandemic;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of experienced clinical trial sites for prospective patients;

- the conduct of clinical trials by competitors for product candidates that treat the same indications as our product candidates; and
- the lack of adequate compensation for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary regulatory approvals. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

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. As a result, we 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, we may relinquish valuable rights to that product candidate through collaboration, licensing, other royalty arrangements, or strategic transactions in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may need to conduct future clinical trials for product candidates at sites outside of the United States, and the FDA may not accept data from trials conducted in such locations.

Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to conditions imposed by the FDA. For example, the clinical trial must be well-designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to applicable local laws, FDA acceptance of the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of the applicable product candidates.

Other risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could restrict or limit our ability to conduct our clinical trials;
- administrative burdens of conducting clinical trials under multiple sets of foreign regulations;
- failure of enrolled patients to adhere to clinical protocols as a result of differences in healthcare services or cultural customs;
- foreign exchange fluctuations;
- diminished protection of intellectual property in some countries; and
- political and economic risks relevant to foreign countries.

The FDA and other regulatory agencies have demonstrated caution in their regulation of gene therapy treatments. Ethical and legal concerns about gene therapy and genetic testing may result in additional regulations or restrictions on the development and commercialization of our product candidates, which may be difficult to predict.

The FDA and other regulatory agencies at both the federal and state level in the United States, U.S. congressional committees, and foreign governments, have expressed interest in further regulating the biotechnology industry, including gene therapy and genetic testing. Any such further regulation may delay or prevent commercialization of some or all of our product candidates.

Regulatory requirements in the United States and abroad governing gene therapy products have changed frequently and may continue to change in the future. In addition to the FDA, the Institutional Biosafety Committee and institutional review boards, or IRBs, of each institution at which we conduct or will conduct our planned clinical trials, would need to review the proposed clinical trial to assess the safety of the trial. Within the FDA, the Office of Tissues and Advanced Therapies ("OTAT") within the Center for Biologics Evaluation and Research ("CBER") consolidates the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee advises CBER on its review. Adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates.

These regulatory review committees and advisory groups and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval

limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all.

Our business and operations would suffer in the event of computer system failures or security breaches.

In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information, health information and personal information. Despite the implementation of security measures, our internal computer systems, and those of our contract research organizations, or CROs, and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. Cyberattacks are increasing in their frequency, sophistication and intensity. Cyberattacks could include the deployment of harmful malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Significant disruptions of our information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. If such disruptions were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Further, the COVID-19 pandemic has resulted in a significant number of our employees and partners working remotely, which increases the risk of a data breach or issues with data and cybersecurity. To the extent that any disruption or security breach results in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our future product candidates could be delayed. 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.

Moreover, if a computer security breach affects our systems or results in the unauthorized access, use or disclosure of personal information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media and/or affected individuals pursuant to various federal, state and international privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. We would also be exposed to a risk of loss or litigation and potential liability under laws, regulations and contracts that protect the privacy and security of personal information. As described below in "*We are subject to stringent and changing privacy laws, regulations and standards as well as contractual obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business or prospects*," the California Consumer Privacy Act ("CCPA") provides a private right of action for security breaches, which could lead to some form of remedy including regulatory scrutiny, fines, private right of action settlements, and other consequences. The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we may maintain, and there can be no assurance that the limitations of liability in any of our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above. Any of the foregoing could have a material adverse effect on our business, reputation, results of operations, financial condition and prospects.

Risks Related to Manufacturing

We currently rely on third parties for the production of both of our product candidates. This could increase the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We currently rely on third parties for the production of GB-501 and GB-701. While we believe that our existing manufacturing partners have facilities that will be sufficient to meet our requirements for manufacturing GB-501 and GB-701, we may in the future need to rely on additional contract development and manufacturing organizations ("CDMOs") for some aspects of the manufacture of our product candidates.

Reliance on third parties for aspects of the supply of our product candidates entails additional risks, including:

- lack of direct control over regulatory compliance and quality assurance;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;

- the possible breach of an agreement by the third party; and
- the possible termination or nonrenewal of an agreement by the third party at a time that is costly or inconvenient for us.

We, or our third-party suppliers or CDMOs, may not be able to comply with quality assurance standards, current good manufacturing practices regulations or similar regulatory requirements outside the United States. If we or our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and comparable regulatory authorities in other jurisdictions, if the quality and accuracy of the manufacturing and quality control data is compromised due to failure to adhere to protocols or to regulatory requirements or if we or our CDMOs fail to maintain a compliance status acceptable to the FDA or comparable regulatory authorities in other jurisdictions, we may not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we or our CDMOs must maintain adequate quality control, quality assurance and qualified personnel. If we or our CDMOs cannot maintain a compliance status acceptable to the FDA or a comparable regulatory authority in another jurisdiction, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates and that obtained approvals could be revoked, which would adversely affect our business and reputation. Our failure, or the failure of our suppliers or CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates. The same risks, however, would also apply to any internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity.

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

The manufacture of our product development candidates requires outsourced, custom manufacturing and we may encounter difficulties in production, particularly with respect to formulation, process development or scaling up of our manufacturing capabilities. If we, or our CDMOs, encounter such difficulties, our ability to provide supply of our product candidates for preclinical studies, clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

As product candidates are developed, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned preclinical studies or future clinical trials.

Any of these challenges could delay completion of preclinical studies or clinical trials, require bridging studies or trials, or the repetition of one or more studies or trials, increase development costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects.

The competition for gene therapy contract development, manufacturing and testing services is intense. Additionally, these manufacturers do not have experience producing our product candidates at commercial levels and may not achieve the necessary regulatory approvals or produce our product candidates at the quality, quantities, locations and timing needed to support commercialization.

We do not currently plan to independently manufacture the gene therapy material for our planned clinical programs. We currently rely, and expect to continue to rely, on third parties for the production of our preclinical study and planned clinical trial materials, including the materials used to administer our product candidates and, therefore, we can control only certain aspects of their activities. The competition for gene therapy contract development, manufacturing and testing is intense. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves, including but not limited to potential competition from other gene therapy companies for the use of such third-party manufacturers.

We have no experience manufacturing any of our product candidates at a commercial scale. We, or our CDMOs, may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct clinical trials of, and commercialize, our product candidates, we would need to manufacture them in large quantities. We may, in the future, establish and operate our own manufacturing facility, which would require significant amounts of additional capital and adequate personnel infrastructure. We, or any manufacturing partners, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Our current operations are conducted entirely remotely, and we or the third parties upon whom we depend, may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

We no longer occupy our facilities located in Baltimore, Maryland and Redwood City, California, and our remaining employees all work remotely. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, medical epidemic or pandemic, including COVID-19, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to remotely access our systems or telecommunications or fully utilize the manufacturing facilities of our CDMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these systems or CDMO facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, operating results and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our critical infrastructure, such as the manufacturing facilities of our CDMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the long-term effects of climate change on general economic conditions, and the pharmaceutical industry in particular, are unclear and may heighten or intensify existing risk of natural disasters. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If the manufacturing facilities of our CDMOs are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, operating results and prospects.

Risks Related to Commercialization

Our products 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, and the market opportunity for these products may be smaller than we estimate.

GB-501 or any of our product candidates that receives marketing approval may fail to gain market acceptance by physicians, patients, third-party payors and others in the medical community. We have not received marketing approval and have not commercially launched GB-501 or any of our product candidates and cannot yet accurately predict whether it or they will gain market acceptance and become commercially successful.

The degree of market acceptance of GB-501 or any product candidate for which we obtain marketing approval will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- our ability to offer our products for sale at competitive prices, particularly in light of the lower cost of alternative treatments;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments, including the retention of any of our products as preferred treatment by patients and doctors;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

Our assessment of the potential market opportunity for GB-501 and our other product candidates is based on 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. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. If the actual market for GB-501 or any of our product candidates is smaller than we expect, our product revenue may be limited, and it may be more difficult for us to achieve or maintain profitability.

If we are unable to secure a partner that can establish and maintain adequate sales, marketing and distribution capabilities, we may not be successful in commercializing any of our product candidates if and when they are approved. If we are unable to establish and maintain our own adequate sales, marketing and distribution capabilities, we may not be successful in commercializing our other product candidates if and when they are approved.

We have no experience in the sales, marketing and distribution of drug and device products, or in building a commercial team to do so. Furthermore, we lack sufficient capital resources to complete development of GB-501 without a partner, and we will be dependent on such partner, should we secure one, for the successful sales, marketing and distribution of GB-501. To achieve commercial success for any other product candidate for which we obtain marketing approval, we will need to establish and maintain adequate sales, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties. If any of our product candidates are approved for marketing, and our future capital resources permit retention of marketing rights to such products, we would evaluate the attractiveness of commercializing them through our own specialty sales force. Alternatively, we may rely on a network of independent distributors across the United States to sell such products. We expect that a direct sales force may be required to effectively market and sell such products. We cannot be certain when, if ever, we would recognize revenue from commercialization of our product candidates in any international market. If we decide to commercialize our potential products outside of the United States, we would expect to utilize a variety of collaboration, distribution and other marketing arrangements with one or more third parties. These may include independent distributors, pharmaceutical companies or our own direct sales organization.

There are risks involved with both establishing our own sales, marketing, and distribution capabilities and with entering into arrangements with third parties to perform these services. We may not be successful in entering into arrangements with third parties to sell, market and distribute our products or may be unable to do so on terms that are most beneficial to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to market, sell and distribute our products effectively. Our product revenues and our profitability, if any, under third-party collaboration, distribution or other marketing arrangements may also be lower than if we were to sell, market and distribute a product ourselves. On the other hand, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of any product candidate for which we recruit a sales force and establish marketing 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 sales and marketing personnel.

Other factors that may inhibit our efforts to commercialize products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to use or prescribe our products;
- 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 sales and marketing organization.

If we do not establish sales, marketing, and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.

The development and commercialization of new drug and device products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to our product candidates that we may seek to develop or commercialize. 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.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our products. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, certain of these products may be available on a biosimilar basis, and our product candidates may not demonstrate sufficient additional clinical benefits to physicians, patients or payors to justify a higher price compared to generic products. In many cases, insurers or other third-party payors, particularly Medicare, seek to encourage the use of biosimilar products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established

companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Any product candidate for which we obtain marketing approval may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

Our ability to commercialize our product candidates that we may develop successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans and other organizations. 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. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug and device companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for GB-501 or any other product that we commercialize and, even if they are available, the level of reimbursement may not be satisfactory.

Inadequate reimbursement may adversely affect the demand for, or the price of, GB-501 or any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize GB-501 or any other product candidates for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, 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 drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. 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 often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any FDA-approved products that we develop would compromise our ability to generate revenues and become profitable.

Regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug and device products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug 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 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. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Any product candidate for which we obtain marketing approval in the United States or in other countries may not be considered medically reasonable and necessary for a specific indication, may not be considered cost-effective by third-party payors, coverage and an adequate level of reimbursement may not be available and reimbursement policies of third-party payors may adversely affect our ability to sell our product candidates profitably.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we develop.

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

- decreased demand for any product candidates that we develop;
- injury to our reputation and significant negative media attention;

- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize any products that we develop.

We currently hold $10 million in product liability insurance coverage, with a per incident limit of $250,000, which may not be adequate to cover all liabilities that we may incur. We will need to increase our insurance coverage as we conduct additional or larger clinical trials and should we eventually realize sales of any product candidate for which we obtain marketing approval.

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.

Risks Related to Our Dependence on Third Parties

We intend to enter into collaborations with third parties in which they may complete or fund the clinical development, secure the regulatory approval, and conduct the commercialization of GB-501, and may also do so for our other product candidates. If we are unable to secure such our collaborations or they are not successful, we may not be able to capitalize on the market potential of GB-501 or other product candidates.

We may utilize a variety of types of collaboration arrangements with third parties to develop or commercialize GB-501 and any of our other product candidates, including merger, license, or sale. We also may enter into arrangements with third parties to perform these services in the United States if we do not establish our own sales, marketing and distribution capabilities in the United States for our product candidates or if we determine that such arrangements are otherwise beneficial. We also may seek collaborators for development and commercialization of other product candidates. Our likely collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations that we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of our product candidates that receive marketing approval or may elect not to continue or renew development or commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- 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 products or 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;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would divert management attention and resources and be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements, including merger, license, or sale, may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we or our shareholders may not receive any future research funding or milestone or royalty payments under the collaboration. If the funding or performance we expect under these agreements does not occur, further development of our product candidates could be delayed or we may need additional resources to develop our product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report on Form 10-K also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours were to be involved in a future business combination, it might deemphasize or terminate the development or commercialization of any product candidate acquired from or licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be harmed.

If we are not able to establish additional collaborations, we may have to alter our development and commercialization plans and our business could be adversely affected.

For our current product candidates, if our proposed merger fails to close, then we would intend to transact with pharmaceutical, biotechnology or medical device companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate transaction counterparties. Whether we reach a definitive agreement for a transaction will depend, among other things, upon our assessment of the counterparty's resources and expertise, the terms and conditions of the proposed transaction and the proposed counterparty'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 or similar regulatory authorities outside the United States, the potential market for the product candidate, the costs and complexities of manufacturing and delivering a 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 counterparty 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 transaction for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential counterparties. Such transactions are complex and time-consuming to negotiate and document. 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 counterparties.

If we are unable to reach agreements with suitable counterparties on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate, 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 our merger fails to close, we may need to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into such transactions that provide sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform.

We have relied, and may continue to rely, on third parties for certain aspects of our clinical development, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We have relied and may continue to rely on third parties, such as CROs, to conduct clinical trials of our product candidates. If we deem necessary, we may engage CROs, clinical data management organizations, medical institutions and clinical investigators to conduct or assist in our clinical trials or other clinical development work. If we are unable to enter into an agreement with a service provider when required, our product development activities would be delayed.

Our reliance on third parties for development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices ("GCPs") 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. We are also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we engage third

parties and they do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

Risks Related to Our Intellectual Property

If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business.

We own and exclusively license a number of U.S. issued patents, non-provisional patent applications, associated foreign patents and patent applications, and a U.S. provisional patent application. Our success depends in large part on our ability to obtain and maintain patent protection both in the United States and in other countries for our product candidates. Our ability to protect our product candidates from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering pharmaceutical and gene therapy-based inventions and the scope of claims made under these patents, our ability to maintain, obtain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any issued patents may not provide us with sufficient protection for our product candidates or provide sufficient protection to afford us a commercial advantage against competitive products or processes. We cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us.

The patent prosecution process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions. Under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our research and development before it is too late to obtain patent protection.

We currently solely own or exclusively license patents and patent applications that encompass our current product candidates. We do not control the prosecution of the exclusively licensed patents and patent applications from the University of North Carolina at Chapel Hill ("UNC") which encompass our GB-501 product, although we have input into the prosecution. In the future, we may choose to license additional patents or patent applications from third parties that we conclude are useful or necessary for our business goals. We may not have the right to control the preparation, filing, prosecution or maintenance of such additional licensed patent applications. Therefore, if we do license additional patents or patent applications in the future, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office ("PTO") for the entire time prior to issuance as a U.S. patent. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Consequently, we cannot be certain that we or our licensors were the first to invent, or the first to file patent applications on, our product candidates or their intended uses. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our products or by covering similar technologies that affect our product market or patentability, or all prior art that could be considered relevant to our patent claims.

On October 3, 2022, we provided written notification to Johns Hopkins University ("JHU") of our complete termination of our exclusive license agreement to all licensed patent rights owned by JHU that are relevant to our GB-102 and GB-401 programs. The termination became effective 30 days from the date of notice.

The claims of any patents which have already issued or may issue in the future and are owned by or licensed to us, may not confer on us significant commercial protection against competing products. Additionally, our patents may be challenged by third parties, resulting in the patent being deemed invalid, cancelled, unenforceable or narrowed in scope, or the third party may circumvent any such issued patents.

Our patents may be challenged, for example, in a U.S. federal court or alternatively challenged in an adversarial proceeding at the Patent Trial and Appeals Board ("PTAB") at the PTO, using an inter partes Review or Post Grant Review process. The cost of these procedures is often substantial, and it is possible that our efforts would be unsuccessful resulting in a loss of our U.S. patent position. Further, even if a U.S. federal court or PTAB rules that a patent owned by us is valid and enforceable, if the other venue takes a contrary position, the patent can be considered invalid and not enforceable.

Therefore, a party seeking to invalidate a patent owned by or licensed to us in the United States has the procedural advantage of two alternative venues. To date, the PTAB has cancelled over 60% of the patent claims it has reviewed and is considered to be a forum of choice for infringers for patent cancellation.

Also, our pending patent applications may not issue, and we may not receive any additional patents. Our patents might not contain claims that are sufficiently broad to prevent others from utilizing our technologies. For instance, GB-501 is a recombinant AAV based construct encoding L-iduronidase for use in treating Mucopolysaccharidosis type 1("MPS1") corneal clouding. If a competitor develops

a product that uses a non-AAV construct or delivery mechanism to deliver L-iduronidase to the cornea, then it may be able to compete with our GB-501 product without infringing our licensed patent claims. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. To the extent a competitor can develop similar products using a different delivery system, microparticle or molecule, our patents may not prevent them from directly competing with us.

Furthermore, as a result of our decision to terminate further development of GB-102 and GB-401 in August 2022, we initiated the process of winding down our non-US patent filing footprint that covers our GB-102 and GB-401 programs, including the abandonment of certain patents and patent applications in certain non-US jurisdictions.

The Leahy-Smith America Invents Act ("America Invents Act") was signed into law in September 2011, and many of the substantive changes became effective in March 2013. The America Invents Act revised U.S. patent law in part by changing the standard for patent approval from a "first to invent" standard to a "first to file" standard and developing a post-grant review system. This legislation changes U.S. patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 2013. For example, if we were the first to invent a new product or its use, but another party is the first to file a patent application on this invention, under the new law the other party may be entitled to the patent rights on the invention.

The America Invents Act created for the first time new procedures to challenge issued patents in the United States, including post-grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine-month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent was filed prior to March 16, 2013. A petition for inter partes review can be filed after the nine-month period for filing a post-grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of challenge, whereas inter partes review proceedings can only be brought to raise a challenge based on published prior art. These adversarial actions at the PTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts and use a lower burden of proof than used in litigation in U.S. federal courts. The PTO issued a Final Rule on November 11, 2018, announcing that it will now use the same claim construction currently used in the U.S. federal courts to interpret patent claims, which is the plain and ordinary meaning of words used. If any of our, or our licensors', patents are challenged by a third party in such a PTO proceeding, there is no guarantee that we or our licensors will be successful in defending the patent, which would result in a loss of the challenged patent right to us.

The U.S. Supreme Court has issued opinions in patent cases in the last few years that many consider may weaken patent protection in the United States, either by narrowing the scope of patent protection available in certain circumstances, holding that certain kinds of innovations are not patentable or generally otherwise making it easier to invalidate patents in court. For example, recent Federal Circuit rulings such as Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc), Wyeth & Cordis Corp. v. Abbott Labs, 720 F.3d 1380 (Fed. Cir. 2013), Enzo Life Scis., Inc. v. Roche Molecular Sys., 928 F.3d 1340 (Fed. Cir. 2019), and Idenix Pharms. LLC v. Gilead Scis. Inc., 941 F.3d 1149 (Fed. Cir. 2019), and Amgen Inc. v. Sanofi, 987 F.3d 1080 (Fed. Cir. 2021) have significantly heightened the standard for securing broad claims to pharmaceutical and biological products.

In addition to heightened patentability requirements, recent Supreme Court and Federal Circuit cases relating to biosimilar product approval under the Biologics Price Competition and Innovation Act or BPCIA, have held that the "patent dance" provisions of the statute, which are intended to resolve any patent infringement issues before the approval of a biosimilar, are discretionary, and a biosimilar applicant can opt out by refusing to provide a copy of its application and manufacturing information to the biologic sponsor (see Sandoz Inc. v. Amgen Inc.,137 S. Ct. 1664 (2017)). It may be that we do not learn of a biosimilar application until after FDA publishes its approval (see Immunex v. Samsung Bioepsis, 2:19-cv-117555-CCC-MF (D.N.J. Apr. 30, 2019)). In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the United States federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the PTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

The laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed. For example, we could become a party to foreign opposition proceedings, such as at the European Patent Office, or patent litigation and other proceedings in a foreign court. If so, uncertainties resulting from the initiation and continuation of such proceedings could have a material adverse effect on our ability to compete in the

marketplace. The cost of foreign adversarial proceedings can also be substantial, and in many foreign jurisdictions, the losing party must pay the attorney fees of the winning party.

Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization of our product candidates, thereby reducing or eliminating any advantages of the patent. To the extent our product candidates based on that technology are not commercialized significantly ahead of the date of any applicable patent, or to the extent we have no other patent protection on such product candidates, those product candidates would not be protected by patents, and we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the Federal Food, Drug, and Cosmetic Act ("FDCA") or trade secret protection.

Patents filed by our licensor, University of North Carolina at Chapel Hill, may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and may limit our ability to contract with non-U.S. manufacturers.

Any patents licensed from UNC that cover inventions generated in whole or part through the use of U.S. government funding are subject to certain federal regulations. As a result, the U.S. government may have certain rights to licensed patents embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980 ("Bayh-Dole Act"). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require UNC, and thus us, to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if UNC fails to disclose the invention to the government or fails to file an application to register the patents within specified time limits. Patents generated under a government-funded program are also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.

Our research, development or commercialization activities, including any product candidates or products resulting from these activities, may infringe or be claimed to infringe patents or other proprietary rights owned by third parties and to which we do not hold licenses or other rights. We may not be aware of third-party patents that a third party might assert against us. For example, there may be third-party applications that have been filed but not published that, if issued, could be asserted against us. If a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Further, if we are found to have infringed a third-party patent, we could be obligated to pay royalties and/or other payments to the third party for the sale of our product, which may be substantial, or we could be enjoined from selling our product. We could also incur substantial litigation costs.

Litigation regarding patents, intellectual property and other proprietary rights may be expensive and time-consuming. If we are involved in such litigation, it could cause delays in bringing product candidates to market and harm our ability to operate.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Although we are not currently aware of any litigation or other proceedings or third-party claims of patent infringement against us related to our product candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that we are employing their proprietary technology without authorization. Likewise, third parties may challenge or infringe upon our existing or future patents. Proceedings involving our patents or patent applications or those of others could result in adverse decisions regarding:

- the patentability of our inventions relating to our product candidates; and/or
- the enforceability, validity or scope of protection offered by our patents relating to our product candidates.

Even if we are successful in these proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In

addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may:

- incur substantial monetary damages;
- encounter significant delays in bringing our product candidates to market; and/or
- be precluded from participating in the manufacture, use or sale of our product candidates or methods of treatment requiring licenses.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Because one of our current clinical candidates is based on a small molecule, it will be subject in the United States to the patent litigation process of the Hatch-Waxman Amendments after commercialization, which allows a generic company to submit an Abbreviated New Drug Application ("ANDA") to the FDA to obtain approval to sell our drug using bioequivalence data only. Under the Hatch-Waxman Amendments, we will have the opportunity to list all of our patents that cover our drug product or its method of use in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluation," sometimes referred to as the FDA's Orange Book. Currently, in the United States, the FDA may grant three years of exclusivity to a new formulation, for which none of our current product candidates would qualify, and other changes to a drug, such as the addition of a new indication to the package insert, if the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to the approval of the application. The FDA also may grant five years of exclusivity for new chemical entities ("NCEs") for which GB-701 would qualify. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. A generic company can submit an ANDA to the FDA four years after approval of GB-701. The submission of an ANDA by a generic company is considered a technical act of patent infringement. The generic company can certify that it will wait until the natural expiration date of our listed patents to sell a generic version of our product or can certify that one or more of our listed patents are invalid, unenforceable or not infringed. If the latter, we will have 45 days to bring a patent infringement lawsuit against the generic company. This will initiate a challenge to one or more of our Orange Book listed patents based on arguments from the generic company that either our patent is invalid, unenforceable or not infringed. Under the Hatch-Waxman Amendments, if a lawsuit is brought, the FDA is prevented from issuing a final approval on the generic drug until 30 months after the end of the data exclusivity period, or a final decision of a court holding that our asserted patent claims are invalid, unenforceable or not infringed. If we do not properly list our relevant patents in the Orange Book, or timely file a lawsuit in response to a certification from a generic company under an ANDA, or if we do not prevail in the resulting patent litigation, we can lose our proprietary market, which can rapidly become generic. Further, even if we do correctly list our relevant patents in the Orange Book, bring a lawsuit in a timely manner and prevail in that lawsuit, it may be at a very significant cost to us of attorneys' fees and employee time and distraction over a long period. Further, it is common for more than one generic company to try to sell an innovator drug at the same time, and so we may be faced with the cost and distraction of multiple lawsuits. We may also determine it is necessary to settle the lawsuit in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity, or enforceability of our patent.

Our GB-501 product, if approved under a Biologics License Application ("BLA") may qualify under the provisions of the Biologics Price Competition and Innovation Act ("BPCIA"). Under the BPCIA, innovator manufacturers of biologic products may be granted 12 years of exclusive use before biosimilar versions of such products can be licensed for marketing in the U.S. This means that the FDA may not approve an application for a biosimilar version of our GB-501 product until 12 years after the date our product is approved for sale (with a potential six-month extension of exclusivity if certain pediatric studies are conducted and the results accepted by the FDA), although a biosimilar application may be submitted four years after the date we receive approval from the FDA to sell our GB-501 product. Additionally, the BPCIA establishes procedures by which potentially relevant patents may be shared and litigation over patents may proceed in advance of approval. The BPCIA also provides incentives to biosimilar applicants by providing a period of exclusivity to the first biosimilar of a product approved by the FDA. The 12-year data exclusivity provision of the BPCIA does not prevent a competitor from seeking marketing approval of our GB-501 product, or a product similar thereto, by submitting its own, original BLA. Furthermore, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our GB-501 product to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for GB-501 in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. If a generic competitor seeks a biosimilar approval to our GB-501 product and engages in the "patent dance" provisions of the BPCIA, which are intended to resolve any patent infringement issues before the approval of a biosimilar, it may be at a very significant cost to us of attorneys' fees and employee time and distraction over a long period. We may also determine it is necessary to settle the lawsuit in a manner that allows the generic company to enter our market prior to the expiration of our patent or otherwise in a manner that adversely affects the strength, validity, or enforceability of our patent.

A number of pharmaceutical companies have been the subject of intense review by the U.S. Federal Trade Commission or a corresponding agency in another country based on how they have conducted or settled drug patent litigation, and certain reviews have led to an allegation of an anti-trust violation, sometimes resulting in a fine or loss of rights. We cannot be sure that we would not also be subject to such a review or that the result of the review would be favorable to us, which could result in a fine or penalty.

The U.S. Federal Trade Commission ("FTC") has brought a number of lawsuits in federal court in the past few years to challenge Hatch-Waxman ANDA litigation settlements between innovator companies and generic companies as anti-competitive. The FTC has taken an aggressive position that anything of value is a payment, whether money is paid or not. Under their approach, if an innovator as part of a patent settlement agrees not to launch or delay launch of an authorized generic during the 180-day period granted to the first generic company to challenge an Orange Book listed patent covering an innovator drug, or negotiates a delay in entry without payment, the FTC may consider it an unacceptable reverse payment. The biopharmaceutical industry has argued that such agreements are rational business decisions to dismiss risk and are immune from antitrust attack if the terms of the settlement are within the scope of the exclusionary potential of the patent. In 2013, the U.S. Supreme Court, in a five-to-three decision in FTC v. Actavis, Inc. rejected both the biopharmaceutical industry's and the FTC's arguments with regard to so-called reverse payments, and held that whether a "reverse payment" settlement involving the exchange of consideration for a delay in entry is subject to an anticompetitive analysis depends on five considerations: (a) the potential for genuine adverse effects on competition; (b) the justification of payment; (c) the patentee's ability to bring about anticompetitive harm; (d) whether the size of the payment is a workable surrogate for the patent's weakness; and (e) that antitrust liability for large unjustified payments does not prevent litigating parties from settling their lawsuits, for example, by allowing the generic to enter the market before the patent expires without the patentee's paying the generic. Furthermore, whether a reverse payment is justified depends upon its size, its scale in relation to the patentee's anticipated future litigation costs, its independence from other services for which it might represent payment, as was the case in Actavis, and the lack of any other convincing justification. The Court held that reverse payment settlements can potentially violate antitrust laws and are subject to the standard antitrust rule-of-reason analysis, with the burden of proving that an agreement is unlawful on the FTC and leaving to lower courts the structuring of such rule of reason analysis. If we are faced with drug patent litigation, including Hatch-Waxman litigation or BPCIA litigation with a generic company, we could be faced with such an FTC challenge based on that activity, including how or whether we settle the case, and even if we strongly disagree with the FTC's position, we could face a significant expense or penalty.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting, and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, may not favor the enforcement of our patents and other intellectual property rights.

This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights in certain foreign countries. A number of foreign countries have stated that they are willing to issue compulsory licenses to patents held by innovator companies on approved drugs to allow the government or one or more third-party companies to sell the approved drug without the permission of the innovator patentee where the foreign government concludes it is in the public interest. India, for example, has used such a procedure to allow domestic companies to make and sell patented drugs without innovator approval. There is no guarantee that patents covering any of our drugs will not be subject to a compulsory license in a foreign country, or that we will have any influence over if or how such a compulsory license is granted. Further, Brazil allows its regulatory agency ANVISA to participate in deciding whether to grant a drug patent in Brazil, and patent grant decisions are made based on several factors, including whether the patent meets the requirements for a patent and whether such a patent is deemed in the country's interest. In addition, several other countries have created laws that make it more difficult to enforce drug patents than patents on other kinds of technologies. Further, under the treaty on the Trade-Related Aspects of Intellectual Property ("TRIPS") as interpreted by the Doha Declaration, countries in which drugs are manufactured are required to allow exportation of the drug to a developing country that lacks adequate manufacturing capability. Therefore, our drug markets in the United States or foreign countries may be affected by the influence of current public policy on patent issuance, enforcement or involuntary licensing in the healthcare area.

In addition, in November 2015, members of the World Trade Organization ("WTO") which administers TRIPS, voted to extend the exemption against enforcing pharmaceutical drug patents in least developed countries until 2033. We currently have no patent applications filed in least developed countries, and our current intent is not to file in these countries in the future, at least in part due to this WTO pharmaceutical patent exemption.

Furthermore, in late 2022, we began the process of winding down our non-US patent filing footprint that covers our now-terminated GB-102 and GB-401 programs, including the abandonment of certain patents and patent applications in certain non-US jurisdictions. To the extent a patent and/or patent application has been abandoned in a specific jurisdiction, we will be unable to assert such patent right against an alleged infringer if the alleged infringer practices those claims.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

We rely on our ability to stop others from competing by enforcing our patents; however, some jurisdictions may require us to grant licenses to third parties. Such compulsory licenses could be extended to include some of our product candidates, which may limit our potential revenue opportunities.

Many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties, in certain circumstances. For example, compulsory licensing, or the threat of compulsory licensing, of life-saving products and expensive products is becoming increasingly popular in developing countries, either through direct legislation or international initiatives. Compulsory licenses could be extended to include some of our product candidates, if they receive marketing approval, which may limit our potential revenue opportunities. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may also use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products where such patent rights exist, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement if a government is the infringer, which could materially diminish the value of the patent.

If we fail to comply with our obligations under the license agreement with UNC, we could lose license rights that are necessary for developing and commercializing one or more of our product candidates.

Our exclusive license with UNC for technology relating to our GB-501 product candidate imposes various development, commercialization, royalty payment, diligence and other obligations on us, and we currently do not anticipate being able to fulfill all of our obligations. Specifically, we are required to:

- pay UNC potential milestone payments and annual license maintenance fees;
- pay UNC low single-digit royalties on all net sales of products and a share of any sublicensing revenues;
- meet specific clinical development milestones, one of which must occur by June 1, 2023;
- use commercially reasonable efforts to bring products to market;
- provide royalty reports to UNC; and
- indemnify UNC against certain claims and maintain insurance coverage.

If we breach any of these obligations, UNC may have the right to terminate the license, which would result in our being unable to develop, manufacture and sell products that are covered by the licensed technology, or in a competitor's gaining access to the licensed technology.

The rights we rely upon to protect our unpatented trade secrets may be inadequate.

We rely on unpatented trade secrets, know-how and technology, which are difficult to protect, especially in the pharmaceutical industry, where much of the information about a product must be made public during the regulatory approval process. We seek to protect

trade secrets, in part, by entering into confidentiality agreements with employees, consultants and others. These parties may breach or terminate these agreements or may refuse to enter into such agreements with us, and we may not have adequate remedies for such breaches. Furthermore, these agreements may not provide meaningful protection for our trade secrets or other proprietary information or result in the effective assignment to us of intellectual property and may not provide an adequate remedy in the event of unauthorized use or disclosure of confidential information or other breaches of the agreements. Despite our efforts to protect our trade secrets, we or our collaboration partners, board members, employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors.

If we fail to maintain trade secret protection, our competitive position may be adversely affected. Competitors may also independently discover our trade secrets. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect our intellectual property.

We rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. To protect our proprietary technology and processes, we also rely in part on confidentiality and intellectual property assignment agreements with our current and potential corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to us of intellectual property and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover our trade secrets and proprietary information, and in such case, we could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using our trade secrets is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

We may be required, or choose, to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, the trials are not well-designed, or research participants experience adverse safety outcomes.

Regulatory agencies, IRBs, or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Clinical trials must be conducted in accordance with GCPs and other applicable foreign regulatory authority guidelines. Clinical trials are subject to oversight by the FDA, foreign regulatory authorities and IRBs at the trial sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable current good manufacturing practices. Clinical trials may be placed on a full or partial clinical hold by the FDA, foreign regulatory authorities, or us for various reasons, including, but not limited to: deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols; deficiencies in the clinical trial operations or trial sites; deficiencies in the trial designs necessary to demonstrate efficacy; fatalities or other AEs arising during a clinical trial due to medical problems that may or may not be related to clinical trial treatments; the product candidates may not appear to be more effective than current therapies; or the quality or stability of the product candidates may fall below acceptable standards.

Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, if we elect or are forced to suspend or terminate a future clinical trial of any of our current or future product candidates, the commercial prospects for that product may be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our future partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

In our future clinical trials, any SAEs could result in the FDA delaying such clinical trials or denying or delaying clearance or approval of a product. Even though an AE may not be the result of the failure of one of our drug candidates, the FDA or an IRB could delay or halt a clinical trial for an indefinite period of time while an AE is reviewed, and likely would do so in the event of multiple such events. Any delay or termination of our future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or AEs during the trials, may cause an increase in costs and delays in the submission of any New Drug Applications ("NDAs") to the FDA, delay the approval and commercialization of our products or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects.

Lengthy delays in the completion of clinical trials of our products would adversely affect our business and prospects and could cause us to cease operations.

If preliminary data demonstrate that any of our product candidates has an unfavorable safety profile and is unlikely to receive regulatory approval or be successfully commercialized, we may voluntarily suspend or terminate future development of such product candidate. Any one or a combination of these events could prevent us from obtaining regulatory approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

If we are not able to obtain required regulatory approvals, we will not be able to commercialize our product candidates and our ability to generate significant revenue will be materially impaired. The regulatory approval process is expensive, time-consuming and uncertain. As a result, we cannot predict when or if we, or any collaborators we may have in the future, will obtain regulatory approval to commercialize our product candidates.

The activities associated with the development of our product candidates, including design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing a product candidate. We have not submitted for regulatory approval to market GB-501 or any other product candidate.

The process of obtaining regulatory approvals, both in the United States and abroad, is expensive and may take many years, especially if additional clinical trials are required, if approval is obtained at all. The FDA continually updates and refines its guidance to companies developing products that will require regulatory approval, which can also include material changes to established guidance that results in significant changes to the planned conduct, cost, and timing of clinical development programs.

Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and purity. The FDA's and other regulatory agencies' decision to grant us regulatory approval will depend on our ability to demonstrate with substantial clinical evidence through adequate well-controlled clinical trials, that the product candidates are effective, as measured statistically by comparing the overall improvement in actively-treated patients against improvement in the control group. However, there is a possibility that our data may fail to demonstrate statistically significant non-inferiority versus the active control. Alternatively, there is a possibility that our data may be statistically significant, but that the actual clinical benefit of the product candidates may not be considered to be clinically significant, clinically relevant or clinically meaningful. We cannot predict whether the regulatory agencies will find that our clinical trial results provide compelling data. Even if we believe that the data from our trials will support regulatory approval in the United States or in Europe, we cannot predict whether the agencies will agree with our analyses and approve our applications.

Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, the EMA or other regulatory authorities may determine that our product candidates are not safe or effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining regulatory approval or prevent or limit commercial use. In addition, while we have had general discussions with the FDA concerning the design of some of our clinical trials, we have not discussed with the FDA the specifics of the regulatory pathways for our product candidates. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Approval of our product candidates may be delayed or refused for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical programs or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- potential delays in enrollment, site visits, evaluations, dosing of patients participating in the clinical trial as hospitals prioritize the treatment of COVID-19 patients or patients decide to not enroll in the trial as a result of the COVID-19 pandemic;

- government regulations that may be imposed in response to the COVID-19 pandemic may restrict the movement of our global supply chain, divert hospital resources that are necessary to administer our product candidates;
- the facilities or conduct of the third-party manufacturers with which we contract may not be adequate to support approval of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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.

The regulatory process can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. If we experience delays in obtaining approval, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our product candidates in the European Union and many other jurisdictions, we or our potential third-party collaborators, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be sold in that country. We or our collaborators may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. The United Kingdom and European Union entered into the Trade and Cooperation Agreement, effective January 1, 2021, which sought to resolve some of the outstanding issues related to Brexit, including free trade and an overarching governance structure for business conducted between the jurisdictions. Under the Trade and Cooperation Agreement, there was a transition period in which the U.K. was not designated as a "third country" and, as a result, personal data could flow from the EU to the U.K. without any adequacy mechanisms (e.g., Standard Contractual Clauses, etc.). The Trade and Cooperation Agreement went into full force on May 1, 2021, and the transition period with regard to personal data automatically terminated on June 26, 2021. On June 28, 2021, the European Commission adopted two definitive adequacy decisions addressing the transfers of personal data to the United Kingdom under the General Data Protection Regulation ("GDPR") and the Law Enforcement Directive.

Because this Trade and Cooperation Agreement is still new, it is unclear how it may affect the regulatory framework for our products. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

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The terms of approvals, ongoing regulations and post-marketing restrictions for our products may limit how we manufacture and market our products, which could materially impair our ability to generate revenue.

Once regulatory approval has been granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation. We, and any collaborators we may have in the future, must therefore comply with requirements concerning

advertising and promotion for any of our products for which we or our collaborators obtain regulatory approval. Promotional communications with respect to drug products and medical devices are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, if any of our product candidates receives regulatory approval, the accompanying approved labeling may limit the promotion of our product, which could limit sales of the product.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to current good manufacturing practices applicable to drug manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any CMOs we may engage in the future, our future collaborators and their CMOs will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to physicians, recordkeeping and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a risk evaluation and mitigation strategy.

If any of our product candidates receives regulatory approval and we or others later identify undesirable side effects caused by the product, our ability to market and derive revenue from the products could be compromised.

In the event any of our product candidates receive regulatory approval and we or others identify undesirable side effects, AEs or other problems caused by one of our products, any of the following adverse outcomes could occur, which could result in the loss of significant revenue to us and materially and adversely affect our operating results and business:

- regulatory authorities may withdraw or modify their approval of the product and require us to take the product off the market or seize the product;
- we may need to recall the product or change the way the product is administered to patients;
- we may need to conduct additional preclinical studies or clinical trials or change the labeling of the product;
- additional restrictions may be imposed on the marketing and promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we may not be able to secure or maintain adequate coverage and reimbursement for our products from government (including U.S. federal health care programs) and private payors;
- regulatory authorities may require the addition of labeling statements, such as a boxed warning, or equivalent, or contraindications or limitations on the indications for use;
- regulatory authorities may require us to implement a Risk Evaluation and Mitigation Strategy ("REMS") plan, or to conduct post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be exposed to potential lawsuits and associated legal expenses, including costs of resolving claims;
- the product may become less competitive and sales may decrease; and
- our reputation may suffer both among clinicians and patients.

Any of these events could have a material and adverse effect on our operations and business. The commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

If our product candidates receive regulatory approval, we will also be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and limit our ability to commercialize our drugs.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate and may require us to conduct post-approval clinical studies. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The manufacturing facilities used to manufacture our product candidates will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with current good manufacturing practices requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on

manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action.

In addition, if the FDA or a foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices and GCPs, for any clinical trials that we conduct post-approval.

Moreover, if we obtain regulatory approval for our product candidates, we will only be permitted to market our products for the indication approved by the FDA or foreign regulatory authority, and such approval may involve limitations on the indicated uses or promotional claims we may make for our products, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles. For example, we will not be able to claim that our products have fewer side effects, or improve compliance or efficacy as compared to other drugs unless we can demonstrate those attributes to the FDA or foreign regulatory authority in comparative clinical trials.

If we or our CMOs or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, delay of approval or refusal by the FDA or similar foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

The FDA's and foreign regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained, and we may not achieve or sustain profitability.

We may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Violations of the FDCA relating to the promotion or manufacturing of drug products may lead to investigations by the FDA, the Department of Justice and state Attorneys General alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In addition, later discovery of previously unknown AEs or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure or detention; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, or with requirements related to the development of products for the pediatric population, can also result in significant financial penalties.

If the FDA does not conclude that the product candidates for which we may use the Section 505(b)(2) regulatory approval pathway satisfy the requirements for the use of such pathway, or if the requirements for such product candidates under Section 505(b)(2) are

not as we expect, the approval pathway for any such product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We may seek FDA approval through the Section 505(b)(2) regulatory pathway for future product candidates. The Hatch-Waxman Amendments added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved drug products, which could expedite the development program for our product candidates by potentially decreasing the amount of preclinical or clinical data that we would need to generate in order to obtain FDA approval.

If we cannot pursue the Section 505(b)(2) regulatory pathway for future product candidates, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase.

In addition, notwithstanding the approval of products by the FDA under Section 505(b)(2), certain pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA's current interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for the owner of the NDA of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions could significantly delay, or even prevent, the approval of a new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Our relationships with customers and third-party payors may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation, affordability, and use of any product candidates for which we obtain regulatory approval. Our future arrangements with third-party payors 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 any products for which we obtain regulatory approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH, and their respective implementing regulations, which imposes obligations, including mandatory contractual terms, on covered healthcare providers, health plans and healthcare clearinghouses, as well as their business associates, with respect to safeguarding the privacy, security and transmission of protected health information; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Recently enacted and future legislation, including healthcare legislative reform measures, may adversely affect or limit our ability to commercialize our products, including the prices that we can obtain for any products that are approved in the United States or foreign jurisdictions, and may negatively impact our business and results of operations.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could affect our ability to profitably sell or commercialize any product candidate for which we obtain regulatory approval. The pharmaceutical industry and medical device industry have been a particular focus of these efforts and have been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any FDA approved product.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") changed the way Medicare covers and pays for pharmaceutical products. Cost reduction initiatives and other provisions of this legislation could limit coverage of and reduce the price that we receive for any FDA approved products. While the MMA applies only to product benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA or other healthcare reform measures may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the "ACA". Among the provisions of the ACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are increased manufacturer rebate liability under the Medicaid Drug Rebate Program, imposition of a significant annual fee on companies that manufacture or import branded prescription drug products and the requirement for manufacturers to provide a discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole," which is now 70% of the negotiated price.

There have been executive, legislative and judicial efforts to modify, repeal, or otherwise invalidate all, or certain aspects of, the ACA. On January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and closed on August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. The Medicare reductions

phased back in starting with a 1% reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2% reduction. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. By way of example, in December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. On September 9, 2021, the Biden Administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act ("IRA") in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. It is unclear to what extent new statutory, regulatory, and administrative initiatives will be enacted and implemented and to what extent these or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability.

At the state level, legislatures are 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.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of regulatory approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration. Such reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our therapeutics.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing or selling certain products outside of the United States and such foreign operations would require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The Securities and Exchange Commission ("SEC") also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to stringent and changing privacy laws, regulations and standards as well as contractual obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business or prospects.

We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, in addition to HIPAA, various federal and state regulators have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act ("CCPA") which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020, and became enforceable by the California Attorney General on July 1, 2020, along with related regulations which came into force on August 14, 2020. Additionally, although not effective until January 1, 2023, the California Privacy Rights Act (the "CPRA") which expands upon the CCPA, was passed in the recent election on November 3, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers about their data collection, use and sharing practices and provide such consumers new data protection and privacy rights, including the ability to opt out of certain sales of personal information, right to request correction, access, and deletion of their personal information, the right to opt out of certain personal information sharing, and the right to receive detailed information about how their personal information is processed. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CPRA significantly modifies the CCPA, including by expanding consumers' rights with respect to certain personal information and creating a new state agency to oversee implementation and enforcement efforts. The CCPA and CPRA may increase our compliance costs and potential liability, particularly in the event of a data breach, and could have a material adverse effect on our business, including how we use personal information, our financial condition, the results of our operations or prospects. State laws are changing rapidly and there is discussion in the U.S. of a new comprehensive federal data privacy law to which we would become subject if it is enacted.

Additionally, the CCPA has prompted a number of proposals for new federal and state-level privacy legislation, such as in Nevada, Virginia, New Hampshire, Illinois and Nebraska. Such new privacy laws add additional complexity, requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, and could impact business strategies and the availability of previously useful data.

Internationally, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, the General Data Protection Regulation ("GDPR") of the European Union ("EU") which became effective in May 2018, greatly increased the European Commission's jurisdictional reach of its laws and adds a broad array of requirements for handling personal information, including, for example, requirements to establish a legal basis for processing, higher standards for obtaining consent from individuals to process their personal information, more robust disclosures to individuals and a strengthened individual data rights regime, requirements to implement safeguards to protect the security and confidentiality of personal information that requires the adoption of administrative, physical and technical safeguards, shortened timelines for data breach notifications to appropriate data protection authorities or data subjects, limitations on retention and secondary use of information, increased requirements pertaining to health data and additional requirements that we impose certain contractual obligations on third-party processors in connection with the processing of the personal information. EU member states are tasked under the GDPR to enact, and have enacted, certain implementing legislation that adds to and/or further interprets the GDPR requirements and potentially extends our obligations and potential liability for failing to meet such obligations. The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal information, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal information. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal information relates, the transfer of personal information out of the European Economic Area, security breach notifications and the security and confidentiality of personal information. The GDPR authorizes fines for certain violations of up to 4% of global annual

revenue or €20 million, whichever is greater, and other administrative penalties. Additionally, the United Kingdom ("UK") implemented the Data Protection Act effective in May 2018 and statutorily amended in 2019, that substantially implements the GDPR and contains provisions, including UK-specific derogations, for how GDPR is applied in the UK. On May 1, 2021, the transition period of the Trade and Cooperation Agreement between the EU and the UK ended. Subsequently, the European Commission adopted a definitive adequacy decision addressing the transfers of personal data from the European Economic Area to the United Kingdom under the GDPR on June 28, 2021. As a result, we will have to continue to comply with the GDPR and also the Data Protection Act in the UK as well as the EU, with each regime having the ability to fine up to the greater of €20 million (£17 million) or 4% of global turnover. The costs of compliance with, and other burdens imposed by, such laws and regulations that are applicable to our business operations may limit the use and adoption of our services, reduce overall demand for them. Changes in these legislations may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment in resources for compliance programs, could impact strategies and availability of previously useful data, and could result in increased compliance costs and/or changes in business practices and policies.

Additionally, on July 16, 2020, the Court of Justice of the European Union (the "Court of Justice") invalidated the European Union-United States ("EU-U.S.") Privacy Shield on the grounds that the EU-U.S. Privacy Shield failed to offer adequate protections to EU personal information transferred to the United States. While the Court of Justice upheld the use of other data transfer mechanisms, such as the Standard Contractual Clauses, the decision has led to some uncertainty regarding the use of such mechanisms for data transfers to the United States, and the court made clear that reliance on Standard Contractual Clauses alone may not necessarily be sufficient in all circumstances. The use of Standard Contractual Clauses for the transfer of personal information specifically to the United States also remains under review by a number of European data protection supervisory authorities. For example, German and Irish supervisory authorities have indicated that the Standard Contractual Clauses alone provide inadequate protection for EU-U.S. data transfers. Use of the data transfer mechanisms must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. The European Data Protection Board (the "EDPB") issued additional guidance regarding the Court of Justice's decision on November 11, 2020 which imposes higher burdens on the use of data transfer mechanisms, such as the Standard Contractual Clauses, for cross-border data transfers.

To comply with this guidance, we may need to implement additional safeguards to further enhance the security of data transferred out of the EU, which could increase our compliance costs, expose us to further regulatory scrutiny and liability, and adversely affect our business. Further, in November 2020, the European Commission published new versions of the Standard Contractual Clauses. Other countries (e.g., Australia and Japan) have also adopted certain legal requirements for cross-border transfers of personal information. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. While the Court of Justice of the European Union has upheld the adequacy of the Standard Contractual Clauses, it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services. If we are required to implement additional measures to transfer data from the European Economic Area, this could increase our compliance costs, and could adversely affect our business, financial condition and results of operations.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, distract management or divert resources from other initiatives and projects, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any failure or perceived failure by us to comply with any applicable federal, state or similar foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, results of operations, financial condition and prospects.

If we or any CMOs we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur significant costs.

We and any CMOs we may engage in the future are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous materials, including chemicals and biological materials, and produce hazardous waste products. 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. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain general liability insurance as well as 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 maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Further, with respect to the operations of any CMOs, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

Risks Related to Employee Matters and Managing Growth

Our future success will depend on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the research and development, clinical and business development expertise of Frederic Guerard, our chief executive officer, as well as other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time.

If our planned merger fails to close, recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key 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 have relied on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors 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. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We may need to expand our development, regulatory and manufacturing capabilities and potentially implement sales, marketing, and distribution capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

If our planned merger fails to close, we may require significant growth in the number of our employees and the scope of our operations, particularly in the areas of product development, clinical, regulatory affairs, manufacturing, sales, marketing, finance and distribution, which growth would need to begin before we receive regulatory approval from the FDA or other regulatory authorities, and we may never receive such regulatory approval for any of our future product approvals. To manage such future growth, we would need to continue to implement and improve our managerial, operational, and financial systems, reestablish our facilities and recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Related to Ownership of Our Common Stock

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

If our planned merger fails to close, our operating plan, which currently comprises the development of our two preclinical programs, we would expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results would then be affected by numerous factors, including:

- variations in the level of expense related to the development of our product candidates or future development programs;
- results of clinical trials, or the addition or termination of clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;

- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The market price of our stock has been and may continue to be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been in the past, and may continue to be, highly volatile and subject to wide fluctuations in response to various factors, many of which we cannot control. The market price for our common stock may be influenced by many factors, including the other risks described in this section and elsewhere in this filing, and the following:

- market perception of the value of our proposed merger partner, CalciMedica, or the likelihood of the merger being completed in a timely fashion, if at all;
- results of future preclinical studies and clinical trials of our product candidates, or those of our competitors or our existing or future collaborators;
- the impact of the COVID-19 pandemic on our employees, future preclinical studies or clinical trials, collaboration partners, suppliers, our results of operations, liquidity and financial condition;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- the success of competitive products or technologies;
- introductions and announcements of new product candidates by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our product candidates, future preclinical studies or clinical trials, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our future efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including but not limited to those with our sources of manufacturing supply and our commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure or policies of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- trading volume of our common stock;
- delisting, or the expectation of delisting of our common stock from the Nasdaq Global Market stock exchange;
- sales of our common stock by us or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters, pandemics and other calamities; and
- general economic, industry and market conditions including increased interest rates and the effects of inflation.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. Finally, recent market volatility in certain stocks has at times been driven by factors unrelated to the underlying businesses, or macro or industry fundamentals, of public companies, and it is impossible to predict how long these dynamics will last. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price and results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis of 2007-2008 caused extreme volatility and disruptions in the capital and credit markets. Similarly, the volatility associated with the COVID-19 pandemic has caused significant instability and disruptions in the capital and credit markets and, in recent months, the global economy has been impacted by increasing interest rates and inflation. Likewise, the capital and credit markets may be adversely affected by the 2022 invasion of Ukraine by Russia, and the possibility of a wider European or global conflict, and global sanctions imposed in response thereto. A severe or prolonged economic downturn, such as a global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. A downturn may also make it more difficult for us to consummate a sale of the company, merger or other strategic transaction. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business or our ability to consummate a strategic transaction. Furthermore, our stock price may decline due in part to the volatility of the stock market and any general economic downturn.

Our common stock may be delisted from The Nasdaq Global Market if we do not maintain compliance with Nasdaq's continued listing requirements.

Nasdaq maintains several requirements for continued listing of our common stock ("Nasdaq Listing Rules") one of which is the maintenance of a minimum closing bid price of one dollar ("Minimum Bid Price Requirement"). As a result of our stock having closing bid price of less than a dollar for thirty consecutive trading days, Nasdaq issued a notice of delisting to us on December 27, 2022. Pursuant to the Nasdaq Listing Rules, we were provided an initial compliance period of 180 calendar days to regain compliance with the Minimum Bid Price Requirement. To regain compliance, Nasdaq Listing Rules required that the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days prior to June 26, 2023, and that we must otherwise satisfy Nasdaq's requirements for continued listing.

Our plan to regain compliance includes a reverse stock split, which may result in the liquidity of our common stock being adversely impacted, which may further reduce our stock price. If our stockholders do not approve our proposed reverse split, and we do not achieve compliance during the initial 180 calendar day period, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to transfer the listing of our common stock to the Nasdaq Capital Market, provided that we then meet the continued listing requirement for market value of publicly held shares and all other initial listing standards of the Nasdaq Capital Market, with the exception of the minimum bid price. In the event that we become noncompliant, and are unable to regain compliance, our

common stock could be delisted from Nasdaq and the ability to buy or sell our common stock could be impaired. We intend to take all commercially reasonable actions to maintain our Nasdaq listing, including an evaluation of all reasonable strategic alternatives.

A perception among investors that we are at heightened risk of a deficiency under the Minimum Bid Price Requirement and of subsequent delisting could negatively affect the market price of our securities and trading volume of our common stock. Additionally, any delisting determination, if made following the notification of a deficiency and expiration of any applicable cure period, would have an adverse effect on the market liquidity of our common stock and, as a result, the market price for our common stock could become more volatile. Further, a delisting also could make it more difficult for us to raise additional capital.

If our common stock is delisted in the future, it is unlikely that we will be able to list our common stock on another national securities exchange and, as a result, we expect our securities would be quoted on an over-the-counter market; however, if this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our common stock and reduced liquidity for the trading of our securities. In addition, in the event of such delisting, we could experience a decreased ability to issue additional securities and obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." Because our common stock is listed on the Nasdaq Global Market, shares of our common stock qualify as covered securities under the statute. Although the states are preempted from regulating the sale of our securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were no longer listed on the Nasdaq Global Market, our securities would not qualify as covered securities under the statute, and we would be subject to regulation in each state in which we offer our securities.

Further, there can be no assurance that an active trading market for our common stock will be sustained despite our listing on the Nasdaq Global Market.

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

In the past, securities class action litigation has often followed the announcement or consummation of certain significant business transactions, such as the merger or sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as discontinuations of clinical programs. These events may also result in investigations by the SEC or FINRA. We have received three notices of complaints filed against us for our planned merger with CalciMedica, which we believe are without merit, but we may be exposed to 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, our ability to consummate our planned merger with CalciMedica, or the ultimate value our stockholders receive as a result.

The future sale and issuance of equity or of debt securities that are convertible into equity will dilute our share capital.

If our planned merger fails to close, we may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock.

Sales of a substantial number of shares of our common stock may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. We had a total of 21,696,433 shares of our common stock outstanding as of December 31, 2022. All shares of our common stock are freely tradable, generally without restrictions or further registration under the Securities Act of 1933, as amended (the "Securities Act") subject to certain exceptions for shares held by our "affiliates" as defined in Rule 144 under the Securities Act.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale would have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock.

If our planned merger fails to close, we would also expect that significant additional capital may be needed in the future to continue our operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the analysts or the content and opinions included in their reports. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our future preclinical studies and clinical trials and results of operations fail to meet the expectations of analysts, our stock price would likely decline. Three of our five covering analysts have formally suspended coverage of us, and the remaining two have not published reports on us since May of 2022. If our remaining analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

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.

Based on the beneficial ownership of our common stock as of December 31, 2022, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant percentage of our voting stock. In connection with our planned merger with CalciMedica, all of our officers and directors, along with our two largest investors, signed voting agreements requiring them to each vote for the planned merger, subject to very limited exceptions.

As a result, these stockholders, if continuing to act together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in our periodic reports.

We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our 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," which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of June 30, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an EGC, we may still qualify as a "smaller reporting company," or SRC, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may 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 share price may be more volatile.

Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an EGC, or we affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-EGCs and the date on which we will adopt the recently issued accounting standard.

We are also currently an SRC, in part because 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 are also currently considered an SRC because the market value of our stock held by non-affiliates is less than $250.0 million as of June 30. We may continue to be a SRC if either (i) the market value of our stock held by non-affiliates is less than $250.0 million as of June 30 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 as of June 30. If we are an SRC at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to SRCs. Specifically, as an SRC 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 EGCs, SRCs have reduced disclosure obligations regarding executive compensation.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and our restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, our restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law ("DGCL") our restated certificate of incorporation, or our restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, referred to as a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal courts or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. While neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act of 1934, as amended ("Exchange Act"), Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder also must be brought in federal court. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholder's ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers, and other employees.

In addition, Section 203 of the DGCL may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

We have incurred increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, and particularly if we are no longer deemed an emerging growth company or smaller reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other

applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have substantially increased our legal and financial compliance costs and have made some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties and Facilities.

The lease for our principal executive office located in Redwood City, California expired on January 31, 2023. We had used this facility for operations and administrative purposes. We also have a facility located in Baltimore, Maryland. The Maryland facility consists of 15,649 square feet of office and laboratory space under a lease which expires in June 2023. We had used the Maryland facility for our internal research and development activities, but decommissioned it in October 2022. We no longer have any employees working in facilities owned, leased, or operated by us, and all employees now work remotely. We believe that we do not require physical facilities to meet our needs for the foreseeable future.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. Four lawsuits have been filed in federal courts against Graybug and its directors: *Bushansky v. Graybug Vision, Inc., et al*., 3:22-cv-09131 (N.D. Cal.), *Connelly v. Graybug Vision, Inc., et al*., 3:23-cv-00028 (N.D. Cal.), *Plumly v. Graybug Vision, Inc., et al*., 1:23-cv-00169 (D. Del.), and *Franchi v. Graybug Vision, Inc., et al*., 1:23-cv-1390 (S.D.N.Y) (collectively, the "Stockholder Litigation"). The complaints name Graybug and the Graybug Board as defendants. The complaints assert claims under Section 14(a) and Section 20(a) of the Exchange Act and Rule 14a-19 promulgated thereunder, and generally allege that the proxy statement misrepresents and/or omits certain purportedly material information relating to the merger, including allegations relating to the financial projections and analyses of our financial advisor. The complaints seek a variety of equitable and injunctive relief including, among other things, an injunction enjoining the consummation of the merger, rescission of the merger if it is consummated, rescissory damages and costs and attorneys' fees. We have not yet responded to the complaints filed in the Stockholder Litigation.

In addition, nine purported stockholders of Graybug sent demand letters regarding the proxy statement (the "Demand Letters"). Based on the same core allegations as the Stockholder Litigation, the Demand Letters request that we disseminate corrective disclosures in an amendment or supplement to the proxy statement.

We believe the Stockholder Litigation and the Demand Letters are without merit, but there can be no assurance that we will ultimately prevail in the Stockholder Litigation or all such lawsuits. Further, additional lawsuits may be filed and demand letters may be sent before the Special Meeting and/or the consummation of the merger.

On March 3, 2023, we filed a Form 8-K to update and supplement the proxy statement with additional disclosures relating to the merger. The ultimate outcome of any litigation is uncertain and unfavorable outcomes could have a negative impact on our results of operations and financial condition. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors. Except as provided above, we believe there is no litigation pending that could, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is traded on The Nasdaq Global Market under the symbol "GRAY."

Holders of Record

As of March 3, 2023, there were 35 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table sets forth certain information, as of December 31, 2022, concerning securities authorized for issuance under all of our equity compensation plans: our 2015 Stock Incentive Plan, which terminated when we adopted our 2020 Equity Incentive Plan ("2020 Plan"), and our 2020 Employee Stock Purchase Plan ("ESPP").

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (1)	(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (2)	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (3)
Equity compensation plans approved by security holders	7,668,056	$ 5.49	803,887
Equity compensation plans not approved by security holders	—	—	—
Total	7,668,056	$ 5.49	803,887

(1) The amount shown in column (a) includes 4,352,440 outstanding options and 3,315,616 restricted stock units.

(2) The weighted average exercise price in column (b) includes options only as restricted stock units do not have exercise prices.

(3) The amount shown in column (c) represents 593,887 shares available for issuance under the 2020 Plan, which plan permits the grant of incentive and non-qualified stock options, stock appreciation rights, restricted stock, stock awards and restricted stock units; and 210,000 shares available for issuance under the ESPP. The 2020 Plan and ESPP each contain an "evergreen" provision, pursuant to which on January 1st of each year we automatically add 5% and 1% of our shares of common stock outstanding on the preceding December 31st to the shares reserved for issuance, respectively, provided that the Compensation Committee of our Board may authorize a lesser number in each case. As we have not yet implemented our ESPP, no increase in the shares available for issuance under the ESPP have been authorized by the Compensation Committee. In addition, pursuant to a "pour over" provision in our 2020 Plan, options that are cancelled, expired or terminated under the 2015 Stock Incentive Plan are added to the number of shares reserved for issuance under the 2020 Plan.

Performance Graph

As a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act, we are not required to provide this information.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from our Initial Public Offering

On September 29, 2020, we completed our initial public offering ("IPO") and issued and sold 5,625,000 shares of our common stock at an initial offering price of $16.00 per share and on October 22, 2020, we issued and sold an additional 843,750 shares in connection with the full exercise of the underwriters' option to purchase additional shares. We received net proceeds from the IPO, including the full exercise of the option, of approximately $92.0 million, after deducting underwriting discounts and commissions of approximately $7.2 million and expenses of approximately $4.2 million. The offer and sale of all of the shares in the IPO were registered under the Securities Act pursuant to registration statements on Form S-1 (File Nos. 333-248611 and 333-249030), which were declared effective by the SEC on September 24, 2020.

There has been no material change in the planned use of proceeds from our IPO as described in the Prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act on September 24, 2020.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our financial statements and the related notes included elsewhere in this Annual Report. In addition to historical financial information, this discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties. You should carefully read the sections entitled "Special Note Regarding Forward-Looking Statements" and "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We have historically been a clinical-stage biopharmaceutical company focused on developing transformative medicines for the treatment of diseases of the retina and optic nerve. On June 28, 2022, we announced that our board of directors would conduct a comprehensive review of strategic alternatives focused on maximizing shareholder value. As part of this review of strategic alternatives, we explored the potential for an acquisition, company sale, merger, divestiture of assets, private placement of equity securities, and other strategic transactions. Prior to this announcement, we had devoted substantially all our resources to conducting research and development and raising capital.

After conducting a broad and rigorous search for strategic partners who could fund the clinical development of our most advanced programs, GB-102 for the treatment of wet age-related macular degeneration and GB-401 for glaucoma, we concluded that we did not have sufficient capital to pursue further clinical development of either program on our own, nor did we believe that we had the ability to raise sufficient additional capital to do so. Between October 2021 and August 2022, we contacted 38 parties to solicit interest in licensing or partnering GB-102, and 11 parties to solicit interest in licensing GB-401, but received only one proposal, and it was on terms that were not acceptable to us. As a result, on August 18, 2022, our board of directors approved a restructuring plan, which included the termination of all activities related to GB-102 and GB-401, as well as certain cost-reduction initiatives, including a 71% reduction in our workforce. On October 3, 2022, we provided written notification to Johns Hopkins University ("JHU") of our decision to terminate our exclusive license agreement to all licensed patent rights owned by JHU that were relevant to our GB-102 program. On November 10, 2022, we entered into an agreement with Mireca Medicines GmbH ("Mireca") to assign certain intellectual property and revert all rights to our GB-601 preclinical program for retinitis pigmentosa, Stargardt Disease, and Leber congenital amaurosis back to Mireca, thereby terminating our involvement in that program. On November 21, 2022, we announced that we had entered into a definitive merger agreement with CalciMedica, Inc. ("CalciMedica") to combine our companies in an all-stock transaction, subject to shareholder approval.

We are continuing the preclinical development of our two remaining programs: GB-501, a gene therapy delivered via a recombinant adeno-associated virus ("rAAV") vector to treat corneal clouding caused by mucopolysaccharidosis type 1 ("MPS1"), and GB-701, a novel and potent small-molecule complement factor B inhibitor being developed to target the complement pathway as a potential treatment for geographic atrophy ("GA"). As GB-501 is a biologic, it will not require, nor benefit from, our drug delivery technologies as it is administered via an intrastromal injection into the cornea. GB-701 is a new chemical entity currently being developed in collaboration with Insilico Medicine, a clinical-stage, end-to-end artificial intelligence ("AI")-drug discovery company. As a small molecule that is targeted to treat a chronic disease, GB-701 will likely require a sustained delivery technology.

On November 21, 2022, we entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement"), as may be amended from time to time, with CalciMedica, Inc. ("CalciMedica") a clinical-stage biopharmaceutical company focused on developing first-in-class therapies for serious inflammatory diseases with high unmet need, and Camaro Merger Sub, Inc., our wholly-owned subsidiary ("Merger Sub"). Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, Merger Sub will be merged with and into CalciMedica, with CalciMedica surviving such merger as a wholly owned subsidiary of Graybug (the "Merger"). Based on a CalciMedica valuation of $100.0 million and a Graybug valuation of $40.0 million, the equity holders of Graybug immediately prior to the effective time of the transaction are expected to own approximately 28.6% of the aggregate number of outstanding shares of Graybug common stock immediately after the Effective Time and the equity holders of CalciMedica immediately prior to the effective time are expected to own 71.4% of the aggregate number of outstanding shares of Graybug common stock immediately after the effective time. The Merger, which has been approved by our board of directors and the board of directors and stockholders of CalciMedica, is expected to close in the first quarter of 2023, subject to the satisfaction or waiver of certain closing conditions, including the approval of our stockholders. Certain officers, directors and stockholders of Graybug who in the aggregate own approximately 45% of the outstanding shares of our common stock immediately prior to the date of the Merger Agreement are parties to support agreements whereby such stockholders have agreed, among other things, to vote in favor of the Merger, subject to the terms of the support agreements. Although we have entered into the Merger Agreement and intend to consummate the proposed Merger, there is no assurance that we will be able to successfully consummate the proposed Merger on a timely basis, or at all. If, for any reason, the proposed Merger is not completed, we will reconsider our strategic alternatives and could pursue another strategic transaction similar to the proposed Merger, potential collaborative, partnering or other strategic arrangements for our programs, including a sale or divestiture of our legacy programs, or liquidate and distribute available cash.

We were incorporated in May 2011 and our operations to date have been financed primarily by gross proceeds of approximately $134.0 million from the issuance of convertible promissory notes and convertible preferred stock, and $92.0 million in net proceeds

from our initial public offering of our common stock ("IPO") after deducting underwriters' discounts and commissions of $7.2 million and offering costs of $4.2 million.

Since inception, we have had significant operating losses. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures and, to a lesser extent, general and administrative expenditures. Our net loss was $35.6 million and $35.8 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $204.8 million and cash, cash equivalents and short-term investments of $39.1 million.

We expect to continue to incur net losses for the foreseeable future, and, if the closing of the Merger does not occur, and if we continue to operate our business as we have historically, we expect our research and development expenses, general and administrative expenses, and capital expenditures to continue to increase. In particular, we would expect our expenses to increase if we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products, as well as hire additional personnel, develop commercial infrastructure, pay fees to outside consultants, lawyers and accountants, and incur increased costs associated with being a public company, such as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC reporting requirements, insurance and investor relations. If the Merger fails to close and we continue to operate our business as we have historically, our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending upon the timing of our clinical trials and our expenditures on other research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued research and development and other current liabilities.

Recent Developments

Proposed Merger

On February 9, 2023, we filed a definitive proxy statement further describing the Merger including setting March 15, 2023 as the date on which our stockholders can vote on the Merger. Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, including approval of the transaction by our stockholders, our wholly-owned subsidiary will consummate the Merger. Upon the closing of the Merger, we will adopt the business and operating plan of CalciMedica. In the event the Merger is not consummated, our Board will be required to develop a new business plan. We cannot currently ascertain such plan nor the financial impact on us at this time.

Minimum Bid Price

On June 16, 2022, we received a written notification (the "Notice Letter") from Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1), as the closing bid price for our common stock was below the $1.00 per share requirement for the 30 prior consecutive business days which is the minimum closing price required to maintain continued listing on the Nasdaq Stock Market under Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Requirement"). The Notice Letter stated that we had 180 calendar days, or until December 13, 2022, to regain compliance with the Minimum Bid Requirement.

On July 21, 2022, we received a written notification from Nasdaq indicating that we had regained compliance with Nasdaq Listing Rule 5550(a)(2) because the closing bid price of our common stock during the preceding ten consecutive business days, July 7, 2022 to July 20, 2022, had been at $1.00 per share or greater.

On December 27, 2022, we received a second written notification (the "Second Notice Letter") from Nasdaq indicating that we were not in compliance with the Minimum Bid Requirement. The Second Notice Letter stated that we had 180 calendar days, or until June 23, 2023, to regain compliance with the Minimum Bid Requirement. We currently anticipate effecting a reverse stock split in connection with the Merger that would allow us to regain compliance with the Minimum Bid Requirement, but there can be no assurance that we will continue to satisfy Nasdaq's minimum financial and other requirements in future periods.

Business Effects of the COVID-19 Pandemic

The full impact of the ongoing COVID-19 pandemic remains highly uncertain and subject to change. There are many uncertainties around the COVID-19 pandemic and future developments, which are unpredictable, may result in a material, negative impact to our operations and financial condition.

For additional information on the various risks posed by the COVID-19 pandemic, please read Item 1A. Risk Factors.

Components of Operating Results

Research and Development Expenses

Our research and development expenses have included:

- personnel costs, which include salaries, benefits and stock-based compensation;
- expenses incurred under agreements with consultants, third-party contract organizations that conduct research and development activities on our behalf;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical studies and previously planned clinical trials;
- laboratory supplies and materials used for internal research and development activities;
- the acquisition cost of in-licensed and purchased intellectual property;
- the acquisition of acquired in-process research and development; and
- facilities and equipment costs.

Most of our historical research and development expenses have been related to the preclinical and clinical development of GB-102, which was terminated in August 2022. We have not reported program costs since inception because we have not tracked or recorded our research and development expenses on a program-by-program basis historically. We have historically used our personnel and infrastructure resources across the breadth of our research and development activities, which are directed toward identifying and developing product candidates.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

If the Merger fails to close, we would expect our research and development expenditures to increase substantially if we continued to invest in research and development activities related to developing our GB-501 and GB-701 product candidates, and if we elected to continue to advance either of those programs to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates would be highly uncertain.

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of any preclinical studies or clinical trials or if, when, or to what extent we would generate revenues from the commercialization and sale of our product candidates or if we even continue to pursue such product development, commercialization or sales if the Merger fails to close. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our remaining product candidates, to the extent we continue to pursue such activities if the Merger fails to close, will depend on a variety of factors, including:

- securing a strategic transaction, or one or more partnerships, to provide funding for the timely execution of further product development;
- successful completion of preclinical studies and clinical trials to the satisfaction of the FDA, European Medicines Agency ("EMA") or other regulatory authorities;
- demonstrating that our product candidates are safe and effective for any of their proposed indications;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- maintaining a continued acceptable safety and profile of our products following approval;
- obtaining and maintaining coverage and adequate reimbursement from third-party payors;
- applying for and receiving marketing approvals from applicable regulatory authorities for our product candidates;
- scaling up our manufacturing processes and capabilities to support additional or larger clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- developing, validating and maintaining a commercially viable manufacturing process that is compliant with current good manufacturing practices;

- developing and expanding our sales, marketing and distribution capabilities and launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- minimizing and managing any delay or disruption to our ongoing or planned clinical trials, and any adverse impacts to the U.S. and global market for pharmaceutical products, as a result of the current COVID-19 pandemic;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio; and
- the impact of the COVID-19 pandemic and the corresponding responses of businesses and governments.

If the Merger fails to close, we may never succeed in achieving regulatory approval for any of our remaining product candidates. We may obtain unexpected results from our preclinical studies and subsequent clinical trials, if any. We may elect to discontinue, delay or modify future clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current preclinical product candidates. For example, if the FDA, or another regulatory authority, were to require us to conduct clinical trials beyond those that we currently anticipate would be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or future clinical trials, if any, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, costs related to maintenance and filing of intellectual property and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation expense. If the Merger fails to close, and we pursue an operating plan that involves an expansion of our current headcount or operations, we would expect our general and administrative expenses to increase over the next several years to support such an expansion, increased costs of operating as a public company, retaining and motivating our employees, the development of a commercial infrastructure to support the potential commercialization of our product candidates, and the use of outside service providers such as insurers, consultants, lawyers, and accountants.

Restructuring, Impairment and Other Costs of Terminated Programs

Restructuring, impairment and other costs of terminated programs primarily consists of severance and termination benefit expense for the 20 employees terminated during 2022 and non-cash impairment of capital equipment and a right-of-use asset.

Interest Income

Our interest income principally reflects interest earned on our investments. Our investments include U.S. government-backed money-market funds, corporate debt securities, commercial paper and government bonds. We place cash in excess of immediate requirements into a custodial account and invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following sets forth our results of operations (in thousands):

	Year Ended December 31,		Change	
	2022	2021	Amount	%
Operating expenses:				
Research and development	$ 14,113	$ 18,903	$ (4,790)	(25)%
General and administrative	19,104	17,044	2,060	12%
Restructuring, impairment and other costs of terminated programs	2,963	—	2,963	*
Total operating expenses	36,180	35,947	233	1%
Loss from operations	(36,180)	(35,947)	(233)	1%
Interest income	575	126	449	*
Net loss	$ (35,605)	$ (35,821)	$ 216	1%

* *Not meaningful*

Research and Development Expenses

Research and development expenses comprised (dollars in thousands):

	Year Ended December 31,		Change	
	2022	2021	Amount	%
Personnel costs	$ 5,299	$ 7,445	$ (2,146)	(29)%
CRO, CDMO, nonclinical and other services	3,368	6,088	(2,720)	(45)%
Acquired in-process research and development	2,193	—	2,193	*
Facility, travel and other expenses	2,181	3,290	(1,109)	(34)%
Professional services	843	1,079	(236)	(22)%
Materials and supplies	229	1,001	(772)	(77)%
Total research and development expenses	$ 14,113	$ 18,903	$ (4,790)	(25)%

* *Not meaningful*

As of December 31, 2022 and 2021, we had 2 and 19 employees, respectively, engaged in research and development activities.

Research and development expenses were $14.1 million and $18.9 million for the years ended December 31, 2022 and 2021, respectively. The decrease was primarily due to the completion of the extension phase of the GB-102 Phase 2b clinical trial in May 2021, a decrease in licensing fees, and a decrease in personnel costs due to the termination of employees in the second half of 2022 in connection with our restructuring, offset in part by a $2.2 million increase due to the acquisition of in-process research and development related to the acquisition of RainBio, Inc. in March 2022. If our Merger fails to close, we would expect research and development expenses to decrease in 2023 compared to 2022.

General and Administrative Expenses

General and administrative expenses to support our business activities comprised (dollars in thousands):

	Year Ended December 31,		Change	
	2022	2021	Amount	%
Personnel costs	$ 8,276	$ 7,663	$ 613	8%
Professional services	6,637	3,034	3,603	119%
Facility costs, travel and other expenses	3,185	3,917	(732)	(19)%
Patent filing and portfolio costs	1,006	1,078	(72)	(7)%
Write-off deposits on fixed assets purchase commitments	—	1,352	(1,352)	*
Total general and administrative expenses	$ 19,104	$ 17,044	$ 2,060	12%

* *Not meaningful*

As of December 31, 2022 and 2021, we had 6 and 8 employees, respectively, engaged in general and administrative activities.

General and administrative expenses were $19.1 million and $17.0 million for the years ended December 31, 2022 and 2021, respectively. The increase was primarily due to a $2.8 million increase in legal, accounting and investment banking fees resulting from the strategic review, including the proposed Merger with CalciMedica and an increase in stock based compensation of $1.2 million, offset in part by a reduction of $1.4 million in the write-off of deposits on fixed assets purchase commitments in March 2021 and a decrease in the cost of the director and officer liability insurance of $0.5 million.

Restructuring, Impairment and Other Costs of Terminated Programs

For the year ended December 31, 2022, we recorded $3.0 million of restructuring, impairment and other costs of terminated programs. We terminated all development activities relating to the GB-102 and GB-401 programs and reduced our workforce by 71%. Refer to Notes 1 and 6 to our consolidated financial statements in Item 8 of this Annual Report on Form 10-K for more details.

	Year Ended December 31, 2022
Impairment of capital equipment and right-of-use asset	$ 1,599
Severance and termination benefit expense	1,065
Other restructuring costs	299
Total restructuring, impairment and other costs of terminated programs	$ 2,963

Interest Income

Interest income was $0.6 million and $0.1 million for the years ended December 31, 2022 and 2021, respectively. The increase was primarily due to higher interest rates in 2022.

Liquidity and Capital Resources

Overview

To date, we have incurred losses and negative cash flows from operations. As of December 31, 2022, we had available cash, cash equivalents and short-term investments of $39.1 million and an accumulated deficit of $204.8 million. To date, we have financed our operations primarily through private placements of our convertible preferred stock and convertible promissory notes and the issuance of common stock upon our initial public offering ("IPO").

On November 21, 2022, we entered into the Merger Agreement with CalciMedica, which, among other things, prohibits us from raising additional capital without CalciMedica's consent, which is outside of our control.

We incurred net losses of $35.6 million and $35.8 million for the years ended December 31, 2022 and 2021, respectively. If the Merger fails to close, we would expect to continue to incur significant operational expenses and net losses in the upcoming 12 months and beyond. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the stage and complexity of our research and development studies and related expenditures, if any, the receipt of additional payments on the sale or licensing of our technology, if any, and the receipt of payments under any current or future collaborations we may enter into.

If the Merger fails to close, and we continued operations based on our current operating plan, we believe our cash, cash equivalents and short-term investments of $39.1 million at December 31, 2022 would be adequate to meet our cash needs for at least 12 months from the issuance date of this Annual Report on Form 10-K.

Commitments and Other Obligations

For a detailed description of our commitments and obligations, see Note 5 – Commitments and Contingencies, to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K.

Leases

As of December 31, 2022, we had two real property leasing arrangements: one for our Baltimore, MD laboratory, which had been our research and development facility before being decommissioned in October 2022, and a second for our corporate offices in Redwood City, CA, which subsequently expired on January 31, 2023. The lease on the Baltimore facility will expire on June 30, 2023. As of December 31, 2022, we had fixed lease payment obligations of $0.2 million, payable within 12 months.

License Agreements

We are party to an agreement with the University of North Carolina, pursuant to which we have in-licensed intellectual property rights. This agreement obligates us to timely achieve certain development milestones, as well as pay royalties in the low-single digits based on sales of products arising from our GB-501 program. None of these events had occurred as of December 31, 2022, and no royalties were due from the sales of licensed products.

Other Commitments

We have historically entered into contracts in the normal course of business with CDMOs, for manufacturing process development and supply, and with other vendors for preclinical research studies and other services or products for operating purposes. These contracts generally provide for termination on notice of 60 to 90 days. As of December 31, 2022, there was one such contract, worth approximately $1.3 million, still in effect for future services, and there were no unpaid cancellation or other related costs.

In connection with an agreement with an investment banking firm for services related to the proposed Merger with CalciMedica, we incurred and paid approximately $0.8 million during the current year and will be required to make an additional payment of approximately $2.3 million contingent upon the consummation of the proposed Merger with CalciMedica. The $0.8 million incurred during the current year is included in general and administrative expenses.

In connection with the proposed Merger with CalciMedica, all outstanding stock awards will be fully accelerated and we will be required to make change-in-control severance payments to current employees totaling approximately $5.5 million.

As of December 31, 2022, these commitments were approximately $9.1 million due within 3 to 6 months.

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Funding Requirements

The consummation of the Merger with CalciMedica is subject to a number of closing conditions, including the approval by our stockholders, approval by Nasdaq of our application for initial listing of our common stock in connection with the Merger, and other customary closing conditions. We are targeting a closing of the transaction in the first quarter of 2023.

If the proposed Merger is not consummated, we may have to revert to an operating plan more consistent with our historical operations. Our funding requirements, and ability to access additional capital, would then be determined by a number of factors and risks.

Any product candidates we may develop may never achieve commercialization, and we anticipate that we will continue to incur losses for the foreseeable future. If the Merger fails to close, we would expect that our research and development expenses, general and administrative expenses, and capital expenditures would decrease in the aggregate from historical levels as our current development programs are both early stage and preclinical. As a result, until such time, if ever, as we could generate substantial product revenue, we would expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including mergers, acquisitions, potential collaborations, licenses and other similar arrangements. If the Merger fails to close, our primary uses of capital would be compensation and related expenses, third-party clinical research, manufacturing and development services, license payments or milestone obligations that may arise, laboratory and related supplies, clinical costs, manufacturing costs, legal and other regulatory expenses and general overhead costs.

If the Merger fails to close, we believe that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements in excess of 12 months from the issuance date of these financial statements. We base this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We base the sufficiency of our existing cash, cash equivalents and short-term investments to fund our operations on the current period re-forecast of our projected cash burn rate following our decision to terminate all clinical development of our remaining product candidates, as well as our reduced headcount and reliance on CDMOs to perform all of our research and development work in 2023. While we believe that our current cash, cash equivalents and short-term investments are adequate to meet our needs for the next 12 months from issuance, we would need to raise or otherwise access additional funds in order to further advance our research and development programs, operate our business and meet our obligations as they come due if the Merger fails to close.

If the Merger fails to close, we would require additional financing to advance our remaining product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. In addition to exploring an acquisition, company sale, merger, divestiture of assets, private placement of equity securities, or other strategic transactions, we would continue to seek funds through equity offerings, debt financings or other capital sources, potentially including collaborations, licenses and other similar arrangements. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements if the Merger fails to close. Our future funding requirements would depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching, developing and manufacturing our product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing our product candidates or any future product candidates and any products we successfully commercialize, including costs associated with building-out our manufacturing capabilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the timing, receipt and amount of sales of any future approved or cleared products, if any; and

- the impact of the COVID-19 pandemic and the corresponding responses of businesses and governments.

Further, if the Merger fails to close, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our remaining product candidates, we are unable to estimate the amounts of increased capital and operating expenditures associated with our current product development programs.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (22,879)	$ (31,500)
Investing activities	26,958	10,751
Financing activities	(139)	695
Net increase (decrease) in cash and cash equivalents	$ 3,940	$ (20,054)

Operating Activities

Cash used in operating activities of $22.9 million during the year ended December 31, 2022 was primarily attributable to our net loss of $35.6 million, partially offset by non-cash stock-based compensation expense of $6.7 million, $2.2 million in acquired in-process research and development, $1.6 million in impairment of capital equipment and a right-of-use asset, a decrease of $1.8 million in our working capital, $0.3 million in depreciation expense and $0.3 million in non-cash lease expense.

Cash used in operating activities of $31.5 million during the year ended December 31, 2021 was primarily attributable to our net loss of $35.8 million and an increase of $1.6 million in our working capital, partially offset by non-cash stock-based compensation expense of $5.4 million and depreciation expense of $0.5 million.

Investing Activities

Cash provided by investing activities of $27.0 million during the year ended December 31, 2022 consisted of $64.3 million of cash provided upon maturity of short-term investments and $0.4 million in proceeds from the sale of property and equipment, partially offset by $35.6 million of purchases of short-term investments, $1.9 million paid to acquire in-process research and development, and $0.3 million of purchases of property and equipment.

Cash provided by investing activities of $10.8 million during the year ended December 31, 2021 consisted of $105.8 million of cash provided upon maturity of short-term investments, partially offset by $94.6 million of purchases of short-term investments and $0.5 million of purchases of property and equipment.

Financing Activities

There were no material cash activities from financing activities during the year ended December 31, 2022.

Cash provided by financing activities of $0.7 million for the year ended December 31, 2021 was related to proceeds received from the exercise of stock options.

Critical Accounting Policies and Significant Judgments and Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. Generally Accepted Accounting Principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

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.

Research and Development Expense and Accruals

We record research and development expenses to operations as incurred. Research and development expenses represent costs incurred by us for the discovery and development of our product candidates and the development of our technology and include: employee-related expenses, including salaries, benefits, travel and non-cash stock-based compensation expense; external research and development expenses incurred under arrangements with third parties, such as CROs, preclinical testing organizations, CDMOs, academic and non-profit institutions and consultants; license fees; and other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

As part of the process of preparing financial statements, we are required to estimate and accrue expenses. We estimate costs of research and development activities conducted by service providers, which include the conduct of sponsored research, preclinical studies and contract manufacturing activities. Payments made prior to the receipt of goods or services to be used in research and development are deferred and recognized as expense in the period in which the related goods are received or services are rendered. If the costs have been prepaid, this expense reduces the prepaid expenses on the balance sheet, and if not yet invoiced, the costs are included in accrued liabilities on the balance sheet. We classify such prepaid assets as current or non-current assets based on our estimates of the timing of when the goods or services will be realized or consumed. These costs are a significant component of our research and development expenses.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from external CROs, CDMOs, and other third-party service providers. Amounts ultimately incurred in relation to amounts accrued for these services at a reporting date may be substantially higher or lower than our estimates.

Our expenses related to clinical trials are based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services provided and efforts expended pursuant to contracts with multiple research institutions and contract research organizations that may be used to conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

We have and may continue to enter into purchase and license agreements to access and utilize certain technologies. We evaluate if such agreements are an acquisition of an asset or a business. To date none of these agreements have been considered to be an acquisition of a business. For asset acquisitions, the upfront payments to acquire such assets, or licenses to such assets, as well as any future milestone payments made before product approval, will be immediately recognized as research and development expenses when due, provided there is no alternative future use of the rights in other research and development projects. These agreements may also include contingent consideration in the form of cash. We assess whether such contingent consideration meets the definition of a derivative.

Stock-based Compensation

We recognize compensation costs related to stock-based awards to employees and non-employees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation, using the Black-Scholes option-pricing model ("Black-Scholes"). The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

Black-Scholes requires the use of subjective assumptions to determine the fair value of stock-based awards including:

- Fair Value of Common Stock— see subsection entitled Common Stock Valuations below.
- Expected Term—The expected term represents the period that stock-based awards are expected to be outstanding. Our historical share option exercise information is limited due to a lack of sufficient data points and did not provide a reasonable basis upon which to estimate an expected term. The expected term for option grants is therefore determined using the simplified method. The simplified method deems the expected term to be the midpoint between the vesting date and the contractual life of the stock-based awards.
- Expected Volatility—Since we were a privately held company until September 2020, and do not yet have sufficient trading history for our common stock, the expected volatility is estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies are chosen based on their similar size, stage in the life cycle or area of specialty. We will continue to apply this

method until a sufficient amount of historical information over a period equal to the expected term of the stock-based awards becomes available.

- Risk-Free Interest Rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.
- Expected Dividend—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

We will continue to use judgment in evaluating the assumptions utilized for our stock-based compensation expense calculations on a prospective basis. In addition to the assumptions used in Black-Scholes, the amount of stock-based compensation expense we recognize in our financial statements includes stock option forfeitures as they occur. Such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

Common Stock Valuations

Historically, for all periods prior to our IPO, the fair value of the shares of common stock underlying our stock-based awards was estimated on each grant date by our board of directors. In the absence of a public trading market for our common stock, our board of directors exercised their judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including contemporaneous valuations, our stage of development, important developments in our operations, the prices at which we sold shares of our preferred stock, the rights, preferences and privileges of our preferred stock relative to those of our common stock, actual operating results and financial performance, the conditions in the biotechnology industry and the economy in general, the stock price performance and volatility of comparable public companies, and the lack of liquidity of our common stock, among other factors.

In determining the fair value of our common stock, the methodologies used to estimate our enterprise value were performed using methodologies, approaches and assumptions consistent with the guidance outlined in the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately Held Company Equity Securities Issued as Compensation. The grant date fair value of our common stock was determined using valuation methodologies incorporating a number of assumptions including probability weighting of events, volatility, time to liquidation, a risk-free interest rate and an assumption for a discount for lack of marketability (Level 3 inputs). The methodology to determine the fair value of our common stock included estimating the fair value of the enterprise using a hybrid-method market approach, which estimates the fair value of the company by including an estimation of the value of the business based on scenarios in a probability-weighted expected return method ("PWERM") framework. Under the hybrid-method market approach, the per share value calculated under the scenarios are weighted based on expected exit outcomes and the quality of the information specific to each allocation methodology to arrive at a final estimated fair value per share value of the common stock before a discount for lack of marketability is applied.

Following the closing of our IPO, our board of directors determines the fair market value of our common stock based on its closing price as reported on The Nasdaq Global Market on the date of grant.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. 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," as defined by Rule 12b-2 of the Securities Exchange Act of 1934, because both 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.

Recently Adopted Accounting Pronouncements

For a full discussion of recently adopted accounting pronouncements, see Note 2 - Summary of Significant Accounting Policies to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information.

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

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934 and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data.

GRAYBUG VISION, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of Graybug Vision, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Graybug Vision, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

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/ Ernst & Young LLP

We have served as the Company's auditor since 2017.

San Mateo, California
March 8, 2023

GRAYBUG VISION, INC.
Consolidated Balance Sheets
(in thousands, except share and par value information)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 17,304	$ 13,364
Short-term investments	21,824	50,306
Prepaid expenses and other current assets	542	3,408
Total current assets	39,670	67,078
Property and equipment, net	—	1,981
Prepaid expenses and other non-current assets	—	29
Total assets	$ 39,670	$ 69,088
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,716	$ 527
Accrued research and development	200	304
Operating lease liability, current	203	—
Other current liabilities	1,580	3,226
Total current liabilities	3,699	4,057
Deferred rent, long term portion	—	8
Total liabilities	3,699	4,065
Commitments and contingencies (Note 5)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value; 10,000,000 authorized, no shares outstanding as of December 31, 2022 and 2021, respectively	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized, 21,696,433 and 21,357,773 shares issued and outstanding as of December 31, 2022 and 2021, respectively	2	2
Additional paid-in capital	240,799	234,225
Accumulated deficit	(204,793)	(169,188)
Accumulated other comprehensive loss	(37)	(16)
Total stockholders' equity	35,971	65,023
Total liabilities and stockholders' equity	$ 39,670	$ 69,088

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

GRAYBUG VISION, INC.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	$ 14,113	$ 18,903
General and administrative	19,104	17,044
Restructuring, impairment and other costs of terminated programs	2,963	—
Total operating expenses	36,180	35,947
Loss from operations	(36,180)	(35,947)
Interest income	575	126
Net loss	$ (35,605)	$ (35,821)
Net loss per share—basic and diluted	$ (1.66)	$ (1.69)
Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted	21,489,280	21,199,291

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

GRAYBUG VISION, INC.
Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,	
	2022	2021
Net loss	$ (35,605)	$ (35,821)
Unrealized loss on available-for-sale securities, net of tax	(21)	(12)
Comprehensive loss	$ (35,626)	$ (35,833)

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

GRAYBUG VISION, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2020	20,979,265	$ 2	$ 228,155	$ (133,367)	$ (4)	$ 94,786
Stock issued on exercise of stock options	353,508	—	695	—	—	695
Issuance of common stock upon vesting of restricted stock units	25,000	—	—	—	—	—
Stock-based compensation expense	—	—	5,375	—	—	5,375
Net loss	—	—	—	(35,821)	—	(35,821)
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	(12)	(12)
Balance—December 31, 2021	21,357,773	2	234,225	(169,188)	(16)	65,023
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	338,660	—	(139)	—	—	(139)
Stock-based compensation expense	—	—	6,713	—	—	6,713
Net loss	—	—	—	(35,605)	—	(35,605)
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	(21)	(21)
Balance—December 31, 2022	21,696,433	$ 2	$ 240,799	$ (204,793)	$ (37)	$ 35,971

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

GRAYBUG VISION, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2022	2021
Operating activities:		
Net loss	$ (35,605)	$ (35,821)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,713	5,375
Depreciation	338	519
Loss on sale/disposal of assets	97	—
Noncash lease expense	277	—
Accretion of premium and discounts on short-term investments	(319)	58
Acquired in-process research and development	2,194	—
Impairment of capital equipment and right-of-use asset	1,599	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current and non-current assets	2,895	1,378
Accounts payable	1,304	(2,052)
Accrued research and development	(104)	(1,052)
Operating lease liability	(380)	—
Other current and non-current liabilities	(1,888)	95
Net cash used in operating activities	(22,879)	(31,500)
Investing activities:		
Purchases of property and equipment	(308)	(488)
Purchases of investments	(35,569)	(94,570)
Maturity of investments	64,349	105,809
Acquisition of in-process research and development	(1,944)	—
Proceeds from sale of property and equipment	430	—
Net cash provided by investing activities	26,958	10,751
Financing activities:		
Payment of taxes on vested restricted stock units	(139)	—
Proceeds from exercise of stock options	—	695
Net cash (used in) provided by financing activities	(139)	695
Net increase (decrease) in cash and cash equivalents	3,940	(20,054)
Cash and cash equivalents at beginning of period	13,364	33,418
Cash and cash equivalents at end of period	$ 17,304	$ 13,364
Supplemental disclosure of noncash items:		
Right-of-use asset arising from the adoption of ASC 842	$ 567	$ —
Acquired in-process research and development in accrued liabilities	$ 250	$ —
Unpaid balance for purchases of property and equipment	$ —	$ 115

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

1. Organization

Graybug Vision, Inc., the Company or Graybug, has historically been a clinical-stage biopharmaceutical company developing medicines for the treatment of diseases of the retina and optic nerve. On June 28, 2022, the Company announced that it would conduct a comprehensive review of strategic alternatives focused on maximizing shareholder value. As part of this review of strategic alternatives, the Company explored the potential for an acquisition, company sale, merger, divestiture of assets, private placement of equity securities and other strategic transactions. Prior to this announcement, the Company had devoted substantially all of its resources to conducting research and development and raising capital. On August 18, 2022, the Company's board of directors approved the restructuring plan that is described further in *Restructuring* below. On November 21, 2022, the Company entered into a definitive Agreement and Plan of Merger and Reorganization that is described further in *Merger* below. The Company was founded in May 2011 and had maintained facilities in Baltimore, Maryland and Redwood City, California. The Baltimore facility was vacated and decommissioned on October 1, 2022, and the Redwood City facility lease expired on January 31, 2023.

The Company has historically been subject to risks common to clinical stage companies in the biopharmaceutical industry, including dependence on the clinical success of its product candidates, ability to obtain regulatory approvals of its product candidates, compliance with regulatory requirements, the need for substantial additional financing and protection of its proprietary technology.

Restructuring

On August 18, 2022, the Company's board of directors approved certain strategic, operational and organizational steps for the Company to undertake in connection with its announcement on June 28, 2022 that the Company would conduct a comprehensive review of strategic alternatives focused on maximizing shareholder value. These steps included both the termination of all activities relating to the Company's GB-102 and GB-401 programs and certain cost-reduction initiatives, including a reduction in its workforce by 71%. While clinical development of GB-501 remains on hold, preclinical work is still proceeding. Work on GB-701 is still in the drug discovery stage.

In connection with these actions, the Company recorded a restructuring charge of $3.0 million during the year ended December 31, 2022. The restructuring charge includes: (i) severance and termination benefit expense for 20 employees terminated with separation dates between August 31, 2022 and October 31, 2022, (ii) charges related to the impairment of research and development equipment in its Baltimore, Maryland facility and the right-of-use asset for that facility that was decommissioned in October 2022, and (iii) costs to wind-down the GB-102 and GB-401 clinical development programs. Refer to Note 6 for additional information on the restructuring.

Merger

On November 21, 2022, the Company entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with CalciMedica, Inc. ("CalciMedica") a clinical-stage biopharmaceutical company focused on developing first-in-class therapies for serious inflammatory diseases with high unmet need, and Camaro Merger Sub, Inc., Graybug's wholly-owned subsidiary ("Merger Sub"). Upon the terms and subject to the satisfaction of the conditions described in the Merger Agreement, Merger Sub will be merged with and into CalciMedica, with CalciMedica surviving such merger as a wholly owned subsidiary of Graybug (the "Merger").

The Merger, which has been approved by the Company's board of directors and the board of directors and stockholders of CalciMedica, is expected to close in the first quarter of 2023, subject to the satisfaction or waiver of certain closing conditions, including the approval of the Company's stockholders. Although the Company has entered into the Merger Agreement and intends to consummate the proposed Merger, there is no assurance that the Company will be able to successfully consummate the proposed Merger on a timely basis, or at all. If, for any reason, the proposed Merger is not completed, the Company will reconsider its strategic alternatives and could pursue another strategic transaction similar to the proposed Merger, potential collaborative, partnering or other strategic arrangements for its programs, including a sale or divestiture of the Company's remaining programs, or liquidate and distribute available cash.

Going Concern Considerations

The Company incurred losses from operations and had negative cash flows from operating activities since inception, and the Company's accumulated deficit at December 31, 2022 was $204.8 million. If the Merger fails to close, the Company expects that it would continue to incur losses from operations and generate negative cash flows from operating activities, given expenditures related to the research and development that would be required and the Company's lack of revenue-generating activities at this point in the Company's life cycle. Even if the Merger failed to close and the Company's remaining product development efforts were successful, it is uncertain when, if ever, the Company would realize significant revenue from product sales.

In March 2021, the Company decided not to proceed with the significant investment required to initiate two Phase 3 clinical trials for GB-102 that were planned for late 2021 and, in August 2022, terminated all activities relating to GB-102 and GB-401, and reduced its workforce by 71%. As of December 31, 2022, the Company is continuing the preclinical development of two remaining programs and has eight remaining employees. As a result, anticipated operating expenses have been significantly reduced and management continues to believe that, if the Merger fails to close, the Company's current cash, cash equivalents and short-term investments would be adequate to meet its cash needs for at least 12 months from the issuance date of this Annual Report on Form 10-K.

If the Merger fails to close, the Company may pursue financing alternatives, similar to what it has previously executed, which include debt and equity financing. There are no assurances that this process would result in any such transaction and such sources of capital may not be available to the Company in the necessary time frame, in the amounts that the Company requires, on terms that are acceptable to the Company, or at all. If the Merger fails to close, the Company may be unable to consummate a future acquisition, company sale, merger, divestiture of assets or other strategic transaction or raise the necessary funds when needed or reduce spending on required activities, it may not be able to continue the preclinical development of its remaining products, or it could be required to delay, scale back, or eliminate some or all of its research and development programs and other operations, including personnel, any of which may materially harm its business, financial position and results of operations.

COVID-19 Pandemic

The impact of the worldwide spread of a novel strain of coronavirus ("COVID-19") has been unprecedented and unpredictable, including the emergence of new variants of the coronavirus, such as the Delta and Omicron variants, and resurgences in number and rates of infections, but based on the Company's current assessment, the Company does not expect any material impact on its long-term strategic plans, operations, or its liquidity due to the worldwide spread of COVID-19. However, the Company is continuing to assess the effect on its operations by monitoring the spread of COVID-19 and the actions implemented to combat the virus and new variants thereof throughout the world and its assessment of the impact of COVID-19 may change.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and are stated in U.S. dollars. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, RainBio, Inc. ("RainBio"), which was acquired in March 2022 (see Note 5). All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting periods. Actual results could differ from those estimates. Significant items subject to estimates include estimates related to accrued research and development expenses, contingent milestone payments, other long-lived assets, stock-based compensation, incremental borrowing rates for leases and the valuation of deferred tax assets. The Company bases its estimates using historical experience, Company forecasts and future plans, current economic conditions, and information from third-party professionals that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and recorded amounts of expenses that are not readily apparent from other sources, and adjusts those estimates and assumptions when facts and circumstances dictate.

The Company's results can also be affected by economic, political, legislative, regulatory and legal actions. Economic conditions, such as recessionary trends, inflation, interest, changes in regulatory laws and monetary exchange rates, and government fiscal policies, can have a significant effect on operations. While the Company maintains reserves for anticipated liabilities, the Company could be adversely affected by civil, criminal, regulatory or administrative actions, claims, or related proceedings.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents are stated at fair value and may include money market funds, corporate debt securities and commercial paper. The Company's cash equivalents consist of money market fund investments, corporate debt securities, and commercial paper.

Investments

The Company invests its excess cash balances in marketable government agency bonds, corporate debt securities and commercial paper. The Company classifies its investments as available-for-sale, reports available-for-sale investments at their fair value at each balance sheet date, and includes any unrealized holding gains and losses (the adjustment to fair value) on debt securities in accumulated other comprehensive loss, a component of stockholders' equity. Should there be any realized gains or losses, they will be determined using the specific-identification method and included as other income or expense in the statements of operations.

The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Impairment assessments are made at the individual security level each reporting period. When the fair value of an available-for-sale security is less than its cost at the balance sheet date, a determination is made as to whether the impairment is other-than-temporary and, if it is other-than-temporary, an impairment loss is recognized in the statements of operations, equal to the difference between the investment's amortized cost and fair value at such date. The Company did not record any impairment charges related to its marketable securities during the years ended December 31, 2022 and 2021. All investment transactions are recorded on a trade date basis.

The Company classifies its available-for-sale marketable securities as non-current if such instrument's underlying effective maturity date exceeds 12 months and for which the Company has the intent and ability to hold the investment for a period of greater than 12 months. The Company's marketable securities at December 31, 2022 and 2021 mature in less than 12 months and are included in short-term investments in the consolidated balance sheets.

Concentrations of Credit Risk and Off-balance Sheet Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents and available-for-sale marketable securities. The Company's investment policy includes guidelines regarding the quality of the financial institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk. The Company may invest in money market funds, U.S. Treasury securities, corporate debt, U.S. government-related agency securities, commercial paper and certificates of deposit. At December 31, 2022 and 2021, the Company's cash and cash equivalents were held in financial institutions that management believes are creditworthy. These deposits may exceed federally insured limits. The Company has not experienced any losses historically in these accounts and believes it is not exposed to significant credit risk in its cash and cash equivalents. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts, or other hedging arrangements.

Property and Equipment

Property and equipment are stated at cost, subject to adjustments for impairments, less accumulated depreciation. Depreciation is calculated using the straight-line method over the useful lives of the assets as follows:

Asset	Estimated useful life
Manufacturing and laboratory equipment	Three to five years
Computer hardware	Three to five years
Office furniture and equipment	Three to five years

Leasehold improvements were amortized over the shorter of their useful lives or the related lease term. Maintenance and repairs that do not improve or extend the life of the respective asset are expensed to operations as incurred. Manufacturing and laboratory equipment received is classified as construction in progress until placed into service, at which time depreciation commences. Upon disposal of an asset, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations.

Leases

The Company adopted Accounting Standards Codification ("ASC"), Topic 842, Leases ("ASC 842"), on January 1, 2022, as discussed below in *Recently Adopted Accounting Pronouncements*. Under ASC 842, the Company determines if an arrangement is or contains a lease at contract inception.

Operating lease right-of-use assets represent the Company's right and ability to use an underlying asset for the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized based on the present value of lease payments over the lease term at the commencement date of the lease. Right-of-use assets also include any initial direct costs incurred and any lease payments made at or before the lease commencement

date, less any lease incentive received. 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 reflects the rate of interest that a lessee would have to pay to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. Lease expense for an operating lease is recognized on a straight-line basis over the lease term.

The Company elected the practical expedient to not separate lease and non-lease components for all classes of assets. Additionally, the Company has elected an accounting policy to not recognize short-term leases, which have a lease term of 12 months or less, on the condensed consolidated balance sheet. Variable lease payments are primarily related to utilities, property taxes, insurance and common area maintenance, and are recognized as lease cost when incurred.

Restructuring, Impairment and Other Costs of Terminated Programs

Restructuring, impairment and other costs of terminated programs primarily consists of severance and termination benefit expense and non-cash impairment of capital equipment and an operating lease right-of-use asset. These charges are included in restructuring, impairment and other costs of terminated programs in the condensed consolidated statement of operations.

The Company recognizes severance and termination benefits when it is probable that employees will be entitled to such benefits and the amount can be reasonably estimated and recorded at fair value. The timing of the recognition of expense for severance and termination benefits depends on whether employees are required to render service until they are terminated in order to receive the termination benefits. If employees are required to render service until they are terminated in order to receive the severance and termination benefits, a liability is recognized ratably over the future service period. Otherwise, a liability is recognized when management has committed to a restructuring plan and has communicated those actions to affected employees.

Refer to Note 6 for additional information on the severance expense that the Company recognized for employees terminated in connection with the August 2022 reduction-in-force.

Long-lived Asset Impairment

The Company assesses long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amounts of the asset or group of assets may not be recoverable. During the year ended December 31, 2022, the Company commenced restructuring activities which indicated that the carrying amount of the long-lived assets might not be recoverable. The Company evaluated the long-lived assets, consisting primarily of capital equipment and an operating lease right-of-use asset, for impairment. If the carrying amount of an asset group exceeds its estimated undiscounted net future cash flows, an impairment charge is recognized for the amount by which the carrying amount of the asset group exceeds its fair value. To the extent available, the Company will also consider third-party valuations of an asset group that were prepared for other business purposes. An impairment charge is recognized for the amount by which the carrying value exceeds its estimated fair value. When an impairment loss is recognized for equipment to be held and used, the adjusted carrying amounts are depreciated over their remaining useful life.

All of the Company's equipment in its Maryland facility was sold during the year ended December 31, 2022. Additionally, the Company decommissioned the facility in the fourth quarter and all employees that had worked in that facility were either terminated or permanently working remotely as of December 31, 2022. As such, the Company recorded an impairment charge to reflect the net cash proceeds received from the sale of the equipment, and an impairment charge of the operating lease right-of-use asset related to the Maryland facility. Refer to Note 6 for additional information regarding the impairment charges recorded in connection with the Company's restructuring.

Research and Development Expenses

Research and development costs are expensed as incurred. The Company's research and development expenses consist primarily of costs incurred for the development of its product candidates and include expenses incurred under agreements with contract development and manufacturing organizations ("CDMOs") contract research organizations ("CROs") investigative sites and consultants to conduct clinical trials and preclinical and non-clinical studies, costs to acquire, develop and manufacture supplies for clinical trials and other studies, salaries and related costs, including stock-based compensation, depreciation and other allocated facility-related and overhead expenses.

Accrued Research and Development Costs

The Company records accruals for estimated costs of preclinical and clinical studies and manufacturing development. The Company's clinical and manufacturing development activities have been conducted by third-party service providers, including CROs and CDMOs. The financial terms of these contracts are subject to negotiation, which vary by contract and may result in payments that do not match the periods over which materials or services are provided. The Company accrues the costs incurred under the agreements based on an estimate of actual work completed in accordance with the agreements. In the event the Company makes advance payments

for goods or services that will be used or rendered for future research and development activities, the payments are deferred and capitalized as a prepaid expense and recognized as expense as the goods are received or the related services are rendered. Such payments are evaluated for current or non-current classification based on when they are expected to be realized. If the Company does not identify costs that have begun to be incurred or if the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ from the Company's estimates.

Patent Costs

Costs to secure and maintain patents covering the Company's technology and product candidates are expensed as incurred and are classified as general and administrative expenses in the consolidated statements of operations.

Stock-based Compensation

Stock-based compensation expense related to stock options and warrants granted to employees, directors and non-employees is recognized based on the grant-date estimated fair values of the awards using the Black-Scholes option pricing model ("Black-Scholes"). The valuation of restricted stock units ("RSUs"), is determined at the date of grant using the Company's closing stock price on that date. The value is recognized as expense ratably over the requisite service period, which is generally the vesting term of the award. The Company adjusts the expense for actual forfeitures as they occur.

Income Taxes

The Company uses the liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on temporary differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company assesses the likelihood of deferred tax assets being realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. For the Company, the ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Based on the Company's operations to date and the uncertainty as to the timing and amount of future taxable income, the Company has recorded a full valuation allowance in all periods and for all jurisdictions.

Financial statement effects of uncertain tax positions are recognized when it is more likely than not, based on the technical merits of the position, that it will be sustained upon examination. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of an audit, and effective settlement of audit issues. Interest and penalties related to unrecognized tax benefits would be included within the income tax provision.

Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is calculated by dividing net loss by the weighted-average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period if the effect is dilutive. Potentially dilutive securities include warrants, stock options and RSUs. Likewise, adjustments to the denominator are required to reflect the related dilutive shares. In all periods presented, the Company's outstanding stock options, RSUs, and warrants were excluded from the calculation of diluted net loss per share because their effects were antidilutive.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. The Company has determined it operates in one segment.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period arising from transactions and other events and circumstances from non-owner sources. The Company's comprehensive loss comprises changes in unrealized (loss) gain on available-for-sale securities.

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, *Leases* (Topic 842), as amended, with guidance regarding the accounting for and disclosure of leases. The update requires lessees to recognize the liabilities related to all leases, including operating leases, with a term greater than 12 months on the balance sheet. This update also requires lessees and lessors to disclose key information about their leasing transactions. As an emerging growth company, this standard is effective for the Company for fiscal years beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. Early adoption is permitted. The Company adopted this standard on January 1, 2022, using the modified retrospective method by applying the new standard to all leases existing as of the effective date and not restating comparative periods. The Company elected the "package of practical expedients", which permits the Company to not reassess under this standard its prior conclusions about lease identification, lease classification and initial direct costs, as well as the practical expedient to not separate lease and non-lease components for its real estate leases. In addition, the Company elected the short-term lease recognition exemption for all leases that qualify. The impact of adoption and additional disclosures required by the standard have been included in Note 2 - Summary of Significant Accounting Policies above and in Note 5 - Commitments and Contingencies. As a result of the adoption of the new lease accounting guidance, the Company recognized, on January 1, 2022, operating lease right-of-use asset of $0.6 million and operating lease liability of $0.6 million in the consolidated balance sheet. Prior period amounts before January 1, 2022 have not been adjusted and continue to be reported in accordance with the Company's historical accounting under previous lease guidance, ASC Topic 840, *Leases* ("ASC 840").

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*, which removes certain exceptions and amends certain requirements in the existing income tax guidance to ease accounting requirements. As an emerging growth company, this standard is effective for the Company for fiscal years beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022, and must be applied on a retrospective basis. The Company adopted ASU 2019-12 on January 1, 2022, and the adoption did not have a material impact on the consolidated financial statements.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued a clarification to ASU 2016-13 within ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses*, Topic 815, *Derivatives and Hedging*, and Topic 825, *Financial Instruments*, which modified the accounting for available-for-sale securities. As an emerging growth company, ASU 2016-13 is effective for the Company for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company is currently assessing the potential impact of adopting ASU 2016-13 on its consolidated financial statements and financial statement disclosures.

3. Fair Value Measurements

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following three levels:

- *Level 1:* Observable inputs such as unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date.
- *Level 2:* Inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- *Level 3:* Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash equivalents:				
Money market funds	$ 12,374	$ —	$ —	$ 12,374
Total cash equivalents	12,374	—	—	12,374
Short-term investments:				
Corporate debt securities	—	1,000	—	1,000
Commercial paper	—	17,378	—	17,378
U.S. Treasury notes	—	1,490	—	1,490
U.S. Government sponsored entities - mortgage-backed securities	—	1,956	—	1,956
Total short-term investments	—	21,824	—	21,824
Total assets measured at fair value	$ 12,374	$ 21,824	$ —	$ 34,198

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash equivalents:				
Money market funds	$ 8,920	$ —	$ —	$ 8,920
Corporate debt securities	—	1,480	—	1,480
Commercial paper	—	2,749	—	2,749
Total cash equivalents	8,920	4,229	—	13,149
Short-term investments:				
Corporate debt securities	—	1,117	—	1,117
Commercial paper	—	41,954	—	41,954
U.S. Treasury notes	—	7,235	—	7,235
Total short-term investments	—	50,306	—	50,306
Total assets measured at fair value	$ 8,920	$ 54,535	$ —	$ 63,455

Money market funds are highly liquid investments which are actively traded. The pricing information on the Company's money market funds is based on quoted prices in active markets for identical securities. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

The fair value of investments is determined from market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These pricing services utilize industry-standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

There were no transfers between Levels 1, 2 or 3 for the periods presented.

The following tables present information as to cost, unrealized gains and losses and fair value determination of the Company's financial assets measured at fair value on a recurring basis (in thousands):

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 12,374	$ —	$ —	$ 12,374
Total cash equivalents	12,374	—	—	12,374
Short-term investments:				
Corporate debt securities	1,001	—	(1)	1,000
Commercial paper	17,405	2	(29)	17,378
U.S. Treasury notes	1,499	—	(9)	1,490
U.S. Government sponsored entities - mortgage-backed securities	1,956	—	—	1,956
Total short-term investments	21,861	2	(39)	21,824
Total assets measured at fair value	$ 34,235	$ 2	$ (39)	$ 34,198

	December 31, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 8,920	$ —	$ —	$ 8,920
Corporate debt securities	1,480	—	—	1,480
Commercial paper	2,749	—	—	2,749
Total cash equivalents	13,149	—	—	13,149
Short-term investments:				
Corporate debt securities	1,117	—	(1)	1,116
Commercial paper	41,956	6	(8)	41,954
U.S. Treasury notes	7,249	—	(13)	7,236
Total short-term investments	50,322	6	(22)	50,306
Total assets measured at fair value	$ 63,471	$ 6	$ (22)	$ 63,455

As of December 31, 2022 and 2021, the contractual maturities of all available-for-sale investments were less than 12 months. The Company periodically reviews the available-for-sale investments for other-than-temporary impairment loss. The Company had 12 short-term investments in unrealized loss positions as of December 31, 2022. The Company's unrealized losses from short-term investments as of December 31, 2022 were caused by interest rate increases and not by unfavorable changes in the credit quality associated with these securities. The Company does not intend to sell short-term investments that are in an unrealized loss position, and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. Therefore, the Company believes these losses to be temporary and as a result, did not recognize any other-than-temporary impairment losses as of December 31, 2022 and 2021.

4. Balance Sheet Components

Property and Equipment, net

Property and equipment, net, consisted of the following (in thousands):

	December 31,	
	2022	2021
Manufacturing and laboratory equipment	$ —	$ 2,511
Computer hardware	—	28
Office furniture and equipment	—	28
Leasehold improvements	—	234
Construction in progress	—	833
Total property and equipment, at cost	—	3,634
Less: accumulated depreciation	—	(1,653)
Property and equipment, net	$ —	$ 1,981

Depreciation expense for the years ended December 31, 2022 and 2021 was $0.3 million and $0.5 million, respectively. As of December 31, 2022, the Company had disposed all of its property and equipment.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2022	2021
Prepaid expenses	$ 503	$ 1,866
Prepaid clinical and research expenses	—	168
Interest and other receivables	39	21
Other current assets	—	1,353
Total prepaid expenses and other current assets	$ 542	$ 3,408

Other Current Liabilities

Other current liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Salaries and benefits	$ 698	$ 2,278
Professional services	431	461
Holdback liability for acquisition of in-process research and development	250	—
Severance and termination benefits	124	—
Other	77	479
Deferred rent	—	8
Total other current liabilities	$ 1,580	$ 3,226

5. Commitments and Contingencies

The Company has historically entered into contracts in the normal course of business with CDMOs, for manufacturing process development and preclinical/clinical supply manufacturing, and with other vendors for preclinical research studies and other services or products for operating purposes. These contracts generally provide for termination on notice of 60 to 90 days. As of December 31, 2022, there was one such contract, worth approximately $1.3 million, still in effect for future services, and there were no unpaid cancellation or other related costs.

In connection with the Company's agreement with an investment banking firm for services related to the proposed Merger with CalciMedica, the Company incurred and paid approximately $0.8 million during the current year and will be required to make an additional payment of approximately $2.3 million contingent upon the consummation of the proposed Merger with CalciMedica. The $0.8 million incurred during the current year is included in general and administrative expenses.

In connection with the proposed Merger with CalciMedica, all outstanding stock awards will be fully accelerated and the Company will be required to make change-in-control severance payments to its current employees totaling approximately $5.5 million.

As of December 31, 2022, these commitments were approximately $9.1 million due within 3 to 6 months.

Operating Lease Agreements

The Company leases a facility in Baltimore, Maryland under an operating lease with a term through June 2023. The Company also had a short-term lease for approximately 2,560 rentable square feet of office space in Redwood City, California, which was amended in December 2022 to extend the term from August 31, 2022 to January 31, 2023, at which time it expired. The operating cash outflow for the Maryland lease liability was $0.4 million for the year ended December 31, 2022. The remaining term of the Maryland lease was 0.5 years, and the incremental borrowing rate used to determine the operating lease liability was 6.0%.

In the fourth quarter of 2022, following the sale of all equipment in the facility in connection with the restructuring (see Note 6), the Company decommissioned and vacated the Maryland facility and recorded an impairment charge to reduce the carrying value of the right-of-use asset to zero.

Lease expense recognized for the operating leases, including short-term leases not included in the measurement of the lease liability, was $0.5 million for the year ended December 31, 2022. Under the terms of the 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 the operating leases were $0.5 million for the year ended December 31, 2022. Rent expense recognized under ASC 840 for the year ended December 31, 2021 was $0.7 million.

As of December 31, 2022, the Company's remaining future minimum lease payments were $0.2 million.

As of December 31, 2021, future minimum commitments under the Company's non-cancelable operating leases, in accordance with ASC 840, were as follows (in thousands).

	Year Ended December 31,
2022	$ 527
2023	205
Total future minimum lease payments	$ 732

License Agreements

Johns Hopkins University

In June 2011, the Company entered into an Exclusive License Agreement with Johns Hopkins University ("JHU") which has been amended from time to time, such agreement as amended is referred to as the JHU Agreement. Pursuant to the JHU Agreement, JHU granted the Company an exclusive, worldwide, sublicensable license to three patent families to research, develop, make, use and sell products and provide services in any field, and a non-exclusive license to use specified know-how and materials with a provision that JHU would not grant a license to know how and materials to any other commercial entity.

The JHU Agreement was only relevant to our GB-102 and GB-103 programs, both of which had been terminated by August 2022. On October 3, 2022, the Company provided written notification to JHU of complete termination of the exclusive license agreement to all licensed patent rights owned by JHU.

Asset Acquisition & Divestiture

In December 2021, the Company entered into an Assignment and Licensing Agreement with a private company, pursuant to which the Company acquired certain intellectual property rights, including patents and know-how, related to new cyclic monophosphate ("cGMP") compounds for the treatment of ocular disorders.

As consideration for the intellectual property rights acquired, the Company made an upfront cash payment of $0.5 million and may be required to make additional contingent payments of up to $27.0 million in the aggregate upon achievement of certain development and regulatory milestones. Additionally, upon commercialization, the Company would have been required to make tiered single-digit royalty payments based on net product sales.

As the acquired rights related to in-process research and development activities that had no alternative future use to the Company, the upfront payment of $0.5 million was recorded as research and development expense in the accompanying consolidated statements of operations for the year ended December 31, 2021. In November 2022, this Assignment and Licensing Agreement was terminated, and all rights were returned to the licensor. Accordingly, as of December 31, 2022, the Company had no further obligation to pay development or regulatory milestones and, accordingly, no amounts have been recognized in the accompanying consolidated financial statements with respect to these contingent payments.

RainBio Asset Acquisition

In March 2022, the Company acquired RainBio, a private company in the United States whose primary assets are certain gene therapy technology and preclinical data ("GB-501"). RainBio was purchased at a cost of approximately $2.2 million, including transaction costs and a contingent holdback, and the Company may be required to make additional contingent payments of up to $17.5 million in the aggregate upon the achievement of certain milestones. Other than the contingent holdback release, no further payments are required until FDA approval of a product based upon the acquired assets and the sale or utilization of any priority review voucher that may be granted in connection with such approval. The contingent holdback liability of $0.3 million was recorded in other current liabilities in the consolidated balance sheets.

The acquisition was accounted for as an asset acquisition, as substantially all of the fair value of the assets acquired was concentrated in a single in-process research and development ("IPR&D") intangible asset. As the acquired IPR&D did not have an alternative future use to the Company, the purchase price of $2.2 million was recorded as research and development expense in the accompanying consolidated statement of operations for the year ended December 31, 2022. As of December 31, 2022, none of the milestones were probable of achievement and, accordingly, no amounts have been recognized in the accompanying consolidated financial statements with respect to these contingent payments.

Indemnification

The Company, as permitted under Delaware law and in accordance with its certification of incorporation and bylaws and pursuant to indemnification agreements with certain of its officers and directors, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, which the officer or director is or was serving at the Company's request in such capacity.

The Company enters into certain types of contracts that contingently require the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's bylaws, under which the Company must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship, (ii) contracts under which the Company must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, and (iii) procurement, service or license agreements under which the Company may be required to indemnify vendors, service providers or licensees for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the Company's products, technology, intellectual property or services.

From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on the Company's future business, operating results or financial condition. It is not possible to determine the maximum potential amount potentially payable under these contracts since the Company has no history of prior indemnification claims and the unique facts and circumstances involved in each particular claim will be determinative.

Litigation

The Company is a party to legal proceedings and claims which have arisen during the ordinary course of business. The Company is not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on its business. The Company has been served with four complaints asserting that certain disclosures in the proxy statement filed by the Company with the Securities and Exchange Commission on December 14, 2022, in connection with the Merger, are inadequate. These complaints do not currently seek monetary damages. The Company reviews its legal proceedings and claims, regulatory reviews and inspections, and other legal matters on an ongoing basis and follow appropriate accounting guidance when making accrual and disclosure decisions. For all currently unresolved legal proceedings or claims, the Company does not believe there is a reasonable probability that any material loss will be incurred. Accordingly, no material accrual or disclosure of a potential range of loss has been made related to these matters. The Company does not expect the ultimate liability of these unresolved legal proceedings or claims to have a material effect on its financial position, liquidity or capital resources.

6. Restructuring, Impairment and Other Costs of Terminated Programs

As discussed in Note 1, based on the conclusions from the comprehensive review of strategic alternatives focused on maximizing shareholder value, the Company decided to terminate all activities relating to the GB-102 and GB-401 programs and to reduce its workforce as a part of cost-reduction initiatives. In connection with these events, impairment of capital equipment and operating right-of-use asset of its Maryland facility, severance and termination benefit costs for employees, and other costs were recorded under restructuring, impairment and other costs of terminated programs in the consolidated statement of operations for the year ended December 31, 2022.

The Company recorded the following under restructuring, impairment and other costs (in thousands):

	Year Ended December 31, 2022
Impairment of capital equipment and right-of-use asset	$ 1,599
Severance and termination benefit expense	1,065
Other restructuring costs	299
Restructuring, impairment and other costs of terminated programs	$ 2,963

Impairment of Capital Equipment and Right-of-Use Asset

In connection with the restructuring, the Company either sold or disposed of all the equipment in its Maryland facility, including equipment that had been fully depreciated. The fair value of the capital equipment was determined based on the net cash proceeds received from the sale of the equipment. Subsequently, in October 2022, the Company decommissioned and vacated the Maryland

facility and recorded an impairment charge of $0.3 million to reduce the carrying value of the right-of-use asset to zero. The Company recorded an impairment charge as follows (in thousands):

	Amount
Net book value of capital equipment before impairment	$ 1,659
Less: Fair value of capital equipment	(350)
Impairment expense for capital equipment	1,309
Impairment of right-of-use asset	290
Impairment of capital equipment and right-of-use asset	$ 1,599

Severance and Termination Benefit Expense

Employees affected by the reduction-in-force are entitled to receive severance payments and certain Company-funded benefits. Severance and termination benefit expense was recorded in full for all terminated employees. As of December 31, 2022, $0.1 million in severance payments were not yet paid. The Company recorded severance and termination benefit expense as follows (in thousands):

	Total
Total severance and other termination benefits, at fair value	$ 1,065
Expense recognized during the period	$ 1,065
Payments during the period	(941)
Liability balance as of December 31, 2022	$ 124

Adjustments to severance and termination benefit expense may be recorded in future periods as the estimates of the costs of benefits change. However, it is not expected that such adjustments will have a material effect on the results of operations or financial condition.

7. Stock-Based Compensation

2020 Equity Incentive Plan

In August 2020, the Company's board of directors and stockholders adopted the Company's 2020 Equity Incentive Plan (the "2020 Plan") that became effective in connection with the IPO, and serves as the successor to the Company's 2015 Stock Incentive Plan ("2015 Plan"). The Company's 2020 Plan authorizes the award of stock options, restricted stock units ("RSUs") restricted stock awards ("RSAs") stock appreciation rights ("SARs") performance awards and stock bonus awards. The Company initially reserved 1,850,000 shares of its common stock, plus any reserved shares not issued or subject to outstanding grants under the 2015 Plan on the effective date of the 2020 Plan, for issuance pursuant to awards granted under the 2020 Plan. The aggregate number of shares reserved for sale under the 2020 Plan will increase automatically on each January 1st of 2021 through 2030 by the number of shares equal to 5% of the aggregate number of outstanding shares of the Company's common stock as of the immediately preceding December 31, or a lesser number as may be determined by the Company's board of directors.

In conjunction with adopting the 2020 Plan, the Company may not grant any additional stock-based awards under the 2015 Plan, and any shares available for issuance under the 2015 Plan were added to the shares reserved under the 2020 Plan. The 2015 Plan will continue to govern outstanding stock-based awards granted thereunder. On January 1, 2021, the aggregate number of shares reserved for issuance was increased by an additional 1,048,963 shares pursuant to the automatic share reserve increase provision of the 2020 Plan.

In March 2022, the Company increased the aggregate number of shares reserved for issuance by an additional 1,067,888 shares pursuant to the automatic share reserve increase provision of the 2020 Plan and in June 2022, the Company reserved an additional 2,340,000 shares for future issuance under the 2020 Plan following approval by the Company's stockholders. As of December 31, 2022, there were 593,887 shares available for issuance under the 2020 Plan.

2020 Employee Stock Purchase Plan

In August 2020, the Company's board of directors and stockholders adopted the Company's 2020 Employee Stock Purchase Plan (the "ESPP") that became effective in connection with the IPO, in order to enable eligible employees to purchase shares of the Company's common stock with accumulated payroll deductions. The Company's ESPP is intended to qualify under Section 423 of the Internal Revenue Code. The Company initially reserved 210,000 shares of its common stock for sale under the ESPP. Per the terms of the ESPP, the aggregate number of shares reserved for sale under the Company's ESPP will increase automatically on January 1st of each of the first ten calendar years after the first offering date under the ESPP by the number of shares equal to the lesser of 1% of the total outstanding shares of the Company's common stock as of the immediately preceding December 31, or a number of shares as may

be determined by the Company's board of directors in any particular year. The aggregate number of shares issued over the term of the ESPP, subject to stock-splits, recapitalizations or similar events, may not exceed 2,100,000 shares of the Company's common stock. The Company's board of directors have determined that there should be no increase in the number of shares reserved for the ESPP. Accordingly, as of December 31, 2022, there were 210,000 shares available for issuance under the ESPP. There have been no employee withholdings for the purchase of shares under the plan as of December 31, 2022.

Inducement Grants

On January 14, 2022, six newly-hired employees were granted inducement options to purchase an aggregate of 234,200 shares of the Company's common stock at an exercise price of $1.55 per share. These inducement grants were made outside of the 2020 Equity Incentive Plan in accordance with the Nasdaq Listing Rule 5635(c)(4). All six employees have since been terminated in connection with the Company's August 2022 reduction-in-force, which was prior to the first vesting date, resulting in the forfeiture of all such inducement grants.

Stock Option Activity

The following summarizes stock option activity:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding—December 31, 2021	3,777,398	$ 6.58	8.4	$ 42
Granted	1,240,174	$ 1.33		
Exercised	—			
Forfeited and Canceled	(665,132)	$ 3.94		
Outstanding—December 31, 2022	4,352,440	$ 5.49	7.8	$ —
Options Exercisable—December 31, 2022	2,399,117	$ 5.87	7.1	$ —

At December 31, 2022, the aggregate intrinsic value of options granted is calculated as the difference between the exercise price and the closing price on the same date. The aggregate intrinsic value of options exercised in the years ended December 31, 2022 and 2021 was zero and $2.5 million, respectively.

Restricted Stock Units

The following table summarizes restricted stock units ("RSUs") activity for the year ended December 31, 2022:

	RSUs Outstanding	
	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value Per Share
Balance - December 31, 2021	969,700	$ 4.45
Granted	2,885,617	$ 1.04
Vested	(506,219)	$ 3.44
Cancelled/forfeited	(33,482)	$ 3.73
Balance - December 31, 2022	3,315,616	$ 1.65

The fair value of RSUs is determined on the date of grant based on the market price of the Company's common stock on that date. The aggregate grant date fair value of RSUs vested during the year ended December 31, 2022 was $1.7 million.

Fair Value of Stock Option Awards

The Company estimates the fair value of stock option awards on the grant date using Black-Scholes. The weighted-average grant date fair value per option granted during the years ended December 31, 2022 and 2021 was $0.96 and $2.72, respectively. The fair value of each award is estimated using Black-Scholes based on the following assumptions:

	Year Ended December 31,	
	2022	2021
Expected term (years)	5.5 - 6.1	5.1 - 6.1
Expected volatility	87% - 88%	87% - 88%
Risk-free interest rate	1.62% - 2.91%	0.84% - 1.12%
Expected dividend	—	—

Black-Scholes requires the use of subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Expected Term: The expected term represents the period that options are expected to be outstanding and is determined using the simplified method, based on the mid-point between the vesting date and the end of the contractual term.

Expected Volatility: The expected volatility is estimated based on the average volatility for comparable publicly-traded biopharmaceutical companies over a period equal to the expected term of the stock option grants as the Company does not yet have sufficient historical trading history for its own stock. The comparable companies are chosen based on their similarities to the Company, including life cycle stage, therapeutic focus and size. The Company will continue to apply this method until a sufficient amount of historical information over a period equal to the expected term of the stock-based awards becomes available.

Risk-free Interest Rate. The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the stock option grants.

Expected Dividend: The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Stock-Based Compensation Expense

Stock-based compensation expense is classified as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Research and development	$ 1,360	$ 1,210
General and administrative	5,353	4,165
Total stock-based compensation expense	$ 6,713	$ 5,375

As of December 31, 2022, the total unrecognized stock-based compensation expense related to outstanding unvested stock awards that are expected to vest was $11.5 million, which the Company expects to recognize over an estimated weighted-average term of 2.2 years.

8. Income Taxes

The Company has incurred net operating losses for all the periods presented. The Company has not reflected the tax benefit of any such net operating loss carryforwards in the accompanying financial statements.

The effective tax rate for the years ended December 31, 2022 and 2021 is different from the federal statutory rate primarily due to the valuation allowance against deferred tax assets as a result of insufficient sources of income. The reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2022	2021
Federal statutory income tax rate	21.0%	21.0%
State income taxes, net of federal benefit	(2.5)	0.6
Research and development tax credits	1.7	1.4
Other	(5.3)	(0.4)
Change in valuation allowance	(14.9)	(22.6)
Effective income tax rate	—%	—%

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's net deferred tax assets consisted of the following (in thousands):

	December 31,	
	2022	2021
Deferred tax assets		
Federal and state net operating loss carryforwards	$ 38,253	$ 34,431
Research and development tax credits	5,071	5,408
Capitalized research and development expense	2,323	—
Other	882	1,408
Gross deferred tax assets	46,529	41,247
Less: valuation allowance	(46,529)	(41,215)
Total deferred tax assets	—	32
Deferred tax liabilities		
Depreciation	—	(32)
Total deferred tax liabilities	—	(32)
Net deferred tax assets	$ —	$ —

The Company has incurred annual net operating losses in each year since inception. The Company has not reflected the tax benefit of any such net operating loss carryforwards in the financial statements. Due to the Company's history of losses, and lack of other positive evidence, the Company has determined that it is more likely than not that its net deferred tax assets will not be realized and, therefore, the net deferred tax assets are fully offset by a valuation allowance at December 31, 2022 and 2021. The Company increased its valuation allowance by $5.3 million for the year ended December 31, 2022 in order to maintain a full valuation allowance against its deferred tax assets.

As of December 31, 2022, the Company had federal net operating loss carryforwards ("NOLs") of $175.2 million and federal tax credits of $6.6 million available to offset tax liabilities. The Company's federal NOLs and federal tax credit carryforwards begin to expire in 2035 and 2036, respectively. Of the federal NOLs, $141.1 million have an indefinite life. The Company also had gross state NOLs of $23.8 million and state tax credits of $0.6 million which are available to offset state tax liabilities. The state NOLs expire in 2036 and the state tax credit carryforwards can be carried forward indefinitely. Federal and state NOLs and tax credit carryforwards are also subject to annual limitations in the event that cumulative changes in the ownership interests of significant stockholders exceed 50% over a three-year period, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986. The Company has not completed an analysis to determine if the NOLs and tax credits are limited due to a change in ownership. Should there be ownership changes that occurred, or if the Merger will constitute a change in ownership, the Company's ability to utilize existing carryforwards could be substantially restricted.

The Company determines its uncertain tax positions based on whether and how much of a tax benefit taken by the Company in its tax filings is more likely than not to be sustained upon examination by the relevant income tax authorities.

A reconciliation of the unrecognized tax benefit is as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Balance—beginning of year	$ 2,090	$ 1,981
Addition based on tax position related to current year	155	257
Reduction based on tax position related to prior year	(275)	(148)
Balance—end of year	$ 1,970	$ 2,090

The unrecognized tax benefits, if recognized, would not have an impact on the Company's effective tax rate assuming the Company continues to maintain a full valuation allowance position. Based on prior year's operations and experience, the Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may increase or change during the next year for unexpected or unusual items for items that arise in the ordinary course of business. The Company has elected to include interest and penalties as a component of tax expense. During the years ended December 31, 2022 and 2021, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits.

The Company files income tax returns in the U.S. federal, California, and several other tax jurisdictions. The federal and state income tax returns for all years remain subject to examination.

9. Employee Retirement Plan

The Company maintains a 401(k) retirement savings plan ("401(k) Plan"). The 401(k) Plan allows employees to make contributions up to the maximum allowable by the IRS. The Company did not make any contributions to the 401(k) Plan on behalf of its employees in the years ended December 31, 2022 or 2021.

10. Net Loss Per Share

Basic and diluted net loss per common share is calculated as follows (in thousands except share and per share amounts):

	Year Ended December 31,	
	2022	2021
Net loss	$ (35,605)	$ (35,821)
Net loss per share—basic and diluted	$ (1.66)	$ (1.69)
Weighted-average number of shares used in computing net loss per share—basic and diluted	21,489,280	21,199,291

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	As of December 31,	
	2022	2021
Stock options to purchase common stock	4,352,440	3,777,398
Restricted stock units	3,315,616	969,700
Warrants to purchase common stock	27,759	27,759

11. Subsequent Events

On February 10, 2023, the Company and CalciMedica entered into a note purchase agreement (the "Note Purchase Agreement") providing for the Company to make short-term loans (the "Loan" or "Loans") to CalciMedica up to an aggregate principal amount of $2.0 million. The Loans will bear simple interest, in arrears, at 7.5% per annum. On each of February 10 and 24, 2023, the Company purchased from CalciMedica Loans in the amount of $0.5 million for a total indebtedness of $1.0 million. CalciMedica's ability to borrow the remaining $1.0 million under the Note Purchase Agreement is subject to certain conditions and restrictions on use.

In connection with the Note Purchase Agreement, on February 10, 2023, Graybug, CalciMedica and Camaro Merger Sub, Inc. entered into a First Amendment to the Merger Agreement, pursuant to which the parties agreed that the amount of any outstanding principal and accrued interest under the Loans will be included in the calculation of Graybug's net cash at the closing of the Merger.

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.

Under the supervision and with the participation of our management, including our Chief Executive Officer (our Principal Executive Officer) and our Chief Financial Officer (our Principal Financial Officer and Principal Accounting Officer), we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") as of December 31, 2022. Based on our management's evaluation (with the participation of our Chief Executive Officer and our Chief Financial Officer), as of the end of the period covered by this report, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act). Our management, including our Chief Executive Officer, assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control – 2013 Integrated Framework. Based on that assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2022 that have materially affected , or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference from our definitive Proxy Statement to be filed with the SEC in connection with our 2023 Annual Meeting of Stockholders within 120 days after the end of the fiscal year ended December 31, 2022.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this report:

1. Financial Statements

   Information in response to this Item is included in Part II, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules

   All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. Exhibits:

Exhibit Index

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
2.1	Agreement and Plan of Merger and Reorganization, dated November 21, 2022, by and among the Registrant, Camaro Merger Sub, Inc. and CalciMedica, Inc.	DEFM14A	001-39538	2/9/2023	Annex A	
2.2	First Amendment to the Agreement and Plan of Merger and Reorganization, dated November 21, 2022, by and among CalciMedica, Inc., Camaro Merger Sub, Inc. and Graybug Vision, Inc., dated February 10, 2023.	8-K	001-39538	2/16/2023	2.1	
3.1	Restated Certificate of Incorporation of Graybug Vision, Inc.	10-Q	001-39538	11/12/2020	3.1	
3.2	Restated Bylaws of Graybug Vision, Inc.	10-Q	001-39538	11/12/2020	3.2	
4.1	Form of Common Stock Certificate.	S-1/A	333-248611	9/21/2020	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated July 31, 2019, by and among the Registrant and certain of its stockholders.	S-1	333-248611	9/4/2020	4.2	
4.3	Warrant to Purchase Common Stock, dated December 11, 2019, by and between the Registrant and SG DAN Equity Holdings, LLC.	S-1	333-248611	9/4/2020	4.3	
4.4	Description of Common Stock Registered Under Section 12 of the Securities Exchange Act of 1934.	10-K	001-39538	3/5/2021	4.4	
10.1*	Form of Indemnification Agreement.	S-1	333-248611	9/4/2020	10.1	
10.2*	2020 Equity Incentive Plan and forms of award agreements.	S-1/A	333-248611	9/21/2020	10.3	
10.3*	2020 Employee Stock Purchase Plan and forms of award agreements.	S-1/A	333-248611	9/21/2020	10.4	
10.4*	2015 Stock Incentive Plan, as amended, and forms of award agreements thereunder.	S-1	333-248611	9/4/2020	10.2	
10.5*	Employment Agreement, effective as of February 1, 2019, by and between the Registrant and Frederic Guerard.	S-1	333-248611	9/4/2020	10.6	
10.6*	Offer Letter, effective as of May 7, 2020, by and between the Registrant and Parisa Zamiri.	S-1	333-248611	9/4/2020	10.8	
10.7*	Offer Letter, effective as of September 4, 2020, by and between the Registrant and Robert S. Breuil.	S-1	333-248611	9/4/2020	10.9	
10.8*	Change in Control and Severance Policy.	S-1	333-248611	9/4/2020	10.11	
10.9	Lease, dated October 8, 2019, by and between the Registrant and Ventas Beckley, LLC, as amended by that certain First Amendment to Lease, dated December 5, 2019, and that certain Second Amendment to Lease, dated June 26, 2020.	S-1	333-248611	9/4/2020	10.13	
10.10†	Exclusive License Agreement, dated June 23, 2011, by and between the Registrant and Johns	S-1	333-248611	9/4/2020	10.14	

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
	Hopkins University School of Medicine, as amended.					
10.11†	Settlement and License Agreement, dated October 24, 2014, by and among the Registrant, Johns Hopkins University School of Medicine, and Kala Pharmaceuticals, Inc.	S-1	333-248611	9/4/2020	10.15	
10.12	Letter Agreement, dated July 31, 2019, by and between the Registrant and AffaMed Project Limited.	S-1	333-248611	9/4/2020	10.16	
10.13	Note Purchase Agreement, by and between CalciMedica, Inc. and Graybug Vision, Inc., dated February 10, 2023.	8-K	001-39538	2/16/2023	99.1	
10.14	Form of CalciMedica, Inc. Support Agreement, dated November 21, 2022.	8-K	001-39538	11/22/2022	10.1	
10.15	Form of Graybug Vision, Inc. Support Agreement, dated November 21, 2022.	8-K	001-39538	11/22/2022	10.2	
10.16	Form of Lock-Up Agreement, dated November 21, 2022.	8-K	001-39538	11/22/2022	10.3	
10.17	Separation Agreement, dated February 28, 2023, between the Registrant and Parisa Zamiri.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
31.1	Certification of Principal Executive 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.					X
31.2	Certification of 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.					X
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					X

† Registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K.
* Indicates a management contract or compensatory plan or arrangement.
** This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of the Exchange Act.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GRAYBUG VISION, INC.

Date: March 8, 2023

By: /s/ Frederic Guerard
Frederic Guerard, Pharm.D.
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Frederic Guerard Frederic Guerard, Pharm.D.	Chief Executive Officer (Principal Executive Officer)	March 8, 2023
/s/ Robert S. Breuil Robert S. Breuil	Chief Financial Officer (Principal Accounting and Financial Officer)	March 8, 2023
/s/ Christina Ackermann Christina Ackermann	Director	March 8, 2023
/s/ Eric Bjerkholt Eric Bjerkholt	Director	March 8, 2023
/s/ Dirk Sauer Dirk Sauer	Director	March 8, 2023
/s/ Julie Eastland Julie Eastland	Director	March 8, 2023
/s/ Christy Shaffer Christy Shaffer, Ph.D.	Chairperson, Director	March 8, 2023

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