# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended June 30, 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.)** |

**203 Redwood Shores Parkway, Suite 620**
**Redwood City, CA 94065**
**(Address of principal executive offices including zip code)**

**Registrant's telephone number, including area code: (650) 487-2800**

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 |

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☐ | Accelerated filer | ☐ |
| Non-accelerated filer | ☒ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☒ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The number of shares of the Registrant's common stock outstanding as of August 5, 2022 was 21,517,682.

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In this Quarterly Report on Form 10-Q, "we," "our," "us," "Graybug" and the "Company" refer to Graybug Vision, Inc. This report contains references to trademarks belonging to other entities, which are the property of their respective holders. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, including statements regarding our future financial condition, business strategy and plans, 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 outcome of our exploration of potential strategic alternatives;
- the potential of our technologies and our ability to execute on our corporate strategy;
- our ability to fund our working capital needs;
- our ability to develop and commercialize our product candidates;
- our ability to use and expand our technologies to build a pipeline of product candidates;
- our ability to secure a partnership for GB-102;
- our ability to obtain and maintain regulatory approval of our product candidates;
- the strength and breadth of our patent portfolio;
- the potential for receipt of additional milestone payments;
- our ability to obtain and adequately protect intellectual property rights for our product candidates;
- our continued reliance on third parties for manufacturing our product candidates, conducting our clinical trials and certain research activities;
- our ability to in-license, acquire or invest in complementary businesses, technologies, products or assets to further expand or complement our portfolio of product candidates;
- expected timing of our clinical trials;
- the timing and availability of results of our clinical trials and those of our collaborators; and
- our ability to extend our operating capital.

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 Quarterly Report on Form 10-Q. 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.

We obtained industry, market and competitive position data in this report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information or estimates.

## PART I—FINANCIAL INFORMATION

**Item 1. Financial Statements.**

**GRAYBUG VISION, INC.**
**Condensed Consolidated Balance Sheets**
**(in thousands)**

| | June 30, 2022 (unaudited) | December 31, 2021 (See Note 2) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 13,872 | $ 13,364 |
| Short-term investments | 36,817 | 50,306 |
| Prepaid expenses and other current assets | 1,038 | 3,408 |
| Total current assets | 51,727 | 67,078 |
| Property and equipment, net | 1,911 | 1,981 |
| Operating lease right-of-use asset | 384 | — |
| Prepaid expenses and other non-current assets | — | 29 |
| Total assets | $ 54,022 | $ 69,088 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,014 | $ 527 |
| Accrued research and development | 463 | 304 |
| Operating lease liability, current | 398 | — |
| Other current liabilities | 2,455 | 3,226 |
| Total current liabilities | 4,330 | 4,057 |
| Deferred rent, long term portion | — | 8 |
| Total liabilities | 4,330 | 4,065 |
| Commitments and contingencies (Note 5) | | |
| Stockholders' equity: | | |
| Preferred stock | — | — |
| Common stock | 2 | 2 |
| Additional paid-in capital | 237,447 | 234,225 |
| Accumulated deficit | (187,578) | (169,188) |
| Accumulated other comprehensive loss | (179) | (16) |
| Total stockholders' equity | 49,692 | 65,023 |
| Total liabilities and stockholders' equity | $ 54,022 | $ 69,088 |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Operating expenses: | | | | |
| Research and development | $ 4,058 | $ 4,166 | $ 10,115 | $ 10,614 |
| General and administrative | 4,243 | 3,575 | 8,370 | 8,615 |
| Total operating expenses | 8,301 | 7,741 | 18,485 | 19,229 |
| Loss from operations | (8,301) | (7,741) | (18,485) | (19,229) |
| Interest income | 60 | 33 | 95 | 72 |
| Net loss | (8,241) | (7,708) | (18,390) | (19,157) |
| Net loss per common share—basic and diluted | $ (0.38) | $ (0.36) | $ (0.86) | $ (0.91) |
| Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted | 21,433,396 | 21,148,743 | 21,395,793 | 21,084,915 |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Net loss | $ (8,241) | $ (7,708) | $ (18,390) | $ (19,157) |
| Unrealized (loss) gain on available-for-sale securities, net of tax | (3) | 6 | (163) | 10 |
| Comprehensive loss | $ (8,244) | $ (7,702) | $ (18,553) | $ (19,147) |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive Loss | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance—December 31, 2021** | 21,357,773 | $ 2 | $ 234,225 | $ (169,188) | $ (16) | $ 65,023 |
| Stock-based compensation expense | — | — | 1,542 | | — | 1,542 |
| Net loss | — | — | — | (10,149) | — | (10,149) |
| Unrealized loss on available-for-sale securities, net of tax | — | — | — | — | (160) | (160) |
| **Balance—March 31, 2022** | 21,357,773 | 2 | 235,767 | (179,337) | (176) | 56,256 |
| Stock-based compensation expense | — | — | 1,749 | — | — | 1,749 |
| Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes | 159,909 | — | (69) | — | — | (69) |
| Net loss | — | — | — | (8,241) | — | (8,241) |
| Unrealized loss on available-for-sale securities, net of tax | — | — | — | — | (3) | (3) |
| **Balance—June 30, 2022** | 21,517,682 | $ 2 | $ 237,447 | $ (187,578) | $ (179) | $ 49,692 |

| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (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 | 76,679 | — | 92 | — | — | 92 |
| Stock-based compensation expense | — | — | 1,129 | — | — | 1,129 |
| Net loss | — | — | — | (11,449) | — | (11,449) |
| Unrealized gain on available-for-sale securities, net of tax | — | — | — | — | 4 | 4 |
| **Balance—March 31, 2021** | 21,055,944 | 2 | 229,376 | (144,816) | — | 84,562 |
| Stock issued on exercise of stock options | 228,732 | — | 495 | — | — | 495 |
| Stock-based compensation expense | — | — | 1,312 | — | — | 1,312 |
| Net loss | — | — | — | (7,708) | — | (7,708) |
| Unrealized gain on available-for-sale securities, net of tax | — | — | — | — | 6 | 6 |
| **Balance—June 30, 2021** | 21,284,676 | $ 2 | $ 231,183 | $ (152,524) | $ 6 | $ 78,667 |

See accompanying notes to unaudited condensed consolidated financial statements.

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2022 | 2021 |
| **Operating activities:** | | |
| Net loss | $ (18,390) | $ (19,157) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 3,291 | 2,441 |
| Depreciation | 247 | 247 |
| Noncash lease expense | 183 | — |
| Accretion of premium and discounts on short-term investments | (31) | 67 |
| Acquired in-process research and development | 2,194 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current and non-current assets | 2,399 | 2,214 |
| Accounts payable | 467 | (415) |
| Accrued research and development | 159 | (960) |
| Operating lease liability | (185) | — |
| Other current and non-current liabilities | (997) | (1,482) |
| Net cash used in operating activities | (10,663) | (17,045) |
| **Investing activities:** | | |
| Purchases of property and equipment | (173) | (304) |
| Purchases of investments | (16,393) | (58,126) |
| Maturity of investments | 29,750 | 49,334 |
| Acquisition of in-process research and development | (1,944) | — |
| Net cash provided by (used in) investing activities | 11,240 | (9,096) |
| **Financing activities:** | | |
| Payment of taxes on vested restricted stock units | (69) | — |
| Proceeds from exercise of stock options | — | 587 |
| Net cash (used in) provided by financing activities | (69) | 587 |
| Net increase (decrease) in cash and cash equivalents | 508 | (25,554) |
| Cash and cash equivalents at beginning of period | 13,364 | 33,418 |
| Cash and cash equivalents at end of period | $ 13,872 | $ 7,864 |
| **Supplemental disclosure of noncash items:** | | |
| Right-of-use asset obtained in exchange for operating lease liability | $ 567 | $ — |
| Acquired in-process research and development in accrued liabilities | $ 250 | $ — |
| Property and equipment purchases included in accounts payable | $ 27 | $ 52 |

See accompanying notes to unaudited condensed 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 is exploring the potential for an acquisition, company sale, merger, divestiture of assets, private placement of equity securities, or 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 11, 2022, the Company announced that all clinical development of GB-102, GB-401, and GB-501 had been put on hold to conserve capital pending the outcome of its strategic review. The Company was founded in May 2011 and maintains facilities in Redwood City, California and Baltimore, Maryland.

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.

### *Going Concern Considerations*

The Company incurred losses from operations and had negative cash flows from operating activities for the six months ended June 30, 2022, and 2021, and the Company's accumulated deficit at June 30, 2022 was $187.6 million. The Company's current operating plan, which is subject to change based on the ongoing strategic review, indicates it will continue to incur losses from operations and generate negative cash flows from operating activities, given ongoing expenditures related to anticipated research and development and the Company's lack of revenue-generating activities at this point in the Company's life cycle. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will 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 in late 2021. As a result, management continues to believe that the Company's current cash, cash equivalents and short-term investments are adequate to meet its cash needs for at least 12 months from the issuance date of this Quarterly Report on Form 10-Q.

As part of the Company's review of strategic alternatives, it is exploring the potential for an acquisition, company sale, merger, divestiture of assets, private placement of equity securities, or other strategic transactions. As part of this process the Company is exploring an outright sale or merger as well as a process to raise additional funds in order to further advance our research and development programs, operate our business, secure research and development collaborations, and meet our obligations as they come due. 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 will 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 Company is unable to consummate an acquisition, company sale, merger, divestiture of assets or other strategic transaction or raise the necessary funds when needed or reduce spending on currently planned activities, it may not be able to continue the preclinical development of its 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, or 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 unaudited condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission, or SEC, and, therefore, certain information and disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, have been omitted.

In the opinion of management, the information reflects all adjustments necessary to make the results of operations for the interim periods a fair statement of such operations. All such adjustments are of a normal recurring nature. Interim results are not necessarily indicative of results for the full year. The condensed balance sheet at December 31, 2021 has been derived from the audited financial statements at that date, but does not include all information and footnotes required by GAAP for complete financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 11, 2022.

The accompanying condensed 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 condensed consolidated 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.

***Leases***

The Company adopted Accounting Standards Codification (ASC) Topic 842, *Leases* (ASC 842) on January 1, 2022, as discussed below in the section titled 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 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 twelve months or less, on the condensed consolidated balance sheet. Variable lease payments are primarily related to property taxes, insurance and common area maintenance, and are recognized as lease cost when incurred.

***Recently Adopted Accounting Pronouncements***

In February 2016, the 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 on the balance sheet the liabilities related to all leases, including operating leases, with a term greater than 12 months. 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. 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. 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 "Summary of Significant Accounting Policies – Leases" above and in Note 5. 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 unaudited condensed 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 its condensed consolidated financial statements.

**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):

| | June 30, 2022 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| **Current assets:** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 7,282 | $ — | $ — | $ 7,282 |
| Commercial paper | — | 4,246 | — | 4,246 |
| Total cash equivalents | 7,282 | 4,246 | — | 11,528 |
| Short-term investments: | | | | |
| Corporate debt securities | — | 2,099 | — | 2,099 |
| Commercial paper | — | 23,797 | — | 23,797 |
| U.S. Treasury notes | — | 10,921 | — | 10,921 |
| Total short-term investments | — | 36,817 | — | 36,817 |
| Total assets measured at fair value | $ 7,282 | $ 41,063 | $ — | $ 48,345 |

| | 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 are 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. The 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):

| | June 30, 2022 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Aggregate Fair Value |
| **Current assets:** | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 7,282 | $ — | $ — | $ 7,282 |
| Commercial paper | 4,247 | — | (1) | 4,246 |
| Total cash equivalents | 11,529 | — | (1) | 11,528 |
| Short-term investments: | | | | |
| Corporate debt securities | 2,115 | — | (16) | 2,099 |
| Commercial paper | 23,882 | 2 | (87) | 23,797 |
| U.S. Treasury notes | 10,998 | — | (77) | 10,921 |
| Total short-term investments | 36,995 | 2 | (180) | 36,817 |
| Total assets measured at fair value | $ 48,524 | $ 2 | $ (181) | $ 48,345 |

| | 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 June 30, 2022 and December 31, 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. All investments with unrealized losses have been in a loss position for less than 12 months. As a result, the Company did not recognize any other-than-temporary impairment losses as of June 30, 2022 and December 31, 2021.

## 4. Balance Sheet Components

### *Other Current Liabilities*

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

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| Salaries and benefits | $ 1,159 | $ 2,278 |
| Professional services | 803 | 461 |
| Holdback liability for acquisition of in-process research and development | 250 | — |
| Deferred rent | — | 8 |
| Other | 243 | 479 |
| Total other current liabilities | $ 2,455 | $ 3,226 |

## 5. Commitments and Contingencies

The Company enters into contracts in the normal course of business with contract research organizations, or CROs, for clinical trials and contract manufacturing organizations, or CMOs, for clinical supply manufacturing and with vendors for equipment, preclinical research studies, research supplies and other services and products for operating purposes. As of June 30, 2022, these commitments were approximately $3.2 million due within 3 to 9 months. These contracts generally provide for termination on notice of 60 to 90 days. As of June 30, 2022, there were no unpaid cancellation or other related costs and none are anticipated.

***Operating Lease Agreements***

The Company leases a facility in Baltimore, Maryland under an operating lease with a term through June 2023. The Company also has a short-term lease for approximately 2,560 rentable square feet of office space in Redwood City, California, which was amended in July 2022 to extend the term from August 31, 2022 to December 31, 2022.

On January 1, 2022, the Company adopted ASC 842 and the following disclosures as of and for the six months ended June 30, 2022 are presented under ASC 842. The operating cash outflow for the Baltimore lease liability was $0.2 million for the six months ended June 30, 2022. As of June 30, 2022, the remaining term of the Company's Baltimore lease was 1.0 years, and the incremental borrowing rate used to determine the operating lease liability was 6.0%.

Lease expense recognized for the operating leases, including short-term leases not included in the measurement of the lease liability, was $0.2 million for the six months ended June 30, 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 immaterial for the six months ended June 30, 2022. Rent expense recognized under ASC 840 for the six months ended June 30, 2021 was $0.2 million.

As of June 30, 2022, future minimum commitments under the Company's non-cancelable operating leases, in accordance with ASC 842, are as follows (in thousands):

| | | |
|---|---|---|
| 2022 (remaining six months) | $ | 204 |
| 2023 | | 205 |
| Total undiscounted future minimum lease payments | | 409 |
| Less: imputed interest | | (11) |
| Operating lease liabilities | $ | 398 |

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

| | | |
|---|---|---|
| 2022 | $ | 527 |
| 2023 | | 205 |
| Total future minimum lease payments | $ | 732 |

***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. 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 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, or 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 condensed consolidated statement of operations for the six months ended June 30, 2022. As of June 30, 2022, none of the milestones were probable of achievement and, accordingly, no amounts have been recognized in the accompanying condensed consolidated financial statements with respect to these contingent payments.

***Indemnifications***

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of June 30, 2022, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

***Litigation***

From time to time, the Company may become involved in legal proceedings arising in the ordinary course of business. The Company is not presently a party to any legal proceedings that it believes would have a material adverse effect on its business, operating results, financial condition or cash flows.

**6. 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, or the 2020 Plan, that became effective in connection with the IPO, and serves as the successor to the Company's 2015 Stock Incentive Plan, or the 2015 Plan. The Company's 2020 Plan authorizes the award of stock options, restricted stock units, or RSUs, restricted stock awards, or RSAs, stock appreciation rights, or SARs, performance awards and stock bonus awards. 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 for future issuance under the 2020 Plan following approval by the Company's stockholders. As of June 30, 2022, there were 2,446,844 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, or 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. As of June 30, 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 June 30, 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). One-fourth of the options will vest on the one-year anniversary of the vesting commencement date and the remainder will vest in equal monthly installments over the next three years, in each case subject to the new employee's continued service with the Company. The stock options have a ten-year term and are subject to the terms and conditions of a stock option agreement covering the grant.

***Stock-Based Compensation Expense***

Stock-based compensation expense recognized for options and RSUs granted was as follows (in thousands):

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| Research and development | $ 418 | $ 334 | $ 776 | $ 591 |
| General and administrative | 1,331 | 978 | 2,515 | 1,850 |
| Total stock-based compensation expense | $ 1,749 | $ 1,312 | $ 3,291 | $ 2,441 |

As of June 30, 2022, the total unrecognized stock-based compensation expense related to outstanding unvested stock awards that are expected to vest was $13.9 million, which the Company expects to recognize over an estimated weighted-average term of 2.3 years.

**7. Income Taxes**

The Company did not record a provision or benefit for income taxes during the six months ended June 30, 2022 and 2021. As of both June 30, 2022 and December 31, 2021, the Company continues to maintain a full valuation allowance against all of its deferred tax assets in light of its history of cumulative net losses.

**8. Net Loss Per Share**

The Company calculates basic net loss per share based on the weighted-average number of common shares outstanding during the periods presented and calculates diluted net loss per share based on the weighted-average number of shares of common stock outstanding, including potentially dilutive securities.

For the six months ended June 30, 2022 and 2021, basic and diluted net loss per share are the same due to the Company's net losses and requirement to exclude potentially dilutive securities which would have an antidilutive effect on net loss per share. During the six months ended June 30, 2022 and 2021, potentially dilutive securities consisted of the common shares underlying outstanding stock options, RSUs and warrants.

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 June 30, | |
|---|---|---|
| | 2022 | 2021 |
| Stock options to purchase common stock | 4,951,408 | 3,919,090 |
| Restricted stock units | 1,276,642 | 1,068,700 |
| Warrants to purchase common stock | 27,759 | 27,759 |

**Item 2. 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 unaudited condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and the related notes and the discussion under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the Securities and Exchange Commission, or SEC, on March 11, 2022. 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 ocular diseases. Our diversified portfolio was designed to treat vision-threatening diseases of the retina, optic nerve, and cornea, by either maintaining effective drug levels in ocular tissues for long periods of time, using innovative technologies, such as injectable sustained-release formulations, or by restoring vision with gene therapies. Our novel proprietary technologies are designed to improve patient compliance, reduce healthcare burdens and, ultimately, deliver better clinical outcomes. Our lead product candidate, GB-102, is an intravitreal injection of a microparticle depot formulation of sunitinib, a potent pan-VEGF inhibitor that reduces neovascular growth and permeability, which are leading causes of wet age-related macular degeneration or wet AMD. We developed GB-102 as a once-every-six-month intravitreal injection for the treatment of wet AMD. In our Phase 1/2a clinical trial, GB-102 administered as a single 1 mg dose was well-tolerated in wet AMD patients and demonstrated durable clinical evidence of disease control of at least six months in 7 out of the 8 patients (88%) in this cohort. GB-102 has also completed a dose-ranging, standard-of-care controlled, masked, Phase 2b safety and efficacy clinical trial in patients with wet AMD, in which 1 mg and 2 mg doses were evaluated over a 12-month treatment period. We reported topline data from this trial in March of 2021, and additional data from its observational six-month extension period in September 2021. In this trial, both GB-102 cohorts demonstrated good durability up to Month 12, with the GB-102 (1 mg/1 mg) cohort demonstrating 6 months durability in 48% of patients and 12 months in 29% of patients. Of the patients who enrolled in the extension trial, 6 of the 11 patients (55%) in the GB-102 (1 mg/1 mg) cohort did not receive rescue treatment until Month 18 compared to 17% (1 of 6 patients) in the aflibercept cohort. Control of central sub-field thickness (CST) of the retina was comparable in all groups. The mean best-corrected visual acuity (BCVA) trended lower as compared to aflibercept in both GB-102 cohorts. In the GB-102 (1 mg/1 mg) cohort, the decrease in BCVA was mainly driven by a small subgroup of patients.

We also used our proprietary implant technology to develop the second most advanced program in our pipeline, GB-401, a first-in-class implant formulation containing a novel prodrug of timolol, a beta-adrenergic blocking agent, for the treatment of primary open-angle glaucoma. GB-401 is designed for a twice-per-year intravitreal injection with a proprietary applicator.

In March 2022, we acquired a novel adeno-associated virus (AAV) gene therapy program to treat corneal clouding caused by mucopolysaccharidosis type 1 (MPS1), a lysosomal storage disorder. This program was granted both Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) by the FDA and is therefore eligible for a Priority Review Voucher (PRV) if approved. This single-injection treatment is designed to both prevent and reverse severe visual impairment in MPS1 patients.

In December 2021, we acquired patents and certain exclusive license rights to a portfolio of novel cyclic guanosine mono-phosphate (cGMP) analogs to address hereditary retinal diseases, such as retinitis pigmentosa, comprising a group of genetic disorders that involve a loss of cells in the retina. We also formed a strategic partnership with a clinical-stage, end-to-end artificial intelligence (AI)-drug discovery company to develop novel and potent small-molecule complement factor B inhibitors targeting the complement pathway as a potential treatment for geographic atrophy.

We believe that our product candidates could significantly improve clinical outcomes versus the respective standards of care for several ocular diseases.

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, or 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 $8.2 million and $7.7 million for the three months ended June 30, 2022 and 2021, respectively, and $18.4 million and $19.2 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $187.6 million and cash, cash equivalents and short-term investments of $50.7 million.

On June 28, 2022 we announced that we would conduct a comprehensive review of strategic alternatives focused on maximizing shareholder value. As part of our review, we are exploring the potential for an acquisition, company sale, merger, divestiture of assets, private placement of equity securities, or other strategic transactions. On August 11, 2022, we announced that all clinical development of GB-102, GB-401, and GB-501 had been put on hold to conserve capital pending the outcome of our strategic review.

We expect to continue to incur net losses for the foreseeable future, and, subject to our strategic review, 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 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 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**

***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. Our continued compliance with the Minimum Bid Requirement is dependent on our share price and 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 current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, communities and business operations, as well as the U.S. economy and financial markets. To date, our financial condition and operations have not been significantly impacted by the COVID-19 outbreak; however, the ongoing challenges associated with the pandemic, including the emergence of new variants of the coronavirus, such as the Delta and Omicron variants, and resurgences in the number and rates of infections, make it difficult to assess the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, liquidity and financial condition, all of which will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

To date, our contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and other vendors have been able to continue to provide services and supply reagents, materials, and products and currently do not anticipate any disruption in services or interruptions in supply. Our CMOs continue to operate their manufacturing facilities at or near normal levels. While we currently do not anticipate any interruptions in our manufacturing process, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our third-party suppliers and contract manufacturing partners' ability to manufacture reagents, materials or products that we need to use in our research and clinical trial. However, we are continuing to assess the potential impact of the COVID-19 pandemic on our business and operations, including our expenses, our clinical trials, and our ability to hire and retain employees.

Given the persistent uncertainty of the evolving pandemic, we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our future clinical trial activities due to the inability of patients to come to their screening or monitoring visits, the closing of eye clinics, and/or diversion of resources that are necessary to conduct our future studies to care for COVID-19 patients.

The COVID-19 pandemic has caused us to modify our business practices including, but not limited to, curtailing or modifying employee travel, moving to partial remote work, and cancelling physical participation in meetings, events and conferences. We may

take further actions as may be required by government authorities or that we determine are in the best interests of our employees, patients and business partners.

The majority of our office-based employees have been working from home since March 2020, while ensuring essential staffing levels in our operations remain in place, including maintaining key personnel in our laboratories.

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 include:

- 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 sponsored research service agreements;
- 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 planned clinical trials;
- milestones and royalty expense from our Johns Hopkins University Exclusive License Agreement;
- 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 research and development expenses have been related to the preclinical and clinical development of GB-102. 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 use 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.

Based on our current operating plan, which is subject to change pursuant to our strategic review, we expect our research and development expenditures to increase substantially for the foreseeable future if we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, and if we continue to advance our programs and 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 is highly uncertain.

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future preclinical studies and clinical trials or if, when, or to what extent we will generate revenues from the commercialization and sale of our product candidates or if we even continue to pursue such product development, commercialization or sales. 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 product candidates, to the extent we continue to pursue such activities, will depend on a variety of factors, including:

- securing funding for GB-102 and GB-401, and the timely execution of resulting development plans, if any;
- successful completion of preclinical studies and clinical trials to the satisfaction of the FDA, European Medicines Agency, or 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.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify 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 and future preclinical and clinical 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 will 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 clinical trials, 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. We expect our general and administrative expenses to increase over the next several years to support our expanding headcount and operations, 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.

***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 Three Months Ended June 30, 2022 and 2021***

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

| | Three Months Ended June 30, | | Change | |
|---|---|---|---|---|
| | 2022 | 2021 | Amount | % |
| Operating expenses: | | | | |
| Research and development | $ 4,058 | $ 4,166 | $ (108) | (3%) |
| General and administrative | 4,243 | 3,575 | 668 | 19% |
| Total operating expenses | 8,301 | 7,741 | 560 | 7% |
| Loss from operations | (8,301) | (7,741) | (560) | 7% |
| Interest income | 60 | 33 | 27 | 82% |
| Net loss | $ (8,241) | $ (7,708) | $ (533) | 7% |

*Research and Development Expenses*

Research and development expenses comprised (in thousands):

| | Three Months Ended June 30, | | Change | |
|---|---|---|---|---|
| | 2022 | 2021 | Amount | % |
| Personnel costs | $ 1,870 | $ 1,939 | $ (69) | (4%) |
| CRO, CMO, nonclinical and other services | 1,041 | 1,476 | (435) | (29%) |
| Facility costs, travel and other | 575 | 334 | 241 | 72% |
| Professional services | 477 | 241 | 236 | 98% |
| Materials and supplies | 95 | 176 | (81) | (46%) |
| Total research and development expenses | $ 4,058 | $ 4,166 | $ (108) | (3%) |

As of June 30, 2022 and 2021, we had 20 and 19 employees, respectively, engaged in research and development activities in our Baltimore, Maryland and Redwood City, California facilities.

Our research and development expenses consist primarily of costs associated with the development of GB-102 for which we completed one U.S. Phase 2b clinical trial in patients with wet AMD in May 2021, and pre-clinical costs associated with the development of GB-401. Research and development expenses were $4.1 million and $4.2 million for the three months ended June 30, 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, largely offset by an increase in non-clinical outside expenses related to GB-401, and an increase in consulting fees related to GB-501. Based on our current operating plan, which is subject to change pursuant to our strategic review, we expect R&D expenses to increase in 2022 compared to 2021.

*General and Administrative Expenses*

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

| | Three Months Ended June 30, | | Change | |
|---|---|---|---|---|
| | 2022 | 2021 | Amount | % |
| Personnel costs | $ 2,092 | $ 1,779 | $ 313 | 18% |
| Professional services | 984 | 615 | 369 | 60% |
| Facility costs, travel and other | 817 | 856 | (39) | (5%) |
| Patent filing and portfolio costs | 350 | 325 | 25 | 8% |
| Total general and administrative expenses | $ 4,243 | $ 3,575 | $ 668 | 19% |

As of June 30, 2022 and 2021, we had 9 and 8 employees, respectively, engaged in general and administrative activities principally in our Redwood City, California facility.

General and administrative expenses were $4.2 million and $3.6 million for the three months ended June 30, 2022 and 2021, respectively. The increase was primarily due to an increase in stock-based compensation and an increase in professional services, including legal and accounting.

***Comparison of the Six Months Ended June 30, 2022 and 2021***

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

| | Six Months Ended June 30, | | Change | |
|---|---|---|---|---|
| | 2022 | 2021 | Amount | % |
| Operating expenses: | | | | |
| Research and development | $ 10,115 | $ 10,614 | $ (499) | (5%) |
| General and administrative | 8,370 | 8,615 | (245) | (3%) |
| Total operating expenses | 18,485 | 19,229 | (744) | (4%) |
| Loss from operations | (18,485) | (19,229) | 744 | (4%) |
| Interest income | 95 | 72 | 23 | 32% |
| Net loss | $ (18,390) | $ (19,157) | $ 767 | (4%) |

*Research and Development Expenses*

Research and development expenses comprised (in thousands):

| | Six Months Ended June 30, | | Change | |
|---|---|---|---|---|
| | 2022 | 2021 | Amount | % |
| Personnel costs | $ 3,662 | $ 4,207 | $ (545) | (13%) |
| Acquired in-process research and development | 2,193 | — | 2,193 | 0% |
| CRO, CMO, nonclinical and other services | 2,133 | 4,041 | (1,908) | (47%) |
| Facility costs, travel and other | 1,161 | 997 | 164 | 16% |
| Professional services | 752 | 627 | 125 | 20% |
| Materials and supplies | 214 | 742 | (528) | (71%) |
| Total research and development expenses | $ 10,115 | $ 10,614 | $ (499) | (5%) |

Our research and development activities consist primarily of costs associated with the development of GB-102 for which we completed one U.S. Phase 2b clinical trial in patients with wet AMD during 2021, and pre-clinical costs associated with the development of GB-401. Research and development expenses were $10.1 million and $10.6 million for the six months ended June 30, 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, and a decrease in personnel costs due to severance expense incurred in the first half of 2021, this decrease was mostly offset 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. Based on our current operating plan, which is subject to change pursuant to our strategic review, we expect R&D expenses to increase in 2022 compared to 2021.

*General and Administrative Expenses*

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

| | Six Months Ended June 30, | | Change | |
|---|---|---|---|---|
| | 2022 | 2021 | Amount | % |
| Personnel costs | $ 4,132 | $ 3,441 | $ 691 | 20% |
| Professional services | 2,147 | 1,433 | 714 | 50% |
| Facility costs, travel and other | 1,552 | 1,827 | (275) | (15%) |
| Patent filing and portfolio costs | 539 | 562 | (23) | (4%) |
| Write-off of deposits on fixed assets purchase commitments | — | 1,352 | (1,352) | (100%) |
| Total general and administrative expenses | $ 8,370 | $ 8,615 | $ (245) | (3%) |

General and administrative expenses were $8.4 million and $8.6 million for the six months ended June 30, 2022 and 2021, respectively. The decrease was primarily due to the write-off of deposits on fixed-asset purchase commitments in March 2021, which was offset in part by an increase in stock compensation and professional services, including legal and accounting.

**Liquidity and Capital Resources**

**Overview**

To date, we have incurred losses and negative cash flows from operations. As of June 30, 2022, we had available cash, cash equivalents and short-term investments of $50.7 million and an accumulated deficit of $187.6 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, or IPO.

On June 28, 2022 we announced that we would conduct a comprehensive review of strategic alternatives focused on maximizing shareholder value. As part of our review we are exploring the potential for an acquisition, company sale, merger, divestiture of assets, private placement of equity securities, or other strategic transactions.

We incurred net losses of $8.2 million and $7.7 million for the three months ended June 30, 2022 and 2021, respectively, and $18.4 million and $19.2 million for the six months ended June 30, 2022 and 2021, respectively. Based on our current operating plan, which is subject to change pursuant to our strategic review, we 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, the receipt of additional payments on the licensing of our technology, if any, and the receipt of payments under any current or future collaborations we may enter into.

Based on our current operating plan, which is subject to change pursuant to our strategic review, we believe our cash, cash equivalents and short-term investments of $50.7 million at June 30, 2022 will fund our projected operations into the fourth quarter of 2023.

***Commitments and Other Obligations***

For a detailed description of our commitments and obligations as of June 30, 2022, see Note 5 – Commitments and Contingencies, to the condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

*Leases*

We have lease arrangements for certain equipment and facilities, including corporate and research and development facilities. As of June 30, 2022, we had fixed lease payment obligations of $0.4 million which are payable within 12 months.

*License Agreements*

We are party to agreements pursuant to which we have in-licensed and purchased various intellectual property rights. These agreements obligate us to make certain milestone payments related to achievement of specified events, as well as royalties in the low-single digits based on sales of certain products. None of these events had occurred as of June 30, 2022, and no royalties were due from the sales of licensed products.

*Other Commitments*

We enter into contracts in the normal course of business with CROs for clinical trials and CMOs for clinical supply manufacturing and with vendors for equipment, preclinical research studies, research supplies and other services and products for operating purposes. As of June 30, 2022, these commitments were approximately $3.2 million due within 3 to 9 months. These contracts generally provide for termination on notice of 60 to 90 days, and therefore we believe that our non-cancelable obligations under these agreements are not material.

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***

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. Based on our current operating plan, which is subject to change pursuant to our strategic review, we expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. Our primary uses of capital are, and, subject to our strategic review, we currently expect will continue to be, compensation and related expenses, third-party clinical research, manufacturing and development services, costs relating to the build-out of our headquarters, laboratories and manufacturing facility, 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.

Based on our current operating plan, which no longer includes the cost of Phase 3 clinical trials for GB-102 and is subject to change pursuant to our strategic review, we believe 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 only proceed with further Phase 3 clinical trials for GB-102 if fully or partially funded by a partner. 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 will 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.

Subject to our strategic review, our current business plan will continue to require additional financing to advance our current 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 will 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. Our future funding requirements will 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, 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 product candidates, we are unable to estimate the amounts of increased capital and operating expenditures associated with our current and anticipated product development programs.

***Cash Flows***

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2022** | **2021** |
| Net cash (used in) provided by: | | |
| Operating activities | $ (10,663) | $ (17,045) |
| Investing activities | 11,240 | (9,096) |
| Financing activities | (69) | 587 |
| Net increase (decrease) in cash and cash equivalents | $ 508 | $ (25,554) |

***Operating Activities***

Cash used in operating activities of $10.7 million during the six months ended June 30, 2022 was primarily attributable to our net loss of $18.4 million partially offset by non-cash stock-based compensation of $3.3 million, $2.2 million in acquired in-process research and development and a decrease of $1.8 million in our working capital.

Cash used in operating activities of $17.0 million during the six months ended June 30, 2021 was primarily attributable to our net loss of $19.2 million and an increase of $0.6 million in our working capital, partially offset by non-cash charges of $2.8 million principally with respect to stock-based compensation.

***Investing Activities***

Cash provided by investing activities of $11.2 million during the six months ended June 30, 2022 consisted of $29.8 million cash provided upon maturity of short-term investments, partially offset by $16.4 million of purchases of short-term investments, $1.9 million paid during the period to acquire in-process research and development, and $0.2 million of purchases of property and equipment.

Cash used in investing activities of $9.1 million during the six months ended June 30, 2021 consisted of $58.1 million of purchases of investments and $0.3 million of purchases of property and equipment, partially offset by $49.3 million provided upon maturity of short-term investments.

***Financing Activities***

There were no material cash activities from financing activities during the six months ended June 30, 2022.

Cash provided by financing activities of $0.6 million during the six months ended June 30, 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.

Refer to "Recently Adopted Accounting Pronouncements" within Note 2 to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for a discussion of how we changed the way we account for leases under Topic 842.

**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, or 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 as of June 30th. 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**

See Note 2 to our condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for more information about the recent accounting pronouncements, the timing of their adoption, and our assessment.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk.**

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information required under this item.

**Item 4. Controls and Procedures.**

***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated 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, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

**Item 1. Legal Proceedings.**

We are not party to any material legal proceedings at this time. From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business.

**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 Quarterly Report on Form 10-Q, 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:

- We may not be successful in identifying and implementing any strategic business combination or other transaction, including, but not limited to, a failure to secure any required approvals from regulators, stockholders or other parties.
- Any strategic transactions that we may consummate in the future could have negative consequences.
- We may seek to liquidate the Company in a voluntary dissolution under Delaware law, and in this event, it is possible that shareholders would receive significantly less than the current market value of their shares.
- If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.
- 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.
- We are seeking a strategic transaction to fund further development of GB-102 for wet AMD. Without such a transaction, further development of GB-102 for wet AMD is unlikely.
- We 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-102 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.
- If serious adverse or unacceptable side effects are identified during the development of GB-102 or any other product candidates that we may develop, we may need to abandon or limit our development of such product candidates.
- The ongoing COVID-19 pandemic may, directly or indirectly, adversely affect our business, results of operations and financial condition.
- We may not be successful in our efforts to develop product candidates based on our proprietary technology other than GB-102 or expand the use of our proprietary technology for treating additional eye diseases and conditions.
- Sunitinib, the active ingredient of GB-102, has a boxed warning regarding hepatotoxicity for its use in oncology indications.
- 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, or 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.
- We may enter into collaborations with third parties for the development and commercialization of GB-102 or other product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.
- 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 licensors, Johns Hopkins University and 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 limit our ability to contract with non-U.S. manufacturers.
- If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.
- 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.
- We expect 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 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.
- 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.
- 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.

**Risks Related to Our Financial Position and Need For Additional Capital**

***We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transactions that we may consummate in the future could have negative consequences.***

We continue to evaluate all of our potential strategic options, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we may incur significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges, as well as the ordinary costs of our operations. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or such a transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders. Any delays in identifying a potential counterparty will cause our cash balance to continue to deplete, which could make us less attractive as a strategic counterparty. The continued review of our strategic options may also create continued uncertainty for our employees and this uncertainty may adversely affect our ability to retain key employees and to hire new talent necessary to maintain our ongoing operations or to execute additional potential strategic options, which could have a material adverse effect on our business. Further, the market capitalization of our company is below the value of our cash, cash equivalents and short-term investments. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our remaining assets.

In addition, any strategic business combination or other transaction that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affect our business and decrease the remaining cash available for use in our business or the execution of our strategic plan. Our board of directors remains dedicated to diligently deliberating upon and making informed decisions that the directors believe are in the best interests of the Company and its stockholders. However, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, be successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any potential future distributions to our stockholders. In addition, given the uncertainties of our financial position, it may be difficult to evaluate our current business and future prospects on the basis of our historical operating performance.

***If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.***

The negotiation and consummation of any strategic transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities and operating risks;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or incurrence of non-recurring, impairment or other charges;

- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- difficulty and cost in transitioning the operations and personnel of any divested business to a buyer's operations;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

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

***We may seek to liquidate the Company in a voluntary dissolution under Delaware law and, in this event, it is possible that shareholders would receive significantly less than the current market value of their shares.***

We have not generated any revenues from product sales and have incurred losses in each year since our inception. We expect that it will be very difficult to raise capital to continue our current operations. We do not believe that we could succeed in raising significant additional capital to sustain our operations without a strategic transaction such as a merger or sale. If we are unable to consummate such a transaction, we expect that we would need to cease all operations and wind down. Although we are currently evaluating our strategic alternatives with respect to all aspects of our business, we cannot assure you that any actions that we would take would raise or generate sufficient capital to fully address the uncertainties of our financial position. If we cease all operations and wind down, we would need to liquidate the Company in a voluntary dissolution under Delaware law. In this event, we would be required to sell all of our assets. The funds resulting from the liquidation of our assets, as well as our other funds, would be used first to satisfy any obligations to creditors and the material expenses of the dissolution process itself before funds, if any, would be available to pay our shareholders. We believe that these costs will consume a significant portion of our funds, thereby reducing the portion of our assets available for this distribution.

***We have historically been 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.***

Since inception, we have incurred significant operating losses. Our net loss was $8.2 million and $7.7 million for the three months ended June 30, 2022 and 2021, respectively, and $18.4 million and $19.2 million for the six months ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of $187.6 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, or 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. Subject to our strategic review, 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 any strategic alternatives and continue exploration of certain pre-clinical research and development initiatives.

Based on our current operating plan, which is subject to change pursuant to our strategic review, we 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-102;
- commence clinical trials of our product candidate GB-401;
- continue the research and development of other product candidates;
- 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, or 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 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.***

Based on our current operating plan, which is subject to change pursuant to our strategic review, we expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct pre-clinical studies or clinical trials for our wet AMD product candidates, preclinical studies and clinical trials for our other product candidates, and seek marketing approval for any such product candidate for which we obtain favorable clinical results. Significant financial resources will be required to conduct research and development and to potentially seek regulatory approval for our other product candidates. In addition, substantial financial resources will be required for 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 will 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 June 30, 2022, we had cash, cash equivalents and short-term investments of $50.7 million, which, based on our current operating plan, which is subject to change pursuant to our strategic review, 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-102;
- the scope, progress, costs and outcome of preclinical development and clinical trials of our product candidates;

- 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 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 do not expect to generate sales of any commercial product for several years, if at all. Accordingly, we believe that we need to obtain substantial additional financing to achieve our current business objectives, which are subject to change pursuant to our strategic review. 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 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. We will 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 approach to the treatment of retinal diseases is unproven, and we do not know whether we will be able to successfully develop any products.***

GB-102 is designed to deliver therapeutic drug levels to the retinal tissue for up to six months from a single intravitreal injection. There are currently no FDA-approved therapies that treat retinal diseases with a six-month dosing regimen. Subject to our strategic review, our future success currently depends on the successful development of product candidates, including GB-102, based on this novel therapeutic approach. We have not yet demonstrated efficacy and safety for GB-102 or any other product candidates in a pivotal trial or obtained marketing approval of any product candidate. GB-102 may not demonstrate in patients any or all of the pharmacological 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-102 or any other product candidate, commercialize products, raise capital, expand our business or continue our operations.

***We will require a strategic transaction to fund further development of GB-102 for wet AMD. Without such a transaction, further clinical development of GB-102 for wet AMD is unlikely.***

We do not have sufficient cash resources to complete additional clinical trials for both GB-102 and GB-401 at this time. As part of our strategic review, we are evaluating transactions to fund continued development of GB-102 and GB-401. Such transactions generally require substantial amounts of time to secure, and often involve economic returns that are significantly reduced from that attainable by developing and commercializing the product without a strategic transaction. Moreover, while we are actively seeking such a transaction, there can be no guarantee that we will secure one in a timely fashion, or on reasonable economic terms, if at all. Failing to secure such a transaction could have a material adverse effect on our business.

***We 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. 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-102.

The success of GB-102 and other product candidates 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 secure a transaction to fund future clinical trials in wet AMD with GB-102;
- 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 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.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will 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-102 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-102, 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.

We designed our Phase 1/2a, Phase 2a and Phase 2b clinical trials of GB-102 to assess safety and preliminary efficacy and did not power the trials to measure any efficacy endpoints with statistical significance. We expect that our Phase 3 clinical trials for GB-102 for the treatment of wet AMD will be the first clinical trial for GB-102 to be powered with an appropriate number of patients to allow us to measure with statistical significance the non-inferiority of GB-102 compared to the standard of care. As a result, favorable results from our Phase 1/2a, Phase 2a, and potential future clinical trials may not necessarily predict a likelihood of achieving statistical significance on our primary efficacy endpoint in the Phase 3 clinical trials, which will be required for us to obtain marketing approval of GB-102. Historically, the FDA has required that Phase 3 clinical trials in wet AMD use some measure of patient visual performance as the primary endpoint to evaluate efficacy, most often Best Corrected Visual Acuity, or BCVA. Although it was not powered to statistically determine efficacy, our Phase 2b clinical trial of GB-102 showed that, on average across all time points, patients on the 1 mg dose of GB-102 were assessed to have a mean BCVA across all time points of approximately 9 letters lower than that observed in the trial control arm, in which patients received bi-monthly injections of Eylea. If such a difference were to be repeated in a Phase 3 clinical trial of GB-102, it is unlikely that the FDA would approve the product based on a claim of non-inferiority to Eylea. Additionally, our clinical trials to date have only evaluated GB-102 against treatment with Eylea, and there may be current or future products that deliver better results in terms of safety and/or efficacy.

The success of our product candidates is dependent upon the drug-elution profile during the course of intended therapy. Our Phase 1/2a and our Phase 2a trials have been open label and have not been compared to any active treatments. The treatment phase of our Phase 2b trial with GB-102 in wet AMD included a control arm with Eylea, which is the current standard of care. Compared to Eylea, GB-102 1 mg demonstrated median durability of 5 months and improved safety profile. Compared to Eylea, we observed non-statistical similar control of Central Subfield Thickness, or CST, of the retina, and lower average BCVA across all time points. In March 2020, we terminated the development of the 2 mg dose of GB-102 in all of our clinical trial programs, including the arm of our Phase 2b trial, so the results of that arm have been disregarded. If we make any future changes to the formulation, such changes could affect the outcome of any subsequent clinical trials. As a result of any of these therapeutic or formulation changes, the outcome of our potential future or Phase 3 clinical trials may differ from the outcome of our Phase 1/2a and Phase 2b clinical trials. If the BCVA results of clinical trials with any potential new therapeutic or product formulation, including therapies that do not involve intravitreal delivery, are similar to the results from the Phase 2b trial, we may not be able to obtain regulatory approvals or, even if approved, achieve market acceptance of our product candidates.

***The outcome of preclinical testing and early clinical trials may not be predictive of the success of later-stage clinical trials.***

Successful results in preclinical or early clinical trials do not ensure that later-stage clinical trials will be successful. In January 2019, we completed our Phase 1/2a trial of GB-102 evaluating various doses of GB-102 in patients with wet AMD. Although the data indicated that GB-102 was well-tolerated and reduced the need for supportive anti-vascular endothelial growth factor, or anti-VEGF, treatments, these results may not be indicative of future clinical trials with different designs. For example, 88% of patients in our Phase 1/2a trial of GB-102 1 mg did not require additional supportive therapy for six months or longer, while only 48% of patients in our Phase 2b ALTISSIMO trial of GB-102 1 mg achieved six months without requiring additional supportive therapy. Moreover, as is common for early trials, in our Phase 1/2a trial, we looked at a number of efficacy measures without accounting for multiplicity. Accordingly, it is possible that positive results, including nominally statistically significant results, observed in our Phase 1/2a trial will not be replicated in our future trials with a different design or in other future trials.

Subsequently, we tested two doses of an optimized formulation of GB-102 in a Phase 2a clinical trial in patients with macular edema, or ME, secondary to either DME or branch/central retinal vein occlusion, or RVO, as well as in the completed Phase 2b clinical

trial in wet AMD. In the Phase 2a trial, we observed that there were more incidences of medication present in the anterior chamber with the 2 mg dose of GB-102, which, in a single patient, resulted in two serious adverse events, or SAEs (severe vision loss due to presence of medication in anterior chamber and corneal edema as a result of wash-out of the anterior chamber). As a result, we paused enrollment in our Phase 2b wet AMD trial until an interim safety analysis of both trials could be performed. On the basis of the results of this safety analysis, we terminated the development of the 2 mg dose of GB-102 in all of our clinical trial programs and have disregarded the results, other than those related to safety, of the GB-102 2 mg arm of the ALTISSIMO Phase 2b trial.

Some of our clinical trials, including our Phase 1/2a clinical trial and our completed Phase 2b clinical trial of GB-102 for the treatment of wet AMD, had small patient populations, making it difficult to predict whether the favorable results from such trials will be repeatable in larger, more advanced clinical trials. 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-102 or any other product candidates that we may develop, we may need to abandon or limit our development of such product candidates.***

If GB-102 or any of our other product candidates are associated with 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.

Out of 32 patients enrolled in our Phase 1/2a trial, no GB-102 related non-ocular adverse events, or AEs, and no SAEs or dose limiting toxicities were reported. All drug-related AEs were mild or moderate and transient and resolved by the end of the trial. The most common AE observed in more than one patient was vitreous floaters (n=5). Most vitreous floaters are caused by age-related changes that occur as the vitreous becomes more liquid.

Microscopic fibers in the vitreous tend to clump and can cast tiny shadows on the retina, commonly referred to as floaters. Intravitreal injections can increase the number of floaters, and any other particle that similarly casts a shadow may also be referred to as a floater. For nine patients enrolled in the higher dose cohorts, medication presence was observed in the anterior chamber. All nine of those patients completed the trial. Overall, the medication presence in the anterior chamber appeared to be self-limited and reversible, with no long-term consequences.

In our Phase 2a clinical trial, there were no drug-related, non-ocular AEs. The patients in the 1 mg dose experienced nine drug related AEs, and seven out of ten patients demonstrated no AEs. One patient had only vitreous floaters, medication present in the vitreous, and one patient had vitreous floaters coincident with a reduction in vision. The other AEs occurred in a single patient with medication present in the anterior chamber. The 2 mg dose was associated with medication present in the anterior chamber in five out of 11 patients. The majority of AEs occurred in one patient. Two SAEs were reported in a single patient (severe vision loss due to presence of medication in the anterior chamber and corneal edema as a result of wash-out of the anterior chamber).

Our Phase 2b clinical trial of GB-102 was designed to test two different doses: 1 mg and 2 mg. We conducted an interim safety analysis in the trial and found that the presence of medication in the anterior chamber was reported in four patients in the GB-102 2 mg dose group and one patient in the 1 mg dose group. On the basis of these data, we terminated the development of the 2 mg dose of GB-102 in all of our clinical trial programs. We believe that the number of microparticles injected in the 2 mg dose (approximately 2 million) were too numerous to allow adequate aggregation. All patients in the Phase 2b trial having received GB-102 at either the 1 mg or 2 mg doses for the first six-month period of the trial received the 1 mg dose as repeat therapy at month six.

In the 12-month treatment phase of our Phase 2b clinical trial, there were no drug-related, non-ocular AEs in the GB-102 1 mg arm, nor were there any drug-related SAEs nor dose-limiting toxicity. No treatment-emergent adverse events led to drug discontinuation and none of the adverse events required surgical intervention. Nine out of the 21 patients in the 1 mg dose experienced 23 events of drug related AEs. Five patients had vitreous floaters attributable to GB-102 1 mg and, in the majority of patients, these had no or minimal transient effect on visual acuity. Medication was detected in the anterior chamber, or AC, in three out of 21 patients. In one patient, the presence of particles in the AC was transient with no other associated adverse events. In two patients, the presence of GB-102 microparticles in the AC was associated with transient inflammation and there was an associated moderate BCVA loss in one of these patients. An additional three patients had intraocular inflammation that was mild to moderate, responded well to short courses of treatment with corticosteroids, and was not associated with any change in BCVA. One patient had dispersion of GB-102 microparticles in the vitreous cavity that were not characterized as floaters but was associated with a decrease in visual acuity.

In the six-month, post treatment observational phase of our Phase 2b clinical trial, no drug-related adverse events or vision-threatening inflammation were reported. One patient on GB-102 1 mg developed a cataract, which was evaluated to be unrelated to GB-102 treatment.

There are potential side effects that are related to intravitreal injection procedures. These side effects are shared by any treatment that uses intravitreal 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, our product candidate that is a gene therapy, 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, an adeno-associated virus (AAV) gene therapeutic to treat corneal clouding caused by mucopolysaccharidosis type 1 (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. Serious adverse events 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 ongoing 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, which has spread to many of the countries in which we and our suppliers do business. National, state, and local governments in affected regions have implemented and may continue to implement safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter in place orders and shutdowns, business closures, cancellations of public gatherings and other measures. Organizations, businesses and individuals are taking additional steps to avoid or reduce infection, including business and facility closures or suspensions, limitations on travel and remote working measures. These measures are disrupting normal business operations both in and outside of affected areas and have had significant negative impacts on businesses and financial markets worldwide. As new variants of the coronavirus emerge, or if the rates of infections increase, these measures and associated disruptions could intensify in both scope and adverse impact on our business, results of operations and financial condition.

The COVID-19 pandemic has 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) and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, patients and business partners. The majority of our office-based employees have been working from home since March 2020, while we ensure essential staffing levels in our physical operations remain in place, including maintaining key personnel in our laboratories. Further, given that a greater number of our employees are working remotely than usual in response to the COVID-19 pandemic and related government actions, we could be exposed to greater risks related to cybersecurity and our information technologies systems.

Notwithstanding these measures, the COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third parties we rely on taking similar measures. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to the COVID-19 pandemic, we may not be able to execute on our business strategy and/or our operations may be negatively impacted. We may also experience limitations in employee resources, including because of sickness of employees or their families or the desire of employees to avoid contact with individuals or large groups of people. 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-102 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. COVID-19 could potentially lead to the closure of our research lab and potentially delay IND-enabling activities, which could delay the start of clinical trials. 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-102 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. It is further possible that the COVID-19 pandemic will cause another economic slowdown of potentially extended duration.

While it is not possible at this time to estimate the entirety of the impact that the COVID-19 pandemic will have on our business, operations, employees, customers or suppliers, continued spread of COVID-19, measures taken by governments, actions taken to protect employees and the broad impact of the pandemic on all business activities may materially and adversely affect our business, results of operations and financial condition, and the nature and extent of such impact is highly uncertain and unpredictable.

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

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our retinal 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 contemplate, 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 will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will 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.

***If we 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 our wet AMD, glaucoma, 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 not be successful in our efforts to develop product candidates based on our proprietary technology other than GB-102 or expand the use of our proprietary technology for treating additional eye diseases and conditions.***

We are currently directing the majority of our development efforts towards applying our proprietary technology to product candidates that are designed to provide sustained delivery of therapeutic agents to the eye using active pharmaceutical ingredients that are currently used in FDA-approved drugs, and are just beginning to focus on gene therapies for diseases of the eye. We have a number of product candidates at various stages of development and are exploring the potential use of our proprietary technologies in other eye diseases and conditions. Our existing product candidates and any other potential product candidates that we identify may not be suitable for continued preclinical or clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize our product candidates that we develop based upon our technological approach, we will not be able to obtain substantial product revenues in future periods.

***Sunitinib, the active ingredient of GB-102, has a boxed warning regarding hepatotoxicity for its use in oncology indications.***

Sunitinib, which was originally developed for the treatment of renal cell carcinoma and gastrointestinal stromal tumors, has been shown to cause liver damage, or hepatotoxicity, in some patients. As a result, in 2010, the prescribing information for orally administered sunitinib for its use in treating renal cell carcinoma and gastrointestinal stromal tumors was revised to include a boxed warning regarding hepatotoxicity. A boxed warning is a warning put in the labeling of a drug product that is designed to call attention to serious or life-threatening risks.

There is no approved therapy for retinal diseases using sunitinib. We have not seen any evidence of hepatotoxicity in our preclinical studies or clinical trials. Moreover, preclinical toxicity studies and the results of our Phase 1/2a and Phase 2b clinical trials with GB-102 have not detected the presence of sunitinib in the systemic blood circulation at any time point. However, the boxed warning for orally administered sunitinib may make it more difficult for us to achieve widespread market acceptance or regulatory approval for our product candidates.

Moreover, there can be no assurance that comparable AEs and other side effects will not appear over the course of our trials, which could have a material adverse effect on our business and operating results.

***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 ("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, or OTAT, within the Center for Biologics Evaluation and Research, or 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 HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or 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, or 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 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.***

We currently rely on third parties for the production of GB-102 and our product candidates for preclinical testing and clinical trials, including supply of active pharmaceutical ingredient drug substance, sunitinib, as well as polymers used in the formulations, such as poly (lactic-co-glycolic acid), or PLGA, injection devices, and other raw materials and for sterilization of the finished product. Based on our current operating plan, which is subject to change pursuant to our strategic review, we intend to build our own manufacturing capabilities for our drug formulations, but could also decide to keep contracting with third parties if it is more advantageous. While we believe that our existing manufacturing partners have facilities that will be sufficient to meet our requirements for manufacturing GB-102 and any of our product candidates for which we obtain marketing approval, we may in the future need to rely on additional contract manufacturing organizations, or CMOs, 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 CMOs, 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 CMOs 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 CMOs 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 CMOs must maintain adequate quality control, quality assurance and qualified personnel. If we or our CMOs 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 CMOs, 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 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.***

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. For example, due to adverse events related to presence of medication in the anterior chamber observed in some patients in the Phase 1/2a trial for GB-102, changes were made to the manufacturing process for GB-102. 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.

For our ALTISSIMO Phase 2b trial, GB-102 was manufactured by Lubrizol Life Science Health. We will need to obtain future supplies of GB-102 from our own manufacturing or from third-party manufacturers that we have engaged, or expect to engage. Although we are working to develop commercially viable manufacturing processes, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale up, formulation or formulation changes, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. 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 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.***

In order to conduct clinical trials of, and commercialize, our product candidates, we will need to manufacture them in large quantities. We may, in the future, establish and operate our own manufacturing facility, which will 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.

***Changes in methods of product candidate manufacturing, including changes introduced by building our own manufacturing capabilities, may result in additional costs or delay.***

We currently rely on third parties for the large-scale production of GB-102 as well as for our product candidates used in preclinical testing and clinical trials, including supply of active pharmaceutical ingredient drug substance, sunitinib, as well as polymers used in the formulations, such as PLGA, injection devices, other raw materials, and for the sterilization of the finished product. Based on our current operating plan, which is subject to change pursuant to our strategic review, we intend to build our own manufacturing capabilities for our polymer-based product candidates, and it is common that various aspects of the development program, such as manufacturing methods, may be altered in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates and generate revenue.

***Our current operations are in two locations, 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.***

Our current operations are located in Baltimore, Maryland and Redwood City, California, and our currently planned clinical trials will be conducted at a limited number of other sites. 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 fully utilize our facilities, or the manufacturing facilities of our CMOs, 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 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 headquarters, that damaged critical infrastructure, such as our research or manufacturing facilities or the manufacturing facilities of our CMOs, 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 at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs, 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-102 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-102 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-102 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.

For example, even though we believe that GB-102 will have a longer duration of effect compared to approved treatments for wet AMD, it is possible that the market acceptance of GB-102, if it is approved for marketing, could be less than anticipated.

Our assessment of the potential market opportunity for GB-102 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-102 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-102 without a partner, and we will be dependent on such partner, should we secure one, for the successful sales, marketing and distribution of GB-102. 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 product candidates other than GB-102 are approved for marketing, and our strategic review results in our retention of marketing rights to such products, we plan on 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 will be required to effectively market and sell these products. We cannot be certain when, if ever, we will 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 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.

The current standard of care for wet AMD is monotherapy administration of anti-VEGF drugs, principally Eylea, Avastin and Lucentis, which are well-established therapies and are widely accepted by physicians, patients and third-party payors, as well as the Port Delivery System with ranibizumab, or PDS, and Beovu, the two most recently approved anti-VEGF drugs. There are also several product candidates in late-stage clinical development for wet AMD, including those being developed by F. Hoffmann-La Roche AG, Kodiak Sciences Inc., Samsung Bioepis, Clearside Biomedical, Inc., Regeneron Pharmaceuticals, Inc., REGENXBIO, Inc., Chengdu Kanghong Pharmaceutical Group Co., Ltd, Outlook Therapeutics, Inc., and Opthea Limited. Physicians, patients and third-party payors may not accept the addition of GB-102 to their current treatment regimens for a variety of potential reasons, including:

- if they do not wish to incur the additional cost, if any, of GB-102;
- if they perceive the addition of GB-102 to be of limited benefit to patients compared to existing treatment options;
- if sufficient coverage and reimbursement are not available; and
- if they do not perceive GB-102 to have a favorable risk-benefit profile.

We are developing GB-102 as an alternative to existing anti-VEGF drugs, including Eylea, Avastin, Lucentis, Beovu, and PDS. Accordingly, if approved, GB-102 would directly compete with these therapies. While we believe GB-102 will compete favorably with existing anti-VEGF drugs, future approved standalone or combination therapies for wet AMD with demonstrated improved efficacy over GB-102 or currently marketed therapies with a favorable safety profile and any of the following characteristics might pose a significant competitive threat to us:

- a mechanism of action that does not involve VEGF;
- a duration of action that obviates the need for twice-yearly intravitreal injection;
- a method of administration that effectively avoids intravitreal injection; and
- significant cost savings or reimbursement advantages compared to GB-102 and other anti-VEGF therapies.

We also expect that product candidates currently in clinical development, or that could enter clinical development in the near future, could represent additional competition, if approved. These product candidates may provide efficacy, safety, convenience and other benefits that are not provided by currently marketed therapies. Because there are a variety of means to treat wet AMD, our patents and other proprietary protections for GB-102 will not prevent development or commercialization of product candidates that are different from GB-102.

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.

If the development of GB-102 is delayed due to the time required to secure either a strategic transaction or partner funding, or if such a partner requires additional clinical trials before commencing Phase 3 trials, the commercial launch of GB-102 could be delayed by several years. Such a delay could afford our competitors significant advantages in market adoption, penetration and reimbursement, and the future pricing of our products could be driven down substantially by a larger number of mature competitors. Any or all of these factors could significantly reduce the potential future revenue generated by GB-102 and adversely impact our stock price.

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-102 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-102 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-102 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-102, and may also do so for our other product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.***

We may utilize a variety of types of collaboration arrangements with third parties to develop or commercialize GB-102 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 Quarterly Report on Form 10-Q 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 some of our product candidates, we may decide to transact with pharmaceutical, biotechnology and 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, pursuant to our strategic review, we elect 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 GB-102 and other 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, or 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, pending U.S. provisional and non-provisional patent applications, as well as pending Patent Cooperating Treaty applications and associated foreign patents and patent applications. 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 Johns Hopkins University, or JHU, although we have input into the prosecution. We also do not control the prosecution of the exclusively licensed patent and patent applications from the University of North Carolina at Chapel Hill, or UNC, 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, or 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.

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, or 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-102 uses our proprietary aggregating microparticle technologies to deliver sunitinib for ocular treatment. If a competitor develops a product that uses a different particle or non-particle technology to deliver sunitinib to the eye, it may be able to compete with us without infringing our owned or licensed patents, as the patents on sunitinib expired in August 2021. GB-401 includes our proprietary beta-adrenergic blocking agent prodrug molecule in our proprietary sustained release formulation technology. If a competitor develops a product that uses a different prodrug of the same beta-blocker, or the beta-blocker itself, or uses a delivery system that is different from our proprietary sustained release formulation technologies, then it may be able to compete with our GB-401 product without infringing our owned or licensed patent claims. Likewise, GB-501 is a recombinant adeno-associated virus (AAV)-based construct encoding L-iduronidase for use in treating Mucopolysaccharidosis type I (MPS I) 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. GB-601 includes our proprietary cyclic guanosine monophosphate analog for the treatment of retinitis pigmentosa (RP). If a competitor develops a cGMP analog not encompassed by our owned patent claims, then it may be able to compete with our GB-601 product without infringing. 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.

The Leahy-Smith America Invents Act, or 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 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 (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, or FDCA, or trade secret protection.

***Patents filed by our licensors, Johns Hopkins University, and 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 JHU or 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, or 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 JHU or 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 JHU or 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 several of our current clinical candidates incorporate small molecules, after commercialization they will be subject in the United States to the patent litigation process of the Hatch-Waxman Amendments, which allows a generic company to submit an Abbreviated New Drug Application, or 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 our GB-102 product 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, or NCEs, for which GB-401 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 immediately after FDA approval of our GB-102 product and four years after

approval of GB-401. 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 Biologics License Application (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, or 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 so 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, or 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, or 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.

***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 JHU, we could lose license rights that are necessary for developing and commercializing one or more of our product candidates.***

Our exclusive license with JHU for technology relating to our lead product candidates imposes various development, commercialization, royalty payment, diligence and other obligations on us. Specifically, we are required to:

- pay JHU a minimum royalty fee and potential milestone payments;
- pay JHU low single-digit royalties on all net sales of products and a share of any sublicensing revenues;
- use commercially reasonable efforts to bring products to market;
- provide royalty reports to JHU; and
- indemnify JHU against certain claims and maintain insurance coverage.

If we breach any of these obligations, JHU 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.

***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. 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;
- 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 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 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 Phase 2a trial of GB-102 for the treatment of ME secondary to DME or RVO, 16 of the 21 patients had at least one drug-related AE, with the majority of them in the 2 mg dosing arm. In addition, one patient in the 2 mg dosing arm experienced two ocular SAEs. As a result, we decided to pause enrollment of new patients in our Phase 2b wet AMD trial until we could collect more data on the Phase 2a trial. We

subsequently conducted an interim safety analysis which led to the selection of the 1 mg dose for GB-102. We then amended the Phase 2b protocol such that all patients having originally received the 2 mg dose of GB-102 received the 1 mg dose as their repeat therapy at their six-month visit. In the treatment phase of our Phase 2b trial, nine of 21 patients in the 1 mg arm had at least one drug-related AE, and 17 of 22 patients in the 2 mg arm who were all subsequently re-dosed with 1 mg had at least one drug-related AE.

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 current or 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, or 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-102 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. For example, in 2021, the FDA initiated Project Optimus, which guided oncology drug developers away from faster, less expensive clinical trials focused on determining the maximum tolerable dose and toward more expensive, multi-arm trials studying a wide range of doses in order to find an optimal dose. In March 2022, the FDA published new guidance on drug/device combination products, in direct response to an appellate decision in Genus Med. Techs., LLC v. FDA, 2021. Under this new guidance, GB-401 may be determined by the FDA to be a “drug-led drug/device combination product”. This change in classification may subject our injection devices to regulation as device components of combination products. There can be no guarantee that such guidance will remain materially unchanged, so the actual regulatory classification of GB-401 may change, which may result in unplanned delays or costs associated with adoption of changed regulatory requirements.

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 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, or 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.

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.

***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, or 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 GB-401. 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. For GB-102, we are seeking to rely on the FDA's prior conclusions regarding the safety and effectiveness of sunitinib, which has previously been approved for the treatment of gastrointestinal stromal tumors, advanced renal cell carcinoma, and a certain type of pancreatic cancer. For GB-401, we intend to rely in part on the FDA's prior findings for the previously approved active pharmaceutical ingredient, or API, as well as relevant publications, and to conduct additional good laboratory practice, or GLP, toxicology studies with GB-401, to support the GB-401 IND and any future 505(b)(2) NDA.

If we cannot pursue the Section 505(b)(2) regulatory pathway, 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.

Moreover, our inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than GB-102 or GB-401, which would likely adversely impact our competitive position and prospects. Even if we can pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that GB-102 or GB-401 will receive the requisite approvals for commercialization.

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;
- the federal Health Insurance Portability and Accountability Act of 1996, or 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, or 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. By way of example, the Tax Cuts and Jobs Act of 2017, or the Tax Reform Act, included, among other things, a provision repealing 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." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, 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 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. 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 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 (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, (8) facilitate approval and prescription of biosimilar and generic drugs, (9) increase drug pricing transparency, (10) prohibit certain types of rebates to pharmacy benefit managers, and (11) 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 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, or 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, or 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, or 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, or 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, or GDPR, of the European Union, or 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, or 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 depends 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.

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 rely 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 expect 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.***

We expect to experience 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 we expect 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 product approvals. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and our limited experience in managing such anticipated 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.***

Based on our current operating plan, which is subject to change pursuant to our strategic review, we expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing 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:

- results of 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, 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 products 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 products, 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 efforts to secure a partner to fund further clinical development of GB-102;
- the success of our 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.

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 recent 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 the 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. Our stock has had a closing bid price of less than a dollar on more than one day. As our closing bid price was less than a dollar for thirty consecutive trading days, Nasdaq issued a notice of delisting to us on June 16, 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 December 13, 2022, and that we must otherwise satisfy Nasdaq's requirements for continued listing. On July 21, 2022, Nasdaq notified us that we had regained compliance, as the closing bid price of our common stock had been at $1.00 per share or greater for the then-preceding ten consecutive trading days.

If our closing bid price is less than $1.00 for another thirty consecutive trading days, then we anticipate receiving another notice of delisting from Nasdaq. If this occurs, and our plan to regain compliance includes a reverse stock split, then the liquidity of our common stock could be adversely impacted, which may further reduce our stock price. If we do receive such a notice, 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 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 the company's business, and insurance coverage may not be sufficient to cover all costs and damages.***

In the past, securities class action litigation has often followed 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 may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually

expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

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

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 21,517,682 shares of our common stock outstanding as of June 30, 2022. All shares of our common stock are freely tradable, generally without restrictions or further registration under the Securities Act of 1933, as amended, or 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 will 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.

We also expect that significant additional capital may be needed in the future to continue our currently planned 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 preclinical studies and clinical trials and results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such 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 June 30, 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.

As a result, these stockholders, if acting 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, or 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 $1.07 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 the prior 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. 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 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 30th. 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, or 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, or 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 after we are no longer 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

*Unregistered Sales of Equity Securities*

None.

*Use of Proceeds*

On September 29, 2020, we completed our initial public offering, or 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 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

| Exhibit Number | Description | Form | File No. | Exhibit Filing Date | Exhibit No. | Filed/Furnished Herewith |
|---|---|---|---|---|---|---|
| 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 |
| 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 |

* 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 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: August 11, 2022 By: /s/ Frederic Guerard

**Frederic Guerard, Pharm.D.**
**Chief Executive Officer**
**(Principal Executive Officer)**

Date: August 11, 2022 By: /s/ Robert S. Breuil

**Robert S. Breuil**
**Chief Financial Officer**
**(Principal Accounting and Financial Officer)**

**Exhibit 31.1**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Frederic Guerard, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Graybug Vision, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2022

By: /s/ Frederic Guerard

**Frederic Guerard, Pharm.D.**
**Chief Executive Officer**
**(Principal Executive Officer)**

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO**
**RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,**
**AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robert S. Breuil, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Graybug Vision, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2022

By: /s/ Robert S. Breuil

**Robert S. Breuil**
**Chief Financial Officer**
**(Principal Financial Officer and Principal Accounting Officer)**

**Exhibit 32.1**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Graybug Vision, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 11, 2022

By: /s/ Frederic Guerard

**Frederic Guerard, Pharm.D.**
**Chief Executive Officer**
**(Principal Executive Officer)**

**Exhibit 32.2**

**CERTIFICATION PURSUANT TO**
**18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO**
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Graybug Vision, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 11, 2022

By: /s/ Robert S. Breuil

**Robert S. Breuil**
**Chief Financial Officer**
**(Principal Financial Officer and Principal Accounting Officer)**