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 September 30, 2020

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	**452120079**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

275 Shoreline Drive, Suite 450
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 November 6, 2020 was 20,979,265.

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In this Quarterly Report on Form 10-Q, "we," "our," "us," "Graybug" and the "Company" refer to Graybug Vision, Inc. Graybug, Graybug Vision, Inc., the Graybug logo and other trade names, trademarks or service marks of Graybug are the property of Graybug Vision, Inc. This report contains references to our trademarks and to trademarks belonging to other entities. Trade names, trademarks and service marks of other companies appearing in this report 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 within the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of present and historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products, planned preclinical studies and clinical trials, regulatory approvals, research and development costs, and timing and likelihood of success, as well as plans and objectives of management for future operations, may be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to us. Such statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified in Part I. Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Part II. Item 1A "Risk Factors." These risks and uncertainties include, but are not limited to:

- our ongoing and planned clinical trials of GB-102 and our planned clinical trials of GB-103 and GB-401;
- the success, cost and timing of our development activities, preclinical studies and clinical trials;
- the translation of our preclinical results and data and early clinical trial results into future clinical trials in humans;
- the effects of the ongoing COVID-19 pandemic, and the corresponding responses of businesses and governments, on our business and financial results;
- the timing or likelihood of regulatory filings and approvals;
- our ability to receive the required regulatory approvals to market and sell our products in the United States and other countries;
- our ability to develop sales and marketing capabilities;
- the rate and degree of market acceptance of any products we are able to commercialize;
- the effects of increased competition as well as innovations by new and existing competitors in our market;
- our ability to obtain funding for our operations;
- our ability to establish and maintain collaborations;
- our ability to effectively manage our anticipated growth;
- our ability to maintain, protect and enhance our intellectual property rights and proprietary technologies;
- our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- costs associated with defending intellectual property infringement, product liability and other claims;
- regulatory developments in the United States and other foreign countries;
- our ability to attract and retain qualified employees;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- statements regarding future revenue, hiring plans, expenses, capital expenditures, capital requirements and stock performance.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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

	September 30, 2020	December 31, 2019 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 94,968	$ 15,870
Short-term investments	—	20,086
Prepaid expenses and other current assets	138	315
Total current assets	95,106	36,271
Property and equipment, net	1,788	1,975
Prepaid expenses and other non-current assets	1,491	2,414
Total assets	$ 98,385	$ 40,660
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,562	$ 4,636
Accrued research and development	1,023	2,333
Other current liabilities	2,156	3,124
Preferred stock tranche obligation	—	2,158
Total current liabilities	7,741	12,251
Deferred rent, long term portion	10	—
Total liabilities	7,751	12,251
Commitments and contingencies (Note 6)		
Convertible preferred stock	—	131,363
Stockholders' Equity (Deficit):		
Common stock	2	—
Additional paid-in capital	214,847	2,879
Accumulated deficit	(124,215)	(105,836)
Accumulated other comprehensive income	—	3
Total stockholders' equity (deficit)	90,634	(102,954)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 98,385	$ 40,660

See accompanying notes to unaudited condensed financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 4,757	$ 8,403	$ 15,474	$ 22,570
General and administrative	2,064	1,962	5,183	4,404
Total operating expenses	6,821	10,365	20,657	26,974
Loss from operations	(6,821)	(10,365)	(20,657)	(26,974)
Interest income	3	160	120	211
Change in fair value of preferred stock tranche obligation	2,102	—	2,158	—
Net loss	(4,716)	(10,205)	(18,379)	(26,763)
Cumulative dividends on convertible preferred stock	(2,396)	(2,048)	(7,189)	(4,633)
Net loss attributable to common stockholders	$ (7,112)	$ (12,253)	$ (25,568)	$ (31,396)
Net loss per common share—basic and diluted	$ (2.52)	$ (9.30)	$ (13.74)	$ (24.10)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	2,818,349	1,317,497	1,861,229	1,302,687

See accompanying notes to unaudited condensed financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	$ (4,716)	$ (10,205)	$ (18,379)	$ (26,763)
Unrealized gain (loss) on available-for-sale securities, net of tax	—	7	(3)	7
Comprehensive loss	$ (4,716)	$ (10,198)	$ (18,382)	$ (26,756)

See accompanying notes to unaudited condensed financial statements.

GRAYBUG VISION, INC.
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance—December 31, 2019	117,809,883	$ 131,363	1,371,467	$ —	$ 2,879	$ (105,836)	$ 3	$ (102,954)
Stock issued on exercise of stock options	—	—	5,446	—	11	—	—	11
Stock-based compensation expense	—	—	—	—	226	—	—	226
Net loss	—	—	—	—	—	(7,794)	—	(7,794)
Change in unrealized gains on available-for-sale securities, net of income tax	—	—	—	—	—	—	(3)	(3)
Balance—March 31, 2020	117,809,883	$ 131,363	1,376,913	$ —	$ 3,116	$ (113,630)	$ —	$ (110,514)
Stock issued on exercise of stock options	—	—	5,287	—	12	—	—	12
Stock-based compensation expense	—	—	—	—	214	—	—	214
Net loss	—	—	—	—	—	(5,869)	—	(5,869)
Balance—June 30, 2020	117,809,883	$ 131,363	1,382,200	$ —	$ 3,342	$ (119,499)	$ —	$ (116,157)
Issuance of common stock upon the initial public offering, net	—	—	5,625,000	1	79,528	—	—	79,529
Conversion of convertible preferred stock into common stock upon the initial public offering	(117,809,883)	(131,363)	13,085,913	1	131,362	—	—	131,363
Stock issued on exercise of stock options	—	—	42,402	—	54	—	—	54
Stock-based compensation expense	—	—	—	—	561	—	—	561
Net loss	—	—	—	—	—	(4,716)	—	(4,716)
Balance—September 30, 2020	—	$ —	20,135,515	$ 2	$ 214,847	$ (124,215)	$ —	$ 90,634

See accompanying notes to unaudited condensed financial statements.

GRAYBUG VISION, INC.
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Income	Deficit
Balance—December 31, 2018	80,377,096	$ 78,811	1,292,858	$ —	$ 2,007	$ (68,799)	$ —	$ (66,792)
Stock issued on exercise of stock options	—	—	3,787	—	9	—	—	9
Stock-based compensation expense	—	—	—	—	156	—	—	156
Net loss	—	—	—	—		(6,295)	—	(6,295)
Balance—March 31, 2019	80,377,096	$ 78,811	1,296,645	$ —	$ 2,172	$ (75,094)	$ —	$ (72,922)
Stock issued on exercise of stock options	—	—	—	—	—	—	—	-
Stock-based compensation expense	—	—	—	—	142	—	—	142
Net loss	—	—	—	—	—	(10,263)	—	(10,263)
Balance—June 30, 2019	80,377,096	$ 78,811	1,296,645	$ —	$ 2,314	$ (85,357)	$ —	$ (83,043)
Issuance of Series C convertible preferred stock, net of issuance costs of $217 and discount on allocation of proceeds to preferred stock tranche obligation of $2,230	37,432,787	52,552		—	—	—	—	—
Stock issued on exercise of stock options	—	—	73,213	—	122	—	—	122
Stock-based compensation expense	—	—	—	—	250	—	—	250
Net loss	—	—	—	—	—	(10,205)	—	(10,205)
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	—	7	7
Balance—September 30, 2019	117,809,883	$ 131,363	1,369,858	$ —	$ 2,686	$ (95,562)	$ 7	$ (92,869)

See accompanying notes to unaudited condensed financial statements.

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

	Nine Months Ended September 30,	
	2020	2019
Operating activities:		
Net loss	$ (18,379)	$ (26,763)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,001	548
Depreciation	284	219
Change in fair value of preferred stock tranche obligation	(2,158)	—
Accretion of premium and discounts on short-term investments	(17)	(25)
Changes in operating assets and liabilities:		
Prepaid expenses and other current and noncurrent assets	227	1,505
Accounts payable	(1,204)	2,581
Accrued research and development	(1,310)	(20)
Other current liabilities	(747)	613
Deferred rent, long term portion	10	—
Net cash used in operating activities	(22,293)	(21,342)
Investing activities:		
Purchases of property and equipment	(197)	(457)
Purchases of short-term investments	—	(18,969)
Maturity of short-term investments	20,100	—
Net cash provided by (used in) investing activities	19,903	(19,426)
Financing activities:		
Proceeds from issuance of common stock upon initial public offering, net of underwriting discounts and commissions	83,700	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	54,787
Proceeds from exercise of stock options	77	131
Payment of offering costs	(2,289)	—
Net cash provided by financing activities	81,488	54,918
Net increase in cash and cash equivalents	79,098	14,150
Cash and cash equivalents at beginning of period	15,870	12,834
Cash and cash equivalents at end of period	$ 94,968	$ 26,984
Supplemental disclosure of noncash items:		
Deferred offering costs included in accounts payable and other current liabilities	$ 1,837	$ 13
Conversion of convertible preferred stock into common stock upon initial public offering	$ 131,363	$ —
Property and equipment purchases included in accounts payable	$ 60	$ 6

See accompanying notes to unaudited condensed financial statements.

1. Organization

Graybug Vision, Inc., the Company or Graybug, is a clinical stage biopharmaceutical company developing medicines for the treatment of diseases of the retina and optic nerve. The Company presently devotes substantially all of its resources to conducting research and development and raising capital. The Company was founded in May 2011 and maintains facilities in Redwood City, California and Baltimore, Maryland.

The Company is 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.

Initial Public Offering

On September 24, 2020, the Company completed its initial public offering, or IPO, of 5,625,000 shares of its common stock at a public offering price of $16.00 per share, pursuant to the Company's registration statement on Form S-1, which was declared effective by the Securities and Exchange Commission, or the SEC, on that date. The shares of the Company's common stock began trading on the Nasdaq Global Market on September 25, 2020 and the IPO closed on September 29, 2020. As a result of the IPO, the Company received net proceeds of $79.5 million, after deducting underwriting discounts, commissions and offering expenses, but before giving effect to the underwriters' subsequent exercise of their overallotment option in October 2020 (see Note 11). Prior to the completion of the IPO, all 117,809,883 shares of redeemable convertible preferred stock then outstanding were converted into 13,085,913 shares of common stock.

Reverse Stock Split

On September 18, 2020, the Company effected a 9.0058:1 reverse stock split of its issued and outstanding common stock. Upon the effectiveness of the reverse stock split, (i) all shares of outstanding common stock were adjusted; (ii) the conversion prices of the convertible preferred stock were adjusted; (iii) the number of shares of common stock for which each outstanding option and warrant to purchase common stock is exercisable were adjusted; and (iv) the exercise price of each outstanding option and warrant to purchase common stock was adjusted. All of the outstanding common stock share numbers (including shares of common stock subject to the Company's options, warrants and as converted for the outstanding convertible preferred stock), share prices, exercise prices and per share amounts contained in the condensed financial statements have been retroactively adjusted in the condensed financial statements to reflect this reverse stock split for all periods presented. The par value per share and the authorized number of shares of common stock were not adjusted as a result of the reverse stock split.

Going Concern Considerations

The Company incurred losses from operations and had negative cash flows from operating activities for the three and nine months ended September 30, 2020 and 2019, and the Company's accumulated deficit at September 30, 2020 is $124.2 million. Prior to the IPO, the Company historically funded its operations through the issuance of shares of its convertible preferred stock. The Company's current operating plan indicates it will continue to incur losses from operations and generate negative cash flows from operating activities, given ongoing expenditures related to extensive 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.

As of April 21, 2020, the issuance date of the Company's audited financial statements for the year ended December 31, 2019, the Company concluded that there was substantial doubt about its ability to continue as a going concern for one year after the date that those financial statements were issued. Subsequent to the issuance of those financial statements, the Company received proceeds of $79.5 million, net of the underwriters' discounts, from the IPO in September 2020. Additionally, in October 2020 the Company received additional proceeds of $12.6 million from the underwriters' exercise of their option to purchase additional shares of the Company's common stock (see Note 11). Accordingly, as of the issuance date of these unaudited condensed financial statements, the Company expects its cash and cash equivalents of $95.0 million as of September 30, 2020, will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months beyond the date of issuance of these unaudited condensed financial statements. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company may seek to raise additional funds in order to further advance its research and development programs, operate its business and meet its obligations as they come due. The Company is pursuing financing alternatives, similar to what the Company has previously executed, which include equity financing. However, financing 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 raise the necessary funds when needed or reduce spending on currently planned activities, it may not be able to continue the development of its products or the Company could be required to delay, scale back, or eliminate some or all of its research and development programs and other operations and will materially harm its business, financial position and results of operations.

Coronavirus Outbreak

In March 2020 the World Health Organization declared the global novel coronavirus disease 2019, or COVID-19, outbreak a pandemic. As of September 30, 2020, the Company's operations have not been significantly impacted by the COVID-19 outbreak. However, the Company cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak will have on its financial condition and operations, including ongoing and planned clinical trials. The impact of the COVID-19 outbreak on the financial performance of the Company will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of COVID-19 on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results may be materially adversely affected.

In March 2020, the Families First Coronavirus Response Act, or FFCR Act, and the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, were signed into law in response to the COVID-19 pandemic. The FFCR Act and CARES Act include provisions related to refundable payroll tax credits, deferment of employer side social security payments, and retroactively and temporarily (for taxable years beginning before January 1, 2021) suspending the application of the 80%-of-income limitation on the use of net operating losses, which was enacted as part of the Tax Cuts and Jobs Act of 2017. The CARES Act also provides that net operating losses arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years.

In June 2020, Assembly Bill 85, or A.B. 85, was signed into California law. A.B. 85 provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5.0 million of tax per year. A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021 and 2022 for certain taxpayers with taxable income of $1.0 million or more. The carryover period for any net operating losses that are suspended under this provision will be extended. A.B. 85 also requires that business incentive tax credits including carryovers may not reduce the applicable tax by more than $5.0 million for taxable years 2020, 2021 and 2022.

The enactment of the FFCR Act, CARES Act and A.B. 85 did not result in any material adjustments to the Company's income tax provision for the nine months ended September 30, 2020 or to the Company's net deferred tax assets as of September 30, 2020. Given the Company's history of losses, the Company does not expect the provisions of the FFCR Act, CARES Act and A.B. 85 to have a material impact on the Company's annual effective tax rate or condensed financial statements in 2020; however, the Company will continue to evaluate the impact of tax legislation and will update its disclosures as additional information and interpretive guidance becomes available.

2. Summary of Significant Accounting Policies

Other than with respect to the adoption of ASU 2018-13 discussed below, there have been no changes to the significant accounting policies as disclosed in Note 2 to the Company's audited financial statements and related footnotes included in the Registration Statement on Form S-1 (File No. 333-248611), as amended, and related Prospectus filed with the SEC on September 25, 2020, or the Prospectus.

In August 2018, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2018-13, *Fair Value Measurement* (Topic 820), Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement, or ASU 2018-13. ASU 2018-13 removed the following disclosure requirements: (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; (2) the policy for timing of transfers between levels; and (3) the valuation processes for Level 3 fair value measurements. Additionally, this update added the following disclosure requirements: (1) the changes in unrealized gains and losses for the period included in other comprehensive income and loss for recurring Level 3 fair value measurements held at the end of the reporting period; and (2) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. For certain unobservable inputs, an entity may disclose other quantitative information, such as the median or arithmetic average, in lieu of the weighted average if the entity determines that other quantitative information would be a more reasonable and rational method to reflect the distribution of unobservable inputs used to develop Level 3 fair value measurements. ASU 2018-13 became effective for the Company beginning January 1, 2020 and the adoption of ASU 2018-13 did not have a material impact on the Company's condensed financial statements. For the disclosures regarding the Company's Level 3 fair value measurements, see Note 3, Fair Value Measurements, to these condensed financial statements.

In December 2019, the FASB issued ASU No. 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. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and must be applied on a retrospective basis. The Company is currently evaluating the impact of this new guidance on its financial statements and disclosures.

Basis of Presentation

The accompanying unaudited condensed financial statements contained in this Quarterly Report on Form 10-Q have been prepared in accordance with the rules and regulations of the 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, 2019 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 financial statements should be read in conjunction with the Company's audited financial statements included in the Prospectus.

Related Party Transactions

In August 2019, the Company engaged a consulting firm managed by the then acting chief financial officer of the Company for professional services related to accounting, finance and other administrative functions. For the three months ended September 30, 2020 and 2019, the costs incurred under this arrangement totaled $212,000 and $82,000 and for the nine months ended September 30, 2020 and 2019, the costs totaled $657,000 and $82,000, respectively. These costs were recorded as general and administrative expense in the accompanying condensed statements of operations. As of September 30, 2020, amounts owed under this arrangement totaled $56,000 and are included in accounts payable in the accompanying condensed balance sheet. As of December 31, 2019 and September 30, 2020, amounts owed under this arrangement totaled $104,000 and $56,000, respectively, and are included in accounts payable in the accompanying condensed balance sheets.

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 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 and liabilities 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):

	September 30, 2020			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash equivalents:				
Money market funds	$ 94,355	$ —	$ —	$ 94,355
Total assets measured at fair value	$ 94,355	$ —	$ —	$ 94,355

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash equivalents:				
Money market funds	$ 12,859	$ —	$ —	$ 12,859
Corporate debt securities	—	500	—	500
Total cash equivalents	12,859	500	—	13,359
Short-term investments:				
Government agency bonds	—	2,750	—	2,750
Corporate debt securities	—	11,349	—	11,349
Commercial paper	—	5,987	—	5,987
Total short-term investments	—	20,086	—	20,086
Total assets measured at fair value	$ 12,859	$ 20,586	$ —	$ 33,445
Current liabilities:				
Preferred stock tranche obligation	$ —	$ —	$ 2,158	$ 2,158
Total liabilities measured at fair value	$ —	$ —	$ 2,158	$ 2,158

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):

	September 30, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 94,355	$ —	$ —	$ 94,355
Total assets measured at fair value	$ 94,355	$ —	$ —	$ 94,355

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 12,859	$ —	$ —	$ 12,859
Corporate debt securities	500	—	—	500
Total cash equivalents	13,359	—	—	13,359
Short-term investments:				
Government agency bonds	2,750	—	—	2,750
Corporate debt securities	11,348	2	(1)	11,349
Commercial paper	5,985	2	—	5,987
Total short-term investments	20,083	4	(1)	20,086
Total assets measured at fair value	$ 33,442	$ 4	$ (1)	$ 33,445

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 short-term 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.

In connection with the Company's convertible preferred stock financing in July 2019, certain investors were granted an option to purchase additional shares contingent upon delivery to them of certain clinical trial results (see Note 7). In September 2020, the Board and these investors amended the stock purchase agreement such that the option to purchase additional shares would no longer be exercisable and would expire upon the effectiveness of the Company's Prospectus. As a result, the Preferred Stock Tranche Obligation was remeasured as of the date of the amendment and adjusted to its fair value at that time which was deemed to be immaterial. The Preferred Stock Tranche Obligation was measured at fair value at each reporting period until its expiration on September 24, 2020 using an option pricing valuation methodology. Due to the low probability of the Preferred Stock Tranche Obligation being settled, the fair value immediately prior to the IPO was immaterial.

The fair value of the Preferred Stock Tranche Obligation includes inputs not observable in the market and thus represents a Level 3 measurement. The option methodology utilized requires inputs based on certain subjective assumptions, including (a) expected stock price volatility, (b) calculation of an expected term, (c) a risk-free interest rate, and (d) expected dividends. This approach results in the classification of this security as Level 3 of the fair value hierarchy. The assumptions utilized to value the preferred stock tranche obligation as of December 31, 2019 were (a) expected stock price volatility of 30%; (b) expected term of 0.7 years: (c) a risk-free interest rate of 1.6%; and (d) an expectation of no dividends. The change in the fair value for the three-month and nine-month periods ended September 30, 2020 was $2.1 million and $2.2 million, respectively.

The following table provides a reconciliation of Level 3 liabilities measured at fair value on a recurring basis using significant unobservable inputs (in thousands):

	Amount
Fair value as of January 1, 2020	$ 2,158
Change in fair value and expiration of the preferred stock tranche obligation	(2,158)
Balance as of September 30, 2020	$ —

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

4. Prepaid Expenses and Other Non-current Assets

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

	September 30, 2020	December 31, 2019
Prepaid clinical and research expenses	$ 1,462	$ 1,462
Deferred offering costs	—	894
Deposits	29	58
Total prepaid expenses and other non-current assets	$ 1,491	$ 2,414

5. Other Current Liabilities

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

	September 30, 2020	December 31, 2019
Salaries and benefits	$ 1,562	$ 2,044
Deferred rent	35	—
Other	559	1,080
Total other current liabilities	$ 2,156	$ 3,124

6. Commitments and Contingencies

Operating Lease Agreements

The Company leases a facility in Redwood City, California under an operating lease with a term through August 2021 and in Baltimore, Maryland under an operating lease with a term through June 2023. Rent expense for the three months ended September 30, 2020 and 2019 was $192,000 and $176,000, respectively. Rent expense for the nine months ended September 30, 2020 and 2019 was $544,000 and $520,000, respectively. Future minimum lease payments under the Company's non–cancelable operating leases as of September 30, 2020 were as follows (in thousands):

Year ended December 31:	
2020 (remaining three months)	$ 196
2021	660
2022	405
2023	205
Total future minimum lease payments	$ 1,466

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. 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 September 30, 2020, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

7. Convertible Preferred Stock and Stockholders' Equity (Deficit)

The following table summarizes outstanding Convertible Preferred Stock as of December 31, 2019 (in thousands, except share amounts):

	Shares Authorized	Shares Outstanding	Net Carrying Value	Liquidation Preference
Series A	2,280,000	2,280,000	$ 2,280	$ 2,280
Series A-2	2,018,561	2,018,561	1,605	1,740
Series B	76,078,535	76,078,535	74,926	87,729
Series C	61,773,000	37,432,787	52,552	56,843
Total	142,150,096	117,809,883	$ 131,363	$ 148,592

In July 2019, the Company authorized the sale of up to 61,773,000 shares of its Series C Convertible Preferred Stock, or Series C, at a price of $1.4693 per share, or Series C Financing. In July and August 2019, the Company issued 37,432,787 shares of Series C for aggregate gross proceeds of $55.0 million. In connection with this financing, certain purchasers of the Series C had the option to purchase up to an additional 17,014,902 shares of Series C at a price per share of $1.4693 for a period of up to 30 days after the Company notified them of the three-month readout from the Phase 2a clinical trial of GB-102 in patients with macular edema secondary to diabetic macular edema and retinal vein occlusion, or the Preferred Stock Tranche Obligation. The Company concluded that the Preferred Stock Tranche Obligation met the definition of a freestanding financial instrument, as the rights were legally detachable and separately exercisable from the Series C. Therefore, the Company allocated the proceeds received from the issuance of shares under the Series C Preferred Stock Purchase Agreement between the Preferred Stock Tranche Obligation and the Series C. The fair value of the Preferred Stock Tranche Obligation of $2.2 million on issuance was allocated from the $55.0 million proceeds of the Series C Financing and is classified as a current liability on the balance sheet as of December 31, 2019 as the Series C would become redeemable upon a deemed liquidation event, the occurrence of which was not within the Company's control.

In September 2020, the board of directors and the Series C investors amended the Series C stock purchase agreement such that the Preferred Stock Tranche Obligation was no longer exercisable and expired upon the effectiveness of the Prospectus. As a result, the liability for the Preferred Stock Tranche Obligation was permanently eliminated as of September 30, 2020.

Prior to the completion of the IPO on September 24, 2020, all of the outstanding shares of Convertible Preferred Stock automatically converted into 13,085,913 shares of common stock. Subsequent to the closing of the IPO on September 29, 2020, there were no shares of Convertible Preferred Stock outstanding.

8. 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 awards, or RSAs, stock appreciation rights, or SARs, restricted stock units, or RSUs, performance awards and stock bonus awards. The Company initially reserved 1,850,000 shares of its common stock, plus any reserved shares not issued or subject to outstanding grants under the 2015 Plan on the effective date of the 2020 Plan, for issuance pursuant to awards granted under the 2020 Plan. The aggregate number of shares reserved for sale under the 2020 Plan will increase automatically on each January 1st of 2021 through 2030 by the number of shares equal to the lesser of 5% of the aggregate number of outstanding shares of the Company's common stock as of the immediately preceding December 31, or a number as may be determined by the Company's board of directors.

In conjunction with adopting the 2020 Plan, the Company may not grant any additional stock-based awards under the 2015 Plan, and any shares available for issuance under the 2015 Plan were added to the shares reserved under the 2020 Plan. The 2015 Plan will continue to govern outstanding stock-based awards granted thereunder. As of September 30, 2020, there were 1,826,374 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. The Company's ESPP is intended to qualify under Section 423 of the Internal Revenue Code. The Company has initially reserved 210,000 shares of its common stock for sale under the ESPP. The aggregate number of shares reserved for sale under the Company's ESPP will increase automatically on January 1st of each of the first ten calendar years after the first offering date under the ESPP by the number of shares equal to the lesser of 1% of the total outstanding shares of the Company's common stock as of the immediately preceding December 31, or a number of shares as may be determined by the Company's board of directors in any particular year. The aggregate number of shares issued over the term of the ESPP, subject to stock-splits, recapitalizations or similar events, may not exceed 2,100,000 shares of the Company's common stock.

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 105	$ 46	$ 245	$ 146
General and administrative	456	204	756	402
Total stock-based compensation expense	$ 561	$ 250	$ 1,001	$ 548

As of September 30, 2020, the total unrecognized stock-based compensation expense related to outstanding unvested stock options that are expected to vest was $7.6 million, which the Company expects to recognize over an estimated weighted-average term of 3.3 years.

9. Income Taxes

The Company did not record a provision or benefit for income taxes during the three and nine months ended September 30, 2020 and 2019. The Company continues to maintain a full valuation allowance against all of its deferred tax assets.

The Company has evaluated the positive and negative evidence involving its ability to realize its deferred tax assets. The Company has considered its history of cumulative net losses incurred since inception and its lack of any commercially ready products. As of September 30, 2020, the Company has concluded that it is more likely than not that it will not realize the benefits of its deferred tax assets. The Company reevaluates the positive and negative evidence at each reporting period.

10. Net Loss Per Share Attributable to Common Stockholders

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	$ (4,716)	$ (10,205)	$ (18,379)	$ (26,763)
Cumulative dividends on convertible preferred stock	(2,396)	(2,048)	(7,189)	(4,633)
Net loss attributable to common stockholders	$ (7,112)	$ (12,253)	$ (25,568)	$ (31,396)
Net loss per common share—basic and diluted	$ (2.52)	$ (9.30)	$ (13.74)	$ (24.10)
Weighted-average number of shares used in computing net loss per common share—basic and diluted	2,818,349	1,317,497	1,861,229	1,302,687

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 September 30,	
	2020	2019
Convertible preferred stock	—	117,809,883
Stock options to purchase common stock	2,615,892	1,560,826
Warrants to purchase common stock	27,759	—
Restricted stock awards	80,000	—

Under the Series C Financing, up to 17,014,902 shares of convertible preferred stock could have been contingently issued upon achievement of certain development milestones. However, in September 2020, the board of directors and the Series C investors amended the Series C stock purchase agreement such that the Preferred Stock Tranche Obligation was no longer exercisable and expired upon the effectiveness of the Prospectus.

11. Subsequent Events

Option to Purchase Additional Shares

In connection with the IPO, the underwriters were granted an option, exercisable for 30 days after the date of the Prospectus, September 24, 2020, to purchase up to 843,750 additional shares of the Company’s common stock at the IPO price of $16.00. In connection with the full exercise of this option, in October the underwriters purchased all 843,750 additional shares, resulting in net proceeds to the Company of approximately $12.6 million, after deducting underwriting discounts and commissions.

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 condensed financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our final prospectus, dated September 24, 2020, filed with the Securities and Exchange Commission, or the SEC, pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Prospectus.

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 are a clinical-stage biopharmaceutical company focused on developing transformative medicines for the treatment of diseases of the retina and optic nerve. Our novel proprietary technologies are designed to release drugs in ocular tissue at a controlled rate for up to 12 months in order 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 inhibitor of neovascular growth and permeability, which are leading causes of retinal disease. We are developing GB-102 as a once-every-six months intravitreal injection for the treatment of wet age-related macular degeneration, or wet AMD, and diabetic macular edema, or DME. 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 approximately 88% of patients in this cohort. GB-102 is currently in a dose-ranging, controlled and masked safety and efficacy Phase 2b clinical trial in patients with wet AMD. We expect to report topline data from this trial in the first half of 2021. We are also using our proprietary technologies to develop GB-103, a once-a-year formulation of GB-102, for the treatment of diabetic retinopathy, or DR, as well as GB-401, an intravitreally injectable depot formulation of a beta-adrenergic blocking agent prodrug with a dosing regimen of once-every-six months or longer for the treatment of primary open-angle glaucoma, or POAG. 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 $79.5 million in net proceeds from our IPO, after deducting underwriters' discounts and commissions of $6.3 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 $4.7 million and $10.2 million for the three months ended September 30, 2020 and 2019, respectively, and $18.4 million and $26.8 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $124.2 million and cash and cash equivalents of $95.0 million.

We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as 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. 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

Initial Public Offering

In September 2020, we completed an initial public offering, or IPO, of our common stock. As part of the IPO, we issued and sold 5,625,000 shares of our common stock at a public offering price of $16.00 per share and granted an option to the underwriters of the IPO, exercisable for 30 days after the date of the Prospectus, to purchase up to an additional 843,750 shares of our common stock at the IPO price. In September 2020, we received net proceeds of $79.5 million from the IPO, after deducting underwriting discounts and commissions of $6.3 million and offering costs of $4.2 million. In October 2020, the underwriters exercised their option to purchase all 843,750 shares and we received net proceeds of $12.6 million, after deducting underwriting discounts and commissions.

Business Effects of COVID-19

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, 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 full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, liquidity and financial condition 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, or CROs, contract manufacturing organizations, or 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.

While we are currently continuing to dose patients in our clinical trial at sites across the United States, we expect that COVID-19 precautions may directly or indirectly impact the timeline for some of our clinical trial activities due to the closing of eye clinics and/or diverting the resources that are necessary to conduct our observational study to care for COVID-19 patients. Currently we have experienced minor delays in the dosing of patients due to COVID-19.

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; 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.

We expect our research and development expenditures to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as we 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. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

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. 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 will depend on a variety of factors, including:

- successful completion of preclinical studies and clinical trials to the satisfaction of the FDA, EMA or other regulatory authorities;
- 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 U.S. Food and Drug Administration, or 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 continued research and development activities, manufacturing activities, increased costs of operating as a public company and the potential commercialization of our product candidates. We also anticipate our general and administrative costs will increase and with respect to the hiring of additional personnel, developing commercial infrastructure, fees to outside consultants, lawyers and accountants, and 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.

Interest Income

Our interest income principally reflects interest earned on our investments. Following our Series C financing in July and August 2019, we expanded our investments to include U.S. government-backed money-market funds, corporate debt securities, commercial paper and government agency 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.

Preferred Stock Tranche Obligation

Our Preferred Stock Tranche Obligation is measured at fair value using an option pricing valuation methodology. In September 2020, the Board and the Series C investors amended the Series C stock purchase agreement such that the option to purchase additional shares would no longer be exercisable and would expire upon the effectiveness of the Company's IPO. As a result, the preferred stock tranche obligation expired upon the effectiveness of the Company's Prospectus. The obligation was remeasured and adjusted to fair value each reporting period until its expiration.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

The following sets forth our results of operations:

	Three Months Ended September 30,		Change	
	2020	2019	Amount	%
	(in thousands)			
Operating expenses:				
Research and development	$ 4,757	$ 8,403	$ (3,646)	(43%)
General and administrative	2,064	1,962	102	5%
Total operating expenses	6,821	10,365	(3,544)	(34%)
Loss from operations	(6,821)	(10,365)	3,544	(34%)
Interest income	3	160	(157)	(98%)
Change in fair value of preferred stock tranche obligation	2,102	—	2,102	NM
Net loss	$ (4,716)	$ (10,205)	$ 5,489	(54%)

Research and Development Expenses

Research and development expenses comprised:

	Three Months Ended September 30,		Change	
	2020	2019	Amount	%
	(in thousands)			
CRO, CMO, nonclinical and other services	$ 2,345	$ 5,720	$ (3,375)	(59%)
Personnel costs	1,563	1,322	241	18%
Consulting	272	270	2	1%
Materials and supplies	93	371	(278)	(75%)
Facility costs, travel and other	484	720	(236)	(33%)
Total research and development expenses	$ 4,757	$ 8,403	$ (3,646)	(43%)

Our research and development activities consist primarily of costs associated with the development of GB-102 for which we are conducting two U.S. Phase 2 clinical trials in patients with wet age-related macular degeneration, or wet AMD, and diabetic macular edema, or DME. The decrease for the three months ended September 30, 2020 as compared to 2019 was primarily due to the completion in 2019 of manufacturing of all clinical supplies required for the commencement of our Phase 2b, or ALTISSIMO, trial for GB-102. In addition, we did not engage in any primary manufacturing activities in the three-month period ended September 30, 2020.

General and Administrative Expenses

General and administrative expenses to support our business activities comprised:

	Three Months Ended September 30,		Change	
	2020	2019	Amount	%
	(in thousands)			
Personnel costs	$ 867	$ 1,098	$ (231)	(21%)
Professional services	793	406	387	95%
Patent filing and portfolio costs	237	282	(45)	(16%)
Facility costs, travel and other expenses	167	176	(9)	(5%)
Total general and administrative expenses	$ 2,064	$ 1,962	$ 102	5%

General and administrative expenses increased in the three months ended September 30, 2020 as compared to 2019 primarily due to additional professional services related in part to preparation for our IPO.

Interest Income

Interest income was $2,400 and $159,400 for the three months ended September 30, 2020 and 2019, respectively, primarily reflecting a decline in invested capital.

Preferred Stock Tranche Obligation

The change in fair value of Preferred Stock Tranche Obligation for the three months ended September 30, 2020 relates to the fair value adjustment of $2.1 million in connection with our IPO. In September 2020, the Preferred Stock Tranche Obligation expired upon the effectiveness of the Prospectus, resulting in a corresponding elimination of the associated liability.

Comparison of the Nine Months Ended September 30, 2020 and 2019

The following sets forth our results of operations:

	Nine Months Ended September 30,		Change	
	2020	2019	Amount	%
	(in thousands)			
Operating expenses:				
Research and development	$ 15,474	$ 22,570	$ (7,096)	(31%)
General and administrative	5,183	4,404	779	18%
Total operating expenses	20,657	26,974	(6,317)	(23%)
Loss from operations	(20,657)	(26,974)	6,317	(23%)
Interest income	120	211	(91)	(43%)
Change in fair value of preferred stock tranche obligation	2,158	—	2,158	NM
Net loss	$ (18,379)	$ (26,763)	$ 8,384	(31%)

Research and Development Expenses

Research and development expenses comprised:

	Nine Months Ended September 30,		Change	
	2020	2019	Amount	%
	(in thousands)			
CRO, CMO, nonclinical and other services	$ 8,641	$ 13,941	$ (5,300)	(38%)
Personnel costs	4,481	4,225	256	6%
Consulting	468	654	(186)	(28%)
Materials and supplies	486	1,989	(1,503)	(76%)
Facility costs, travel and other	1,398	1,761	(363)	(21%)
Total research and development expenses	$ 15,474	$ 22,570	$ (7,096)	(31%)

Our research and development activities consist primarily of costs associated with the development of GB-102 for which we are conducting two U.S. Phase 2 clinical trials in patients with wet age-related macular degeneration, or wet AMD, and diabetic macular edema, or DME. The decrease for the nine months ended September 30, 2020 as compared to 2019 was primarily due to the completion in 2019 of manufacturing of all clinical supplies required for the commencement of our Phase 2b, or ALTISSIMO, trial for GB-102. In addition, we did not engage in any primary manufacturing activities in the nine-month period ended September 30, 2020.

General and Administrative Expenses

General and administrative expenses to support our business activities comprised:

	Nine Months Ended September 30,		Change	
	2020	2019	Amount	%
	(in thousands)			
Personnel costs	$ 1,890	$ 2,196	$ (306)	(14%)
Professional services	2,116	920	1,196	130%
Patent filing and portfolio costs	885	799	86	11%
Facility costs, travel and other expenses	292	489	(197)	(40%)
General and administrative expenses	$ 5,183	$ 4,404	$ 779	18%

General and administrative expenses increased in the nine months ended September 30, 2020 as compared to 2019 primarily due to additional professional services related in part to preparation for our IPO.

Interest Income

Interest income was $120,000 and $210,600 for the nine months ended September 30, 2020 and 2019, respectively, primarily reflecting a decline in invested capital.

Preferred Stock Tranche Obligation

The change in fair value of Preferred Stock Tranche Obligation for the nine months ended September 30, 2020 relates to the fair value adjustments of $2.2 million primarily due to the $2.1 million gain recognized in connection with our IPO. In September 2020, the Preferred Stock Tranche Obligation expired upon the effectiveness of the Prospectus, resulting in a corresponding elimination of the associated liability.

Liquidity and Capital Resources

Overview

Our operations through September 30, 2020 have been financed primarily by gross proceeds of approximately $134.0 million from the sale of convertible promissory notes and our convertible preferred stock, and $79.5 million in net proceeds from our IPO, after deducting underwriters' discounts and commissions of $6.3 million and offering costs of $4.2 million. As of September 30, 2020, we had $95.0 million in cash and cash equivalents. We have incurred losses since our inception and, as of September 30, 2020, we had an accumulated deficit of $124.2 million. 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. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Our operations will be further financed by the October 2020 full exercise of the underwriters' option to purchase an additional 843,750 shares of our common stock at the initial public offering price of $16.00 per share. As a result of the exercise, we received net proceeds of $12.6 million, after deducting underwriting discounts and commissions.

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. 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 potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we 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 upon our current operating plan, we believe that our existing cash and cash equivalents combined with the proceeds from the underwriters' full option exercise will enable us to fund our operating expenses and capital expenditure requirements beyond the next 12 months.

We 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. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may 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 lead 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 lead 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 lead product candidate 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:

	Nine Months Ended September 30,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (22,293)	$ (21,342)
Investing activities	19,903	(19,426)
Financing activities	81,488	54,918
Net increase in cash and cash equivalents	$ 79,098	$ 14,150

Operating Activities

Cash used in operating activities of $22.3 million during the nine months ended September 30, 2020 was primarily attributable to our net loss of $18.4 million and an increase of $3.0 million in our working capital. The increase is further driven by a net total of $0.9 million in non-cash charges, primarily comprising stock-based compensation and depreciation expenses, partially offset by the change in the fair value of the Preferred Stock Tranche Obligation.

Cash used in operating activities of $21.3 million during the nine months ended September 30, 2019 was primarily attributable to our net loss of $26.8 million partially offset by a decrease of $4.7 million in our working capital and non-cash charges of $0.8 million with respect to stock-based compensation and depreciation expense.

Investing Activities

Cash provided by investing activities during the nine months ended September 30, 2020 consisted of $20.1 million provided on maturity of short-term investments partially offset by $0.2 million of purchases of property and equipment.

Cash used in investing activities during the nine months ended September 30, 2019 consisted of $19.0 million of purchases of short-term investments and $0.5 million of purchases of property and equipment.

Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2020 consisted of $83.7 million of proceeds, net of the underwriters' discounts and commissions, from the issuance of common stock in our IPO and $0.1 million received from the exercise of stock options, partially offset by $2.3 million related to the payment of offering costs.

Cash provided by financing activities for the nine months ended September 30, 2019 consisted of $54.9 million, comprised $54.8 million of net proceeds upon the issuance of our Series C in July and August 2019, and $0.1 million 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 GAAP. 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.

During the nine months ended September 30, 2020, there were no material changes to our critical accounting policies or in the methodology used for estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Prospectus.

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

Recently Adopted Accounting Pronouncements

For a full discussion of recently adopted accounting pronouncements, see Note 2 – Summary of Significant Accounting Policies to the condensed financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q.

Contractual Obligations and Other Commitments

Contractual Obligations

The following table summarizes our contractual obligations as of September 30, 2020:

	Payments due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5
Operating lease commitments (1)	$ 1,466	$ 756	$ 710	$ —	$ —

(1) We lease a facility in Redwood City, California under an operating lease that extends through August 2021. We also lease a facility in Baltimore, Maryland under an operating lease which, as of September 30, 2020, extends through June 2023, with rent payments of $32,000 monthly in the first 12 months, $33,000 monthly in the second 12 months, and $34,000 monthly in the last 6 months.

We are party to license agreements pursuant to which we have in-licensed various intellectual property rights. The license 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 licensed products. None of these events had occurred as of September 30, 2020, and no royalties were due from the sales of licensed products. The table above does not include any milestone or royalty payments to the counterparties to these agreements as the amounts, timing and likelihood of such payments are not known.

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 preclinical research studies, research supplies and other services and products for operating purposes. As of September 30, 2020, we had commitments of approximately $5.6 million with CROs for clinical trial services due within 6 to 18 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.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents of $95.0 million as of September 30, 2020. We generally hold our cash equivalents in interest-bearing, U.S. government backed money market funds, corporate debt securities, commercial paper and government agency bonds in a custodial account. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

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 (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended September 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that most of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the COVID-19 situation on our internal controls to minimize the impact on their design and operating effectiveness.

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.

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 are a clinical-stage biopharmaceutical company with a limited operating history and 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.
- The ongoing COVID-19 pandemic may, directly or indirectly, adversely affect our business, results of operations and financial condition.
- 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 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.
- We depend heavily on the success of our wet AMD product candidates, in particular GB-102. 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.
- 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.
- 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 and GB-103, has a boxed warning regarding hepatotoxicity for its use in oncology indications.
- 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 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.
- 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 licensor, Johns Hopkins University, 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.
- Sunitinib, the active ingredient in certain of our product candidates, is currently expected to lose patent protection in 2021, as a result, new competitors with similar products or treatments may challenge our business.
- 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.
- The market price of our stock may be volatile, and you could lose all or part of your investment.
- 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.

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, including our financial statements and the related notes and "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.

Risks Related to Our Financial Position and Need For Additional Capital

We are a clinical-stage biopharmaceutical company with a limited operating history and 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 $37.0 million for the year ended December 31, 2019 and $18.4 million for the nine months ended September 30, 2020. As of December 31, 2019 and September 30, 2020, we had an accumulated deficit of $105.8 million and $124.2 million, respectively. 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 the Company's 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. 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 significant and increasingly higher expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- pursue the clinical development and potential commercialization of our most advanced product candidate, GB-102, which includes two Phase 3 clinical trials in wet age-related macular degeneration, or wet AMD, and a Phase 2b clinical trial in diabetic macular edema, or DME, starting in 2021;
- commence clinical trials of our product candidates GB-401 and GB-103;
- continue the research and development of other product candidates;
- seek to identify and 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; and
- increase our product liability and clinical trial insurance coverage as we expand our clinical trials and commercialization efforts.

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 U.S. Food and Drug Administration, or 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 in the near future. 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 will require establishing a strategic partnership;
- 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 will 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.

We expect to devote substantial financial resources to our ongoing and planned activities, particularly as we conduct clinical trials for our wet AMD product candidates, in particular, late-stage clinical trials for GB-102, 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. We also expect to devote significant financial resources to conducting research and development and potentially seeking regulatory approval for our other product candidates. In addition, we plan to devote substantial financial resources to our commercialization efforts, including product manufacturing, sales, marketing and distribution for any of our product candidates for which we obtain marketing approval. Accordingly, we will need to obtain substantial additional funding in connection with our continuing and planned operations. If we are unable to raise 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 September 30, 2020, we had cash and cash equivalents of $95.0 million. Our operations are further financed by the underwriters' full exercise of their option to purchase an additional 843,750 shares of our common stock at the initial public offering price of $16.00 in October 2020. As a result of the exercise, we received net proceeds of $12.6 million, after deducting underwriting discounts and commissions. We believe our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements beyond the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. 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 other 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 may need to obtain substantial additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

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

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.

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. 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.

Separately, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and temporarily postpone routine surveillance inspections of domestic manufacturing facilities. In July 2020, the FDA announced that it intended to restart on-site inspections based on its determination of when and where it is safest to conduct prioritized domestic inspections. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 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 continue our clinical trials may be adversely affected, directly or indirectly, by the COVID-19 pandemic. Currently we are experiencing disruptions in our ability to monitor patients in person due to clinics and hospitals closing sites or diverting the resources that are necessary to conduct our 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 an economic slowdown of potentially extended duration, and it is possible it could cause a global recession.

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.

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. Our future success 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 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.

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 successfully 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.

We depend heavily on the success of our wet AMD product candidates, in particular GB-102. 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 are investing substantial resources to complete the development of GB-102 for wet AMD. We cannot accurately predict when or if any of our retinal 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 our obtaining marketing approval for and commercializing 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;
- 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 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 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.

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 Phase 2b clinical trials may not necessarily predict a likelihood of achieving statistical significance of our primary efficacy endpoint in the Phase 3 clinical trials, which will be required for us to obtain marketing approval of GB-102. Additionally, our clinical trials are only evaluating 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 ongoing Phase 2b trial with GB-102 in wet AMD contains a control arm with Eylea, which is the current standard of care. It is possible that, compared to Eylea, GB-102 will not demonstrate sufficient efficacy, durability and safety. For example, in our Phase 2a clinical trial of GB-102, three of ten patients in the 1 mg dose and five out of 11 in the 2 mg dose experienced adverse events, or AEs, with the most common being presence of medication in the anterior chamber. We have since terminated the development of the 2 mg dose of GB-102 in all of our clinical trial programs. If we determine to 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 Phase 2b clinical trial or Phase 3 clinical trials may differ from the outcome of our Phase 1/2a clinical trial. If the results of clinical trials with any potential new therapeutic or product formulation, including therapies that do not involve intravitreal delivery, differs from the Phase 1/2a results, 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.

Interim results of a clinical trial do not necessarily predict final results. In addition, 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. 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 ongoing Phase 2b trial 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 ongoing Phase 2b clinical trial in wet AMD. In that 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.

Some of our clinical trials, including our Phase 1/2a clinical trial and our ongoing Phase 2b clinical trial of GB-102 for the treatment of wet AMD, had or have 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 and one patient had vitreous floaters, medication present in the vitreous, and 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 this 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). We also conducted an interim safety analysis in the Phase 2b study. No drug related SAEs were reported in the Phase 2b study, but 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 this 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 study have now received the 1 mg dose as repeat therapy at month six. Notwithstanding the results from our clinical trials to date, the 1 mg dose of GB-102, as well as GB-102 for other indications and our other product candidates, may fail to demonstrate favorable efficacy, safety and tolerability.

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.

Finally, 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.

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 or continue clinical trials for our wet AMD, DME, diabetic retinopathy, or DR, or glaucoma product candidates 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 study 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 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 all 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. 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 and GB-103, 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 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 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 or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We intend to conduct, and may in the future conduct, 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.

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 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.

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, and other raw materials and for sterilization of the finished product. We intend to build our own manufacturing capabilities, 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.

Currently, GB-102 is manufactured by Lubrizol Life Science Health. Although we have secured sufficient quantities of drug substance and drug product to supply our trials, we will need to obtain additional supplies 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.

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 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 PLGA and other raw materials and for sterilization of the finished product. We intend to build our own manufacturing capabilities, 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 clinical trials are currently conducted at a limited number of other sites. Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather condition, medical epidemic or pandemic, 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. 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 and cannot yet accurately predict whether it 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 GB-102 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 establish and maintain adequate sales, marketing and distribution capabilities, we may not be successful in commercializing GB-102 or any 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. To achieve commercial success for GB-102 and any 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 GB-102 is approved for marketing, we plan on commercializing GB-102 through our own specialty sales force. Alternatively, we may rely on a network of independent distributors across the United States to sell GB-102. We expect that a direct sales force will be required to effectively market and sell GB-102. 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 GB-102 or any of 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 with respect to our product candidates that we may seek to develop or commercialize, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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 Beovu, the most recently approved anti-VEGF drug. There are also several product candidates in late-stage clinical development, including those being developed by F. Hoffmann-La Roche AG, Kodiak Sciences Inc., Chengdu Kanghong Pharmaceutical Group Co., Ltd 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, and Beovu. 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.

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 expand our 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 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.

We may utilize a variety of types of collaboration arrangements with third parties to develop or commercialize any of our product candidates. 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 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 may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our product candidates could be delayed and 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 business combination, it might deemphasize or terminate the development or commercialization of any product candidate 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 collaborate with pharmaceutical, biotechnology and medical device companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA 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 collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential collaborators. Collaborations 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 collaborators.

If we are unable to reach agreements with suitable collaborators 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 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 collaborations and do not have 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 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 proposed clinical assets. 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. 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 and GB-103 use 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 after the patents on sunitinib expire in August 2021. GB-401 includes our proprietary beta-adrenergic blocking agent prodrug molecule in our proprietary aggregating microparticle 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 aggregating microparticle technologies, then it may be able to compete with our GB-401 product without infringing our owned or licensed patent claims. Consequently, our competitors may independently develop competing products that do not infringe our patents or other intellectual property. To the extent a competitor can develop similar products using a different delivery system, microparticle or molecule, our patents may not prevent them from directly competing with us.

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. 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 market-place. 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 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 licensor, Johns Hopkins University, 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.

Any patents licensed from JHU 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, 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 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.

Sunitinib, the active ingredient in certain of our product candidates, is currently expected to lose patent protection in 2021, as a result, new competitors with similar products or treatments may challenge our business.

Sunitinib, the active ingredient in both GB-102 and GB-103, is currently under patent protection by Pfizer in the United States until August 2021 and in the European Union until July 2021, subject to any extensions that Pfizer may obtain. Although we separately own or license patents or patent applications relating to GB-102 and GB-103 that will not expire until dates ranging from 2031 to 2039, it is possible that new competing products utilizing sunitinib will be introduced for ocular diseases that could compete with our product candidates. We do not currently expect to commercialize any of our product candidates until after the expiration of Pfizer's patent protection. As a result, it is possible that other products may impair our ability to successfully commercialize our product candidates or gain market acceptance, which could adversely affect our business and operating results.

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 our 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 and GB-103 products 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 and GB-103 products and four years after approval of GB-401. The submission of the 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.

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 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 (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 our clinical assets.

Our exclusive license with JHU for technology relating to our clinical assets 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.

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 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, institutional review boards, or 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 study 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. All patients having received GB-102 at either the 1 mg or 2 mg doses previously will now receive the 1 mg dose as repeat therapy at six months.

Any additional SAEs could result in the FDA delaying our 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 our drug candidate, 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 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 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. 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 show a statistically significant difference from the placebo control or 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 analysis 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 study 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 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. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable up to two years). Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult to date. To date, only an outline of a trade agreement has been reached. Much remains open but the Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption.

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 events 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, and 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 our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those 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 plan to seek FDA approval through the Section 505(b)(2) regulatory pathway for each of our current product candidates. The Hatch-Waxman Amendments added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved drug products, which could expedite the development program for our product candidates by potentially decreasing the amount of preclinical or clinical data that we would need to generate in order to obtain FDA approval. For GB-102 and GB-103, 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, GB-103 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, GB-103 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 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 and prescription 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 the Health Information Technology for Economic and Clinical Health Act of 2009, 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 individually identifiable 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 affect our ability to commercialize and the prices we obtain for any products that are approved in the United States or foreign jurisdictions, and 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 in 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 Affordability Reconciliation Act, or collectively, PPACA. Among the provisions of PPACA 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 the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a Medicare Part D coverage gap discount program, in which participating manufacturers must agree to offer 70% point-of-sale discounts off negotiated drug prices during the coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, and the addition of new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs; and
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program.

As implementation of the PPACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013. 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. The CARES Act, which was signed into law on March 27, 2020 and designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 to December 31, 2020 and extended the sequester by one year, through 2030, in order to offset the added expense of the 2020 cancellation. These new laws may result in additional reductions in Medicare and other healthcare funding.

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.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and 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.

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. For example, our former Chief Medical Officer departed in March 2020 and Parisa Zamiri joined us in June 2020 as Chief Medical Officer. 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.

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 may be volatile, and you could lose all or part of your investment.

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some 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 Quarterly Report on Form 10-Q, 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 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 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;
- 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. 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.

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 before or after the lock-up and other legal restrictions on resale lapse in connection with our initial public offering ("IPO"), the market price of our common stock could decline significantly. Each of our officers, directors and stockholders have entered into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares. These lock-up agreements pertaining to our IPO will expire March 24, 2021. However, our underwriters may, in their sole discretion, permit our officers, directors, and other current stockholders who are subject to the contractual lock-up to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire a substantial number of shares of common stock will be eligible for sale in the public market.

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 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 September 30, 2020, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 88% 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" 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 emerging growth company 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 million as of the prior June 30th, 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 emerging growth company, we may still qualify as a "smaller reporting company," 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, emerging growth companies 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 "emerging growth company" or 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-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

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

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 will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new 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.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Unregistered Sales of Equity Securities

From July 1, 2020 through September 24, 2020 (the date of the filing of our registration statement on Form S-8) we issued and sold options to employees, directors and other service providers to purchase an aggregate of 428,618 shares of common stock under our 2015 Stock Incentive Plan, or the 2015 Plan, and 166,624 shares of common stock under our 2020 Equity Incentive Plan, or the 2020 Plan, with per share exercise prices at $3.52 and $16.00 per share. The issuances of the above securities were exempt from registration under the Securities Act of 1933, as amended, or Securities Act, in reliance upon Section 4(2) of the Securities Act, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions.

On September 29, 2020, upon the closing of our initial public offering, or IPO, all shares of our then-outstanding convertible preferred stock automatically converted into 13,085,913 shares of common stock. The issuance of such shares of common stock was exempt from the registration requirements of the Securities Act pursuant to Section 3(a)(9) and Section 4(a)(2) of the Securities Act.

Use of Proceeds

On September 29, 2020, we completed our 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 $92.1 million, after deducting underwriting discounts and commissions of approximately $6.3 million and expenses of approximately $4.2 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates. SVB Leerink LLC and Piper Sandler &Co. acted as joint book-running managers of the offering and as representatives of the underwriters.

Shares of our common stock began trading on The Nasdaq Global Market on September 25, 2020. 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.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index below.

Exhibit Index

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
3.1	Restated Certificate of Incorporation of Graybug Vision, Inc.					X
3.2	Restated Bylaws of Graybug Vision, Inc.					X
10.1	Form of Indemnification Agreement	S-1	333-248611	09/04/2020	10.1	
10.2	2020 Equity Incentive Plan and forms of award agreements	S-1/A	333-248611	09/21/2020	10.3	
10.3	2020 Employee Stock Purchase Plan and forms of award agreements	S-1/A	333-248611	09/21/2020	10.4	
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	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					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.

Company Name

Date: November 12, 2020

By: /s/ Frederic Guerard

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

Date: November 12, 2020

By: /s/ Robert S. Breuil

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

Exhibit 3.1

GRAYBUG VISION, INC.

RESTATED CERTIFICATE OF INCORPORATION

Graybug Vision, Inc., a Delaware corporation, hereby certifies as follows:

1. The name of this corporation is "Graybug Vision, Inc." The date of the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware was February 19, 2015 under the name Graybug, Inc.

2. The Restated Certificate of Incorporation of this corporation attached hereto as Exhibit A, which is incorporated herein by this reference, and which restates, integrates and further amends the provisions of the Certificate of Incorporation of this corporation as previously amended and/or restated, has been duly adopted by this corporation's Board of Directors and by the stockholders in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware, with the approval of this corporation's stockholders having been given by written consent without a meeting in accordance with Section 228 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, this corporation has caused this Restated Certificate of Incorporation to be signed by its duly authorized officer and the foregoing facts stated herein are true and correct.

Dated: September 29, 2020

GRAYBUG VISION, INC.

By: /s/ Frederic Guerard
Name: Frederic Guerard
Title: Chief Executive Officer

EXHIBIT A

GRAYBUG VISION, INC.

RESTATED CERTIFICATE OF INCORPORATION

ARTICLE I: NAME

The name of the corporation is Graybug Vision, Inc. (the "***Corporation***").

ARTICLE II: AGENT FOR SERVICE OF PROCESS

The address of the registered office of this Corporation in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle, 19801, and the name of the registered agent of this Corporation in the State of Delaware at such address is The Corporation Trust Company.

ARTICLE III: PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the "***General Corporation Law***").

ARTICLE IV: AUTHORIZED STOCK

1. Total Authorized. The total number of shares of all classes of stock that the Corporation has authority to issue is 510,000,000 shares, consisting of two classes: 500,000,000 shares of Common Stock, $0.0001 par value per share ("***Common Stock***"), and 10,000,000 shares of Preferred Stock, $0.0001 par value per share ("***Preferred Stock***").

2. Designation of Additional Series.

2.1. The Board of Directors of the Corporation (the "***Board***") is authorized, subject to any limitations prescribed by the law of the State of Delaware, to provide for the issuance of the shares of Preferred Stock in one or more series, and, by filing a Certificate of Designation pursuant to the applicable law of the State of Delaware ("***Certificate of Designation***"), to establish from time to time the number of shares to be included in each such series, to fix the designation, vesting, powers (including voting powers), preferences and relative, participating, optional or other special rights, if any, of the shares of each such series and any qualifications, limitations or restrictions thereof, and, except where otherwise provided in the applicable Certificate of Designation, to thereafter increase (but not above the total number of authorized shares of the Preferred Stock) or decrease (but not below the number of shares of such series then outstanding) the number of shares of any such series. The number of authorized shares of Preferred Stock may also be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of two-thirds of the voting power of all then-outstanding shares of capital stock of the Corporation entitled to vote thereon, voting together as a single class, without a separate vote of the holders of the Preferred Stock, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law, unless a separate vote of the holders of one or more series is required pursuant to the terms of any Certificate of Designation; *provided*, *however*, that if two-thirds of the Whole Board (as defined below) has approved such increase or decrease of the number of authorized shares of Preferred Stock, then only the affirmative vote of the holders of a majority of the voting power of all then-outstanding shares of the capital stock of the Corporation entitled to vote thereon, voting together as a single class, without a separate vote of the holders of the Preferred Stock, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law, unless a separate vote of the holders of one or more series is required pursuant to the terms of any Certificate of Designation, shall be required to effect such increase or decrease. For purposes of this Restated Certificate of Incorporation (as the same may be amended and/or restated from time to time, including pursuant to the terms of any Certificate of Designation designating a series of Preferred Stock, this "***Certificate of Incorporation***"), the term "***Whole Board***" shall mean the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships.

2.2 Except as otherwise expressly provided in any Certificate of Designation designating any series of Preferred Stock pursuant to the foregoing provisions of this Article IV, any new series of Preferred Stock may be designated, fixed and determined as provided herein by the Board without approval of the holders of Common Stock or the holders of Preferred Stock, or any series thereof, and any such new series may have powers, preferences and rights, including, without limitation, voting powers, dividend

rights, liquidation rights, redemption rights and conversion rights, senior to, junior to or pari passu with the rights of the Common Stock, any series of Preferred Stock or any future class or series of capital stock of the Corporation.

2.3 Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Corporation for their vote; *provided*, *that*, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (including any Certificate of Designation relating to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation (including any Certificate of Designation relating to any series of Preferred Stock).

ARTICLE V: AMENDMENT OF BYLAWS

The Board shall have the power to adopt, amend or repeal the Bylaws of the Corporation (as the same may be amended and/or restated from time to time, the "***Bylaws***"). Any adoption, amendment or repeal of the Bylaws by the Board shall require the approval of a majority of the Whole Board. The stockholders shall also have power to adopt, amend or repeal the Bylaws; *provided*, *that*, notwithstanding any other provision of this Certificate of Incorporation or any provision of law that might otherwise permit a lesser or no vote, but in addition to any vote of the holders of any class or series of stock of the Corporation required by applicable law or by this Certificate of Incorporation (including any Preferred Stock issued pursuant to a Certificate of Designation), the affirmative vote of the holders of at least two-thirds of the voting power of all then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required for the stockholders to adopt, amend or repeal any provision of the Bylaws; *provided*, *further*, that, in the case of any proposed adoption, amendment or repeal of any provisions of the Bylaws that is approved by the Board and submitted to the stockholders for adoption thereby, if two-thirds of the Whole Board has approved such adoption, amendment or repeal of any provisions of the Bylaws, then only the affirmative vote of the holders of a majority of the voting power of all then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class (in addition to any vote of the holders of any class or series of stock of the Corporation required by applicable law or by this Certificate of Incorporation (including any Preferred Stock issued pursuant to a Certificate of Designation)), shall be required to adopt, amend or repeal any provision of the Bylaws.

ARTICLE VI: MATTERS RELATING TO THE BOARD OF DIRECTORS

1. Director Powers. Except as otherwise provided by the General Corporation Law, the Bylaws of the Corporation or this Certificate of Incorporation, the business and affairs of the Corporation shall be managed by or under the direction of the Board.

2. Number of Directors. Subject to the special rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the total number of directors constituting the Whole Board shall be fixed from time to time exclusively by resolution adopted by a majority of the Whole Board.

3. Classified Board. Subject to the special rights of the holders of one or more series of Preferred Stock to elect additional directors under specified circumstances, the directors shall be divided, with respect to the time for which they severally hold office, into three classes designated as Class I, Class II and Class III, respectively (the "***Classified Board***"). The Board may assign members of the Board already in office to the Classified Board, which assignments shall become effective at the same time that the Classified Board becomes effective. Directors shall be assigned to each class in accordance with a resolution or resolutions adopted by the Board. The number of directors in each class shall be divided as nearly equal as is practicable. The initial term of office of the Class I directors shall expire at the Corporation's first annual meeting of stockholders following the closing of the Corporation's initial public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, relating to the offer and sale of Common Stock to the public (the "***Initial Public Offering***"), the initial term of office of the Class II directors shall expire at the Corporation's second annual meeting of stockholders following the closing of the Initial Public Offering and the initial term of office of the Class III directors shall expire at the Corporation's third annual meeting of stockholders following the closing of the Initial Public Offering. At each annual meeting of stockholders following the closing of the Initial Public Offering, directors elected to succeed those directors of the class whose terms then expire shall be elected for a term of office expiring at the third succeeding annual meeting of stockholders after their election.

4. Term and Removal. Each director shall hold office until the annual meeting at which such director's term expires and until such director's successor is duly elected and qualified, or until such director's earlier death, resignation, disqualification or removal. Any director may resign at any time by delivering a resignation in writing or by electronic transmission to the Corporation at its principal office or to the Chairperson of the Board, the Chief Executive Officer or the Secretary. Subject to the special rights of the

holders of any series of Preferred Stock, no director may be removed from the Board except for cause and only by the affirmative vote of the holders of at least two-thirds of the voting power of the then-outstanding shares of capital stock of the Corporation entitled to vote thereon, voting together as a single class. In the event of any increase or decrease in the authorized number of directors, (a) each director then serving as such shall nevertheless continue as a director of the class of which he or she is a member and (b) the newly created or eliminated directorships resulting from such increase or decrease shall be apportioned by the Board among the classes of directors so as to make all classes as nearly equal in number as is practicable, provided that no decrease in the number of directors constituting the Board shall shorten the term of any director.

5. Board Vacancies and Newly Created Directorships. Subject to the special rights of the holders of any series of Preferred Stock, any vacancy occurring in the Board for any cause, and any newly created directorship resulting from any increase in the authorized number of directors, shall, unless (a) the Board determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders or (b) as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even if less than a quorum, or by a sole remaining director, and shall not be filled by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for a term expiring at the annual meeting of stockholders at which the term of office of the class to which the director has been assigned expires and until such director's successor shall have been duly elected and qualified, or until such director's earlier death, resignation, disqualification or removal.

6. Vote by Ballot. Election of directors need not be by written ballot unless the Bylaws shall so provide.

ARTICLE VII: DIRECTOR LIABILITY

1. Limitation of Liability. To the fullest extent permitted by law, no director of the Corporation shall be personally liable for monetary damages for breach of fiduciary duty as a director. Without limiting the effect of the preceding sentence, if the General Corporation Law is hereafter amended to authorize the further elimination or limitation of the liability of a director, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law, as so amended.

2. Change in Rights. Neither any amendment nor repeal of this Article VII, nor the adoption of any provision of this Certificate of Incorporation inconsistent with this Article VII, shall eliminate, reduce or otherwise adversely affect any limitation on the personal liability of a director of the Corporation existing at the time of such amendment, repeal or adoption of such an inconsistent provision.

ARTICLE VIII: MATTERS RELATING TO STOCKHOLDERS

1. No Action by Written Consent of Stockholders. Subject to the rights of any series of Preferred Stock then outstanding, no action shall be taken by the stockholders of the Corporation except at a duly called annual or special meeting of stockholders and no action shall be taken by the stockholders of the Corporation by written consent in lieu of a meeting.

2. Special Meeting of Stockholders. Special meetings of the stockholders of the Corporation may be called only by the Chairperson of the Board, the Chief Executive Officer, the Lead Independent Director (as defined in the Bylaws), the President or the Board acting pursuant to a resolution adopted by a majority of the Whole Board and may not be called by the stockholders or any other person or persons.

3. Advance Notice of Stockholder Nominations and Business Transacted at Special Meetings. Advance notice of stockholder nominations for the election of directors of the Corporation and of business to be brought by stockholders before any meeting of stockholders of the Corporation shall be given in the manner provided in the Bylaws. Business transacted at special meetings of stockholders shall be limited to the purpose or purposes stated in the notice of meeting.

ARTICLE IX: CHOICE OF FORUM

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for: (a) any derivative action or proceeding brought on behalf of the Corporation; (b) any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any director, officer, stockholder, employee or agent of the Corporation to the Corporation or the Corporation's stockholders; (c) any action asserting a claim against the Corporation or any director, officer, stockholder, employee or agent of the Corporation arising pursuant to any provision of the General Corporation Law, this Certificate of Incorporation or the Bylaws or as to which the General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; (d) any action to interpret, apply, enforce or

determine the validity of this Certificate of Incorporation or the Bylaws; or (e) any action asserting a claim against the Corporation or any director, officer, stockholder, employee or agent of the Corporation governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Corporation shall be deemed to have notice of and to have consented to the provisions of this Article IX.

ARTICLE X: AMENDMENT OF CERTIFICATE OF INCORPORATION

If any provision of this Certificate of Incorporation shall be held to be invalid, illegal or unenforceable, then such provision shall nonetheless be enforced to the maximum extent possible consistent with such holding and the remaining provisions of this Certificate of Incorporation (including, without limitation, all portions of any section of this Certificate of Incorporation containing any such provision held to be invalid, illegal or unenforceable, which is not invalid, illegal or unenforceable) shall remain in full force and effect.

The Corporation reserves the right to amend or repeal any provision contained in this Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; *provided*, *however*, that, notwithstanding any other provision of this Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote or no vote (but subject to the rights of any series of Preferred Stock set forth in any Certificate of Designation), but in addition to any vote of the holders of any class or series of the stock of the Corporation required by law or by this Certificate of Incorporation, the affirmative vote of the holders of at least two-thirds of the voting power of all then-outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to amend or repeal this Article X or Article V, Article VI, Article VII or Article VIII; *provided*, *further*, that if two-thirds of the Whole Board has approved such amendment or repeal of any provisions of this Certificate of Incorporation, then only the affirmative vote of the holders of a majority of the voting power of all then-outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class (in addition to any other vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation or any Certificate of Designation), shall be required to amend or repeal such provisions of this Certificate of Incorporation.

* * * * * * * * * * *

Exhibit 3.2

GRAYBUG VISION, INC.

(a Delaware corporation)

RESTATED BYLAWS

As Adopted August 31, 2020 and

As Effective September 29, 2020

GRAYBUG VISION, INC.

(a Delaware corporation)

RESTATED BYLAWS

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GRAYBUG VISION, INC.

(a Delaware corporation)

RESTATED BYLAWS

As Adopted August 31, 2020 and
As Effective September 29, 2020

ARTICLE I: STOCKHOLDERS

Section 1.1: Annual Meetings. If required by applicable law, an annual meeting of stockholders shall be held for the election of directors at such date and time as the Board of Directors (the "***Board***") of Graybug Vision, Inc. (the "***Corporation***") shall each year fix. The meeting may be held either at a place, within or without the State of Delaware as permitted by the Delaware General Corporation Law (the "***DGCL***"), or by means of remote communication as the Board in its sole discretion may determine. Any proper business may be transacted at the annual meeting.

Section 1.2: Special Meetings. Special meetings of stockholders for any purpose or purposes shall be called in the manner set forth in the Restated Certificate of Incorporation of the Corporation (as the same may be amended and/or restated from time to time, the "***Certificate of Incorporation***"). The special meeting may be held either at a place, within or without the State of Delaware, or by means of remote communication as the Board in its sole discretion may determine. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of the meeting.

Section 1.3: Notice of Meetings. Notice of all meetings of stockholders shall be given in writing or by electronic transmission in the manner provided by applicable law (including, without limitation, as set forth in Section 7.1.1 of these Bylaws) stating the date, time and place, (if any) of the meeting, the means of remote communication (if any) by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, and the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting). In the case of a special meeting, such notice shall also set forth the purpose or purposes for which the meeting is called. Unless otherwise required by applicable law or the Certificate of Incorporation, notice of any meeting of stockholders shall be given not less than ten (10), nor more than sixty (60), days before the date of the meeting to each stockholder of record entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

Section 1.4: Adjournments. Notwithstanding Section 1.5 of these Bylaws, the chairperson of the meeting shall have the power to adjourn the meeting to another time, date and place (if any), regardless of whether a quorum is present, at any time and for any reason. Any meeting of stockholders, annual or special, may be adjourned from time to time, and notice need not be given of any such adjourned meeting if the time, date and place (if any) thereof and the means of remote communication (if any) by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken; *provided*, *however*, that if the adjournment is for more than thirty (30) days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If, after the adjournment, a new record date for determination of stockholders entitled to vote is fixed for the adjourned meeting, the Board shall fix as the record date for determining stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote at the adjourned meeting, and shall give notice of the adjourned meeting to each stockholder of record as of the record date so fixed for notice of such adjourned meeting. At the adjourned meeting, the Corporation may transact any business that might have been transacted at the original meeting. If a quorum is present at the original meeting, it shall also be deemed present at the adjourned meeting. To the fullest extent permitted by law, the Board may postpone, reschedule or cancel at any time and for any reason any previously scheduled special or annual meeting of stockholders before it is to be held, regardless of whether any notice or public disclosure with respect to any such meeting has been sent or made pursuant to Section 1.3 hereof or otherwise, in which case notice shall be provided to the stockholders of the new date, time and place (if any) of the meeting as provided in Section 1.3 above.

Section 1.5: Quorum. Except as otherwise provided by applicable law, the Certificate of Incorporation or these Bylaws, at each meeting of stockholders the holders of a majority of the voting power of the shares of stock issued and outstanding and entitled to vote at the meeting, present in person or represented by proxy, shall constitute a quorum for the transaction of business; *provided*, *however*, that where a separate vote by a class or classes or series of stock is required by applicable law or the Certificate of Incorporation, the holders of a majority of the voting power of the shares of such class or classes or series of the stock issued and outstanding and entitled to vote on such matter, present in person or represented by proxy at the meeting, shall constitute a quorum entitled to take action with respect to the vote on such matter. If a quorum shall fail to attend any meeting, the chairperson of the meeting or, if directed to be voted on by the chairperson of the meeting, the holders of a majority of the voting power of the shares entitled to vote

who are present in person or represented by proxy at the meeting may adjourn the meeting. Shares of the Corporation's stock belonging to the Corporation (or to another corporation, if a majority of the shares entitled to vote in the election of directors of such other corporation are held, directly or indirectly, by the Corporation) shall neither be entitled to vote nor be counted for quorum purposes; *provided*, *however*, that the foregoing shall not limit the right of the Corporation or any other corporation to vote any shares of the Corporation's stock held by it in a fiduciary capacity and to count such shares for purposes of determining a quorum. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum.

Section 1.6: Organization. Meetings of stockholders shall be presided over by (a) such person as the Board may designate, or (b) in the absence of such a person, the Chairperson of the Board, or (c) in the absence of such person, the Lead Independent Director, or (d) in the absence of such person, the Chief Executive Officer of the Corporation, or (e) in the absence of such person, the President of the Corporation, or (f) in the absence of such person, by a Vice President of the Corporation. The Secretary of the Corporation shall act as secretary of the meeting, but in such person's absence the chairperson of the meeting may appoint any person to act as secretary of the meeting.

Section 1.7: Voting; Proxies. Each stockholder of record entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy. Such a proxy may be prepared, transmitted and delivered in any manner permitted by applicable law. Except as may be required in the Certificate of Incorporation, directors shall be elected by a plurality of the votes cast by the holders of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. At all meetings of stockholders at which a quorum is present, unless a different or minimum vote is required by applicable law, rule or regulation applicable to the Corporation or its securities, the rules or regulations of any stock exchange applicable to the Corporation, the Certificate of Incorporation or these Bylaws, in which case such different or minimum vote shall be the applicable vote on the matter, every matter other than the election of directors shall be decided by the affirmative vote of the holders of a majority of the voting power of the shares of stock entitled to vote on such matter that are present in person or represented by proxy at the meeting and are voted for or against the matter (or if there are two or more classes or series of stock entitled to vote as separate classes, then in the case of each class or series, the holders of a majority of the voting power of the shares of stock of that class or series present in person or represented by proxy at the meeting voting for or against such matter).

Section 1.8: Fixing Date for Determination of Stockholders of Record. In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall, unless otherwise required by law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at 5:00 p.m. Eastern Time on the day next preceding the day on which notice is given, or, if notice is waived, at 5:00 p.m. Eastern Time on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided*, *however*, that the Board may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix, in advance, a record date, which shall not precede the date upon which the resolution fixing the record date is adopted by the Board and which shall not be more than sixty (60) days prior to such action. If no such record date is fixed by the Board, then the record date for determining stockholders for any such purpose shall be at 5:00 p.m. Eastern Time on the day on which the Board adopts the resolution relating thereto.

Section 1.9: List of Stockholders Entitled to Vote. The Corporation shall prepare, at least ten (10) days before every meeting of stockholders, a complete list of stockholders entitled to vote at the meeting (*provided*, *however*, if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth (10th) day before the meeting date), arranged in alphabetical order and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, for a period of at least ten (10) days prior to the meeting, either (a) on a reasonably accessible electronic network as permitted by applicable law (*provided* that the information required to gain access to the list is provided with the notice of the meeting) or (b) during ordinary business hours, at the principal place of business of the Corporation. If the meeting is held at a location where stockholders may attend in person, a list of stockholders entitled to vote at the meeting shall also be produced and kept at the time and place of the meeting during the whole time thereof and may be inspected by any stockholder who is present at the meeting. If the meeting is held solely by means of remote communication, then the list shall be open to the examination of any

stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access the list shall be provided with the notice of the meeting. Except as otherwise provided by law, the stock ledger shall be the only evidence as to who are the stockholders entitled to examine the list of stockholders required by this Section 1.9 or to vote in person or by proxy at any meeting of stockholders.

Section 1.10: Inspectors of Elections.

1.10.1 Applicability. Unless otherwise required by the Certificate of Incorporation or by applicable law, the following provisions of this Section 1.10 shall apply only if and when the Corporation has a class of voting stock that is: (a) listed on a national securities exchange; (b) authorized for quotation on an interdealer quotation system of a registered national securities association; or (c) held of record by more than two thousand (2,000) stockholders. In all other cases, observance of the provisions of this Section 1.10 shall be optional, and at the discretion of the Board.

1.10.2 Appointment. The Corporation shall, in advance of any meeting of stockholders, appoint one or more inspectors of election to act at the meeting and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the person presiding at the meeting shall appoint one or more inspectors to act at the meeting.

1.10.3 Inspector's Oath. Each inspector of election, before entering upon the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of such inspector's ability.

1.10.4 Duties of Inspectors. At a meeting of stockholders, the inspectors of election shall (a) ascertain the number of shares outstanding and the voting power of each share, (b) determine the shares represented at a meeting and the validity of proxies and ballots, (c) count all votes and ballots, (d) determine and retain for a reasonable period of time a record of the disposition of any challenges made to any determination by the inspectors and (e) certify their determination of the number of shares represented at the meeting, and their count of all votes and ballots. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of the inspectors.

1.10.5 Opening and Closing of Polls. The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced by the chairperson of the meeting at the meeting. No ballot, proxies or votes, nor any revocations thereof or changes thereto, shall be accepted by the inspectors after the closing of the polls unless the Court of Chancery upon application by a stockholder shall determine otherwise.

1.10.6 Determinations. In determining the validity and counting of proxies and ballots, the inspectors shall be limited to an examination of the proxies, any envelopes submitted with those proxies, any information provided in connection with proxies pursuant to Section 211(a)(2)b.(i) of the DGCL, or in accordance with Sections 211(e) or 212(c)(2) of the DGCL, ballots and the regular books and records of the Corporation, except that the inspectors may consider other reliable information for the limited purpose of reconciling proxies and ballots submitted by or on behalf of banks, brokers, their nominees or similar persons which represent more votes than the holder of a proxy is authorized by the record owner to cast or more votes than the stockholder holds of record. If the inspectors consider other reliable information for the limited purpose permitted herein, the inspectors at the time they make their certification of their determinations pursuant to this Section 1.10 shall specify the precise information considered by them, including the person or persons from whom they obtained the information, when the information was obtained, the means by which the information was obtained and the basis for the inspectors' belief that such information is accurate and reliable.

Section 1.11: Conduct of Meetings. The Board may adopt by resolution such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board, the person presiding over any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess and/or adjourn the meeting, to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such presiding person, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the presiding person of the meeting, may include, without limitation, the following: (a) the establishment of an agenda or order of business for the meeting; (b) rules and procedures for maintaining order at the meeting and the safety of those present; (c) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as the presiding person of the meeting shall determine; (d) restrictions on entry to the meeting after the time fixed for the commencement thereof; (e) limitations on the time allotted to questions or comments by participants; (f) restricting the use of audio/video recording devices and cell phones; and (g) complying with any state and local laws and regulations concerning safety and security. The presiding person at any meeting of stockholders, in addition to making any other determinations that may be appropriate to the conduct of the meeting, shall, if the facts warrant, determine and declare to the meeting that a matter or business was not properly brought before the meeting and if such presiding person should so determine, such presiding person shall so declare to the meeting and any such matter or business not properly

brought before the meeting shall not be transacted or considered. Unless and to the extent determined by the Board or the person presiding over the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

Section 1.12: Notice of Stockholder Business; Nominations.

1.12.1 Annual Meeting of Stockholders.

(a) Nominations of persons for election to the Board and the proposal of other business to be considered by the stockholders may be made at an annual meeting of stockholders only: (i) pursuant to the Corporation's notice of such meeting (or any supplement thereto), (ii) by or at the direction of the Board or any committee thereof or (iii) by any stockholder of the Corporation who was a stockholder of record at the time of giving of the notice provided for in this Section 1.12 (the "***Record Stockholder***"), who is entitled to vote at such meeting and who complies with the notice and other procedures set forth in this Section 1.12 in all applicable respects. For the avoidance of doubt, the foregoing clause (iii) shall be the exclusive means for a stockholder to make nominations or propose business (other than business included in the Corporation's proxy materials pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, as amended (such act, and the rules and regulations promulgated thereunder, the "***Exchange Act***")), at an annual meeting of stockholders, and such stockholder must fully comply with the notice and other procedures set forth in this Section 1.12 to make such nominations or propose business before an annual meeting.

(b) For nominations or other business to be properly brought before an annual meeting by a Record Stockholder pursuant to Section 1.12.1(a) of these Bylaws:

(i) the Record Stockholder must have given timely notice thereof in writing to the Secretary of the Corporation and provide any updates or supplements to such notice at the times and in the forms required by this Section 1.12;

(ii) such other business (other than the nomination of persons for election to the Board) must otherwise be a proper matter for stockholder action;

(iii) if the Proposing Person (as defined below) has provided the Corporation with a Solicitation Notice (as defined below), such Proposing Person must, in the case of a proposal other than the nomination of persons for election to the Board, have delivered a proxy statement and form of proxy to holders of at least the percentage of the Corporation's voting shares required under applicable law to carry any such proposal, or, in the case of a nomination or nominations, have delivered a proxy statement and form of proxy to holders of a percentage of the Corporation's voting shares reasonably believed by such Proposing Person to be sufficient to elect the nominee or nominees proposed to be nominated by such Record Stockholder, and must, in either case, have included in such materials the Solicitation Notice; and

(iv) if no Solicitation Notice relating thereto has been timely provided pursuant to this Section 1.12, the Proposing Person proposing such business or nomination must not have solicited a number of proxies sufficient to have required the delivery of such a Solicitation Notice under this Section 1.12.

To be timely, a Record Stockholder's notice must be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation not later than 5:00 p.m. Eastern Time on the seventy-fifth (75th) day nor earlier than 5:00 p.m. Eastern Time on the one hundred and fifth (105th) day prior to the first anniversary of the preceding year's annual meeting (except in the case of the Corporation's first annual meeting following its initial public offering, for which such notice shall be timely if delivered in the same time period as if such meeting were a special meeting governed by Section 1.12.3 of these Bylaws); *provided*, *however*, that in the event that the date of the annual meeting is more than thirty (30) days before or more than sixty (60) days after such anniversary date, notice by the Record Stockholder to be timely must be so delivered (A) no earlier than 5:00 p.m. Eastern Time on the one hundred and fifth (105th) day prior to such annual meeting and (B) no later than 5:00 p.m. Eastern Time on the later of the ninetieth (90th) day prior to such annual meeting or 5:00 p.m. Eastern Time on the tenth (10th) day following the day on which Public Announcement (as defined below) of the date of such meeting is first made by the Corporation. In no event shall an adjournment or postponement of an annual meeting commence a new time period (or extend any time period) for providing the Record Stockholder's notice.

(c) As to each person whom the Record Stockholder proposes to nominate for election or reelection as a director, in addition to the matters set forth in paragraph (e) below, such Record Stockholder's notice shall set forth:

(i) the name, age, business address and residence address of such person;

(ii) the principal occupation or employment of such nominee;

(iii) the class, series and number of any shares of stock of the Corporation that are beneficially owned or owned of record by such person or any Associated Person (as defined in Section 1.12.4(c));

(iv) the date or dates such shares were acquired and the investment intent of such acquisition;

(v) all other information relating to such person that would be required to be disclosed in solicitations of proxies for election of directors in an election contest (even if an election contest is not involved), or would be otherwise required, in each case pursuant to and in accordance with Section 14(a) (or any successor provision) under the Exchange Act and the rules and regulations thereunder;

(vi) such person's written consent to being named in the Corporation's proxy statement as a nominee, to the public disclosure of information regarding or related to such person provided to the Corporation by such person or otherwise pursuant to this Section 1.12 and to serving as a director if elected;

(vii) whether such person meets the independence requirements of the stock exchange upon which the Corporation's Common Stock is primarily traded;

(viii) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three (3) years, and any other material relationships, between or among such Proposing Person or any of its respective affiliates and associates, on the one hand, and each proposed nominee, and his or her respective affiliates and associates, on the other hand, including all information that would be required to be disclosed pursuant to Rule 404 promulgated under Regulation S-K if the Proposing Person or any of its respective affiliates and associates were the "registrant" for purposes of such rule and the nominee were a director or executive officer of such registrant; and

(ix) a completed and signed questionnaire, representation and agreement required by Section 1.12.2 of these Bylaws.

(d) As to any business other than the nomination of a director or directors that the Record Stockholder proposes to bring before the meeting, in addition to the matters set forth in paragraph (e) below, such Record Stockholder's notice shall set forth:

(i) a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the Bylaws, the text of the proposed amendment), the reasons for conducting such business at the meeting and any material interest in such business of such Proposing Person, including any anticipated benefit to any Proposing Person therefrom; and

(ii) a description of all agreements, arrangements and understandings between or among any such Proposing Person and any of its respective affiliates or associates, on the one hand, and any other person or persons, on the other hand, (including their names) in connection with the proposal of such business by such Proposing Person.

(e) As to each Proposing Person giving the notice, such Record Stockholder's notice shall set forth:

(i) the current name and address of such Proposing Person, including, if applicable, their name and address as they appear on the Corporation's stock ledger, if different;

(ii) the class or series and number of shares of stock of the Corporation that are directly or indirectly owned of record or beneficially owned by such Proposing Person, including any shares of any class or series of the Corporation as to which such Proposing Person has a right to acquire beneficial ownership at any time in the future;

(iii) whether and the extent to which any derivative interest in the Corporation's equity securities (including without limitation any option, warrant, convertible security, stock appreciation right or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of the Corporation or with a value derived in whole or in part from the value of any class or series of shares of the Corporation, whether or not such instrument or right shall be subject to settlement in the underlying class or series of shares of the Corporation or otherwise, and any cash-settled equity swap, total return swap, synthetic equity position or similar derivative arrangement (any of the foregoing, a "***Derivative Instrument***"), as well as any rights to dividends on the shares of any class or series of shares of the Corporation that are separated or separable from the underlying shares of the Corporation) or any short interest in any security of the Corporation (for purposes of this Bylaw a person shall be deemed to have a short interest in a security if such person directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has the opportunity to profit or share in any profit derived from any increase or decrease in the value of the subject security, including through performance-related fees) is held directly or indirectly by or for the benefit of such Proposing Person, including without limitation whether and the extent to which any ongoing hedging or other transaction or series of transactions has been entered into by or on behalf of, or any other agreement, arrangement or understanding (including without limitation any short position or any borrowing or lending of shares) has been made, the effect or intent of which is to mitigate loss to or manage risk or benefit of share price changes for, or to increase or decrease the voting power of, such Proposing Person with respect to any share of stock of the Corporation (any of the foregoing, a "***Short Interest***");

(iv) any proportionate interest in shares of the Corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such Proposing Person or any of its respective affiliates or associates is a general partner or, directly or indirectly, beneficially owns an interest in a general partner of such general or limited partnership;

(v) any direct or indirect material interest in any material contract or agreement with the Corporation, any affiliate of the Corporation or any Competitor (as defined below) (including, in any such case, any employment agreement, collective bargaining agreement or consulting agreement);

(vi) any significant equity interests or any Derivative Instruments or Short Interests in any Competitor held by such Proposing Person and/or any of its respective affiliates or associates;

(vii) any other material relationship between such Proposing Person, on the one hand, and the Corporation, any affiliate of the Corporation or any Competitor, on the other hand;

(viii) all information that would be required to be set forth in a Schedule 13D filed pursuant to Rule 13d-1(a) or an amendment pursuant to Rule 13d-2(a) if such a statement were required to be filed under the Exchange Act and the rules and regulations promulgated thereunder by such Proposing Person and/or any of its respective affiliates or associates;

(ix) any other information relating to such Proposing Person that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies or consents by such Proposing Person in support of the business proposed to be brought before the meeting pursuant to Section 14(a) (or any successor provision) under the Exchange Act and the rules and regulations thereunder;

(x) such Proposing Person's written consent to the public disclosure of information provided to the Corporation pursuant to this Section 1.12;

(xi) a complete written description of any agreement, arrangement or understanding (whether oral or in writing) (including any knowledge that another person or entity is Acting in Concert (as defined in Section 1.12.4(c)) with such Proposing Person) between or among such Proposing Person, any of its respective affiliates or associates and any other person Acting in Concert with any of the foregoing persons;

(xii) a representation that the Record Stockholder is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business or nomination;

(xiii) a representation whether such Proposing Person intends (or is part of a group that intends) to deliver a proxy statement or form of proxy to holders of, in the case of a proposal, at least the percentage of the Corporation's voting shares required under applicable law to carry the proposal or, in the case of a nomination or nominations, a sufficient number of holders of the Corporation's voting shares to elect such nominee or nominees (an affirmative statement of such intent being a "***Solicitation Notice***"); and

(xiv) any proxy, contract, arrangement or relationship pursuant to which the Proposing Person has a right to vote, directly or indirectly, any shares of any security of the Corporation.

The disclosures to be made pursuant to the foregoing clauses (ii), (iii), (iv) and (vi) shall not include any information with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these Bylaws on behalf of a beneficial owner.

(f) A stockholder providing written notice required by this Section 1.12 shall update such notice in writing, if necessary, so that the information provided or required to be provided in such notice is true and correct in all material respects as of (i) the record date for determining the stockholders entitled to notice of the meeting and (ii) 5:00 p.m. Eastern Time on the tenth (10th) business day prior to the meeting or any adjournment or postponement thereof. In the case of an update pursuant to clause (i) of the foregoing sentence, such update shall be received by the Secretary of the Corporation at the principal executive office of the Corporation not later than five (5) business days after the record date for determining the stockholders entitled to notice of the meeting, and in the case of an update and supplement pursuant to clause (ii) of the foregoing sentence, such update and supplement shall be received by the Secretary of the Corporation at the principal executive office of the Corporation not later than eight (8) business days prior to the date for the meeting and, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed). For the avoidance of doubt, the obligation to update as set forth in this paragraph shall not limit the Corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any proposal or nomination or to submit any new proposal, including by changing or adding nominees, matters, business and/or resolutions proposed to be brought before a meeting of the stockholders.

(g) Notwithstanding anything in Section 1.12 or any other provision of these Bylaws to the contrary, any person who has been determined by a majority of the Whole Board to have violated Section 2.11 of these Bylaws or a Board Confidentiality Policy (as defined below) while serving as a director of the Corporation in the preceding five (5) years shall be ineligible to be nominated or be qualified to serve as a member of the Board, absent a prior waiver for such nomination or qualification approved by two-thirds of the Whole Board.

1.12.2 Submission of Questionnaire, Representation and Agreement. To be eligible to be a nominee of any stockholder for election or reelection as a director of the Corporation, the person proposed to be nominated must deliver (in accordance with the time periods prescribed for delivery of notice under Section 1.12 of these Bylaws) to the Secretary of the Corporation at the principal executive offices of the Corporation a completed and signed questionnaire in the form required by the Corporation (which form the stockholder shall request in writing from the Secretary of the Corporation and which the Secretary shall provide to such stockholder within ten days of receiving such request) with respect to the background and qualification of such person to serve as a director of the Corporation and the background of any other person or entity on whose behalf, directly or indirectly, the nomination is being made and a signed representation and agreement (in the form available from the Secretary upon written request) that such person: (a) is not and will not become a party to (i) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the Corporation, will act or vote on any issue or question (a "***Voting Commitment***") that has not been disclosed to the Corporation or (ii) any Voting Commitment that could limit or interfere with such person's ability to comply, if elected as a director of the Corporation, with such person's fiduciary duties under applicable law, (b) is not and will not become a party to any Compensation Arrangement (as defined below) that has not been disclosed therein, (c) if elected as a director of the Corporation, will comply with all informational and similar requirements of applicable insurance policies and laws and regulations in connection with service or action as a director of the Corporation, (d) if elected as a director of the Corporation, will comply with all corporate governance, conflict of interest, stock ownership requirements, confidentiality and trading policies and guidelines of the Corporation publicly disclosed from time to time, (e) if elected as a director of the Corporation, will act in the best interests of the Corporation and its stockholders and not in the interests of individual constituencies, (f) consents to being named as a nominee in the Corporation's proxy statement pursuant to Rule 14a-4(d) under the Exchange Act and any associated proxy card of the Corporation and agrees to serve if elected as a director and (g) intends to serve as a director for the full term for which such individual is to stand for election.

1.12.3 Special Meetings of Stockholders. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation's notice of such meeting. Nominations of persons for election to the Board may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of such meeting (a) by or at the direction of the Board or any committee thereof or (b) *provided* that the Board has determined that directors shall be elected at such meeting, by any stockholder of the Corporation who is a stockholder of record at the time of giving of notice of the special meeting, who shall be entitled to vote at the meeting and who complies with the notice and other procedures set forth in this Section 1.12 in all applicable respects. In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board, any such stockholder may nominate a person or persons (as the case may be), for election to such position(s) as specified in the Corporation's notice of meeting, if the stockholder's notice required by Section 1.12.1(b) of these Bylaws shall be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation (i) no earlier than the one hundred and fifth (105th) day prior to such special meeting and (ii) no later than 5:00 p.m. Eastern Time on the later of the seventy-fifth (75th) day prior to such special meeting or the tenth (10th) day following the day on which Public Announcement is first made of the date of the special meeting and of the nominees proposed by the Board to be elected at such meeting. In no event shall an adjournment or postponement of a special meeting commence a new time period (or extend any time period) for providing such notice.

1.12.4 General.

(a) Except as otherwise expressly provided in any applicable rule or regulation promulgated under the Exchange Act, only such persons who are nominated in accordance with the procedures set forth in this Section 1.12 shall be eligible to be elected at a meeting of stockholders and serve as directors and only such business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 1.12. Except as otherwise provided by law or these Bylaws, the chairperson of the meeting shall have the power and duty to determine whether a nomination or any other business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with the procedures set forth in this Section 1.12 and, if any proposed nomination or business is not in compliance herewith, to declare that such defective proposal or nomination shall be disregarded. Notwithstanding the foregoing provisions of this Section 1.12, unless otherwise required by law, if the stockholder (or a Qualified Representative of the stockholder (as defined below)) does not appear at the annual or special meeting of stockholders of the Corporation to present a nomination or proposed business, such nomination shall be disregarded and such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation.

(b) Notwithstanding the foregoing provisions of this Section 1.12, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations thereunder with respect to the matters set forth herein. Nothing in this Section 1.12 shall be deemed to affect any rights of (a) stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act or (b) the holders of any series of the Corporation's Preferred Stock to elect directors pursuant to any applicable provisions of the Certificate of Incorporation.

(c) For purposes of these Bylaws the following definitions shall apply:

(A) a person shall be deemed to be "***Acting in Concert***" with another person if such person knowingly acts (whether or not pursuant to an express agreement, arrangement or understanding) in concert with, or toward a common goal relating to the management, governance or control of the Corporation in substantial parallel with, such other person where (1) each person is conscious of the other person's conduct or intent and this awareness is an element in their decision-making processes and (2) at least one additional factor suggests that such persons intend to act in concert or in substantial parallel, which such additional factors may include, without limitation, exchanging information (whether publicly or privately), attending meetings, conducting discussions or making or soliciting invitations to act in concert or in substantial parallel; *provided* that a person shall not be deemed to be Acting in Concert with any other person solely as a result of the solicitation or receipt of revocable proxies or consents from such other person in response to a solicitation made pursuant to, and in accordance with, Section 14(a) (or any successor provision) of the Exchange Act by way of a proxy or consent solicitation statement filed on Schedule 14A. A person Acting in Concert with another person shall be deemed to be Acting in Concert with any third party who is also Acting in Concert with such other person;

(B) "***affiliate***" and "***associate***" shall have the meanings ascribed thereto in Rule 405 under the Securities Act of 1933, as amended (the "***Securities Act***"); *provided*, *however*, that the term "partner" as used in the definition of "associate" shall not include any limited partner that is not involved in the management of the relevant partnership;

(C) "***Associated Person***" shall mean with respect to any subject stockholder or other person (including any proposed nominee) (1) any person directly or indirectly controlling, controlled by or under common control with such stockholder or other person, (2) any beneficial owner of shares of stock of the Corporation owned of record or beneficially by such stockholder or other person, (3) any associate of such stockholder or other person and (4) any person directly or indirectly controlling, controlled by or under common control or Acting in Concert with any such Associated Person;

(D) "***Compensation Arrangement***" shall mean any direct or indirect compensatory payment or other financial agreement, arrangement or understanding with any person or entity other than the Corporation, including any agreement, arrangement or understanding with respect to any direct or indirect compensation, reimbursement or indemnification in connection with candidacy, nomination, service or action as a nominee or as a director of the Corporation;

(E) "***Competitor***" shall mean any entity that provides products or services that compete with or are alternatives to the principal products produced or services provided by the Corporation or its affiliates;

(F) "***Proposing Person***" shall mean (1) the Record Stockholder providing the notice of business proposed to be brought before an annual meeting or nomination of persons for election to the Board at a stockholder meeting, (2) the beneficial owner or beneficial owners, if different, on whose behalf the notice of business proposed to be brought before the annual meeting or nomination of persons for election to the Board at a stockholder meeting is made and (3) any Associated Person on whose behalf the notice of business proposed to be brought before the annual meeting or nomination of persons for election to the Board at a stockholder meeting is made;

(G) "***Public Announcement***" shall mean disclosure in a press release reported by a national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act; and

(H) to be considered a "***Qualified Representative***" of a stockholder, a person must be a duly authorized officer, manager, trustee or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as a proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction thereof, at the meeting. The Secretary of the Corporation, or any other person who shall be appointed to serve as secretary of the meeting, may require, on behalf of the Corporation, reasonable and appropriate documentation to verify the status of a person purporting to be a "Qualified Representative" for purposes hereof.

ARTICLE II: BOARD OF DIRECTORS

Section 2.1: Number; Qualifications. The total number of directors constituting the Whole Board shall be fixed from time to time in the manner set forth in the Certificate of Incorporation and the term "**Whole Board**" shall have the meaning specified in the Certificate of Incorporation. No decrease in the authorized number of directors constituting the Whole Board shall shorten the term of any incumbent director. Directors need not be stockholders of the Corporation.

Section 2.2: Election; Resignation; Removal; Vacancies. Election of directors need not be by written ballot. Each director shall hold office until the annual meeting at which such director's term expires and until such director's successor is elected and qualified or until such director's earlier death, resignation, disqualification or removal. Any director may resign by delivering a resignation in writing or by electronic transmission to the Corporation at its principal office or to the Chairperson of the Board, the Chief Executive Officer or the Secretary. Such resignation shall be effective upon delivery unless it is specified to be effective at a later time or upon the happening of an event. Subject to the special rights of holders of any series of the Corporation's Preferred Stock to elect directors, directors may be removed only as provided by the Certificate of Incorporation and applicable law. All vacancies occurring in the Board and any newly created directorships resulting from any increase in the authorized number of directors shall be filled in the manner set forth in the Certificate of Incorporation.

Section 2.3: Regular Meetings. Regular meetings of the Board may be held at such places, within or without the State of Delaware, and at such times as the Board may from time to time determine. Notice of regular meetings need not be given if the date, times and places thereof are fixed by resolution of the Board.

Section 2.4: Special Meetings. Special meetings of the Board may be called by the Chairperson of the Board, the Chief Executive Officer, the Lead Independent Director or a majority of the members of the Board then in office and may be held at any time, date or place, within or without the State of Delaware, as the person or persons calling the meeting shall fix. Notice of the time, date and place of such meeting shall be given orally, in writing or by electronic transmission (including electronic mail), by the person or persons calling the meeting to all directors at least four (4) days before the meeting if the notice is mailed, or at least twenty-four (24) hours before the meeting if such notice is given by telephone, hand delivery, telegram, telex, mailgram, facsimile, electronic mail or other means of electronic transmission; *provided, however*, that if, under the circumstances, the Chairperson of the Board, the Lead Independent Director or the Chief Executive Officer calling a special meeting deems that more immediate action is necessary or appropriate, notice may be delivered on the day of such special meeting. Unless otherwise indicated in the notice, any and all business may be transacted at a special meeting.

Section 2.5: Remote Meetings Permitted. Members of the Board, or any committee of the Board, may participate in a meeting of the Board or such committee by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting pursuant to conference telephone or other communications equipment shall constitute presence in person at such meeting.

Section 2.6: Quorum; Vote Required for Action. At all meetings of the Board, a majority of the Whole Board shall constitute a quorum for the transaction of business. If a quorum shall fail to attend any meeting, a majority of those present may adjourn the meeting to another place, date or time. Except as otherwise provided herein or in the Certificate of Incorporation, or required by law, the vote of a majority of the directors present at a meeting at which a quorum is present shall be the act of the Board.

Section 2.7: Organization. Meetings of the Board shall be presided over by (a) the Chairperson of the Board, or (b) in the absence of such person, the Lead Independent Director, or (c) in such person's absence, by the Chief Executive Officer, or (d) in such person's absence, by a chairperson chosen by the Board at the meeting. The Secretary of the Corporation shall act as secretary of the meeting, but in such person's absence the chairperson of the meeting may appoint any person to act as secretary of the meeting.

Section 2.8: Unanimous Action by Directors in Lieu of a Meeting. Any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or such committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or committee, as applicable. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

Section 2.9: Powers. Except as otherwise provided by the Certificate of Incorporation or the DGCL, the business and affairs of the Corporation shall be managed by or under the direction of the Board.

Section 2.10: Compensation of Directors. Members of the Board, as such, may receive, pursuant to a resolution of the Board, fees and other compensation for their services as directors, including without limitation their services as members of committees of the Board.

Section 2.11: Confidentiality. Each director shall maintain the confidentiality of, and shall not share with any third-party person or entity (including third parties that originally sponsored, nominated or designated such director (the "***Sponsoring Party***")), any non-public information learned in their capacities as directors, including communications among Board members in their capacities as directors. The Board may adopt a board confidentiality policy further implementing and interpreting this Section 2.11 (a "***Board Confidentiality Policy***"). All directors are required to comply with this Section 2.11 and any Board Confidentiality Policy unless such director or the Sponsoring Party for such director has entered into a specific written agreement with the Corporation, in either case as approved by the Board, providing otherwise with respect to such confidential information.

ARTICLE III: COMMITTEES

Section 3.1: Committees. The Board may designate one or more committees, each committee to consist of one or more of the directors of the Corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of the committee, the member or members thereof present at any meeting of such committee who are not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in place of any such absent or disqualified member. Any such committee, to the extent provided in a resolution of the Board, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation and may authorize the seal of the Corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority in reference to the following matters: (a) approving, adopting or recommending to the stockholders any action or matter (other than the election or removal of members of the Board) expressly required by the DGCL to be submitted to stockholders for approval or (b) adopting, amending or repealing any bylaw of the Corporation.

Section 3.2: Committee Rules. Each committee shall keep records of its proceedings and make such reports as the Board may from time to time request. Unless the Board otherwise provides, each committee designated by the Board may make, alter and repeal rules for the conduct of its business. In the absence of such rules, each committee shall conduct its business in the same manner as the Board conducts its business pursuant to Article II of these Bylaws. Except as otherwise provided in the Certificate of Incorporation, these Bylaws or the resolution of the Board designating the committee, any committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and may delegate to any such subcommittee any or all of the powers and authority of the committee.

ARTICLE IV: OFFICERS; CHAIRPERSON; LEAD INDEPENDENT DIRECTOR

Section 4.1: Generally. The officers of the Corporation shall consist of a Chief Executive Officer (who may be the Chairperson of the Board or the President), a President, a Secretary and a Treasurer and may consist of such other officers, including, without limitation, a Chief Financial Officer, and one or more Vice Presidents, as may from time to time be appointed by the Board. All officers shall be elected by the Board; *provided*, *however*, that the Board may empower the Chief Executive Officer of the Corporation to appoint any officer other than the Chief Executive Officer, the President, the Chief Financial Officer or the Treasurer. Except as otherwise provided by law, the Certificate of Incorporation or these Bylaws, each officer shall hold office until such officer's successor is duly elected and qualified or until such officer's earlier resignation, death, disqualification or removal. Any number of offices may be held by the same person. Any officer may resign by delivering a resignation in writing or by electronic transmission to the Corporation at its principal office or to the Chairperson of the Board, the Chief Executive Officer or the Secretary. Such resignation shall be effective upon delivery unless it is specified to be effective at some later time or upon the happening of some later event. Any vacancy occurring in any office of the Corporation by death, resignation, removal or otherwise may be filled by the Board and the Board may, in its discretion, leave unfilled, for such period as it may determine, any offices. Each such successor shall hold office for the unexpired term of such officer's predecessor and until a successor is duly elected and qualified or until such officer's earlier resignation, death, disqualification or removal.

Section 4.2: Chief Executive Officer. Subject to the control of the Board and such supervisory powers (if any) as may be given by the Board, the powers and duties of the Chief Executive Officer of the Corporation are:

(a) to act as the general manager and, subject to the control of the Board, to have general supervision, direction and control of the business and affairs of the Corporation;

(b) subject to Section 1.6 of these Bylaws, to preside at all meetings of the stockholders;

(c) subject to Section 1.2 of these Bylaws, to call special meetings of the stockholders to be held at such times and, subject to the limitations prescribed by law or by these Bylaws, at such places as he or she shall deem proper; and

(d) to affix the signature of the Corporation to all deeds, conveyances, mortgages, guarantees, leases, obligations, bonds, certificates and other papers and instruments in writing which have been authorized by the Board or which, in the judgment of the Chief Executive Officer, should be executed on behalf of the Corporation; to sign certificates for shares of stock of the Corporation (if any); and, subject to the direction of the Board, to have general charge of the property of the Corporation and to supervise and control all officers, agents and employees of the Corporation.

The person holding the office of President shall be the Chief Executive Officer of the Corporation unless the Board shall designate another officer to be the Chief Executive Officer.

Section 4.3: Chairperson of the Board. Subject to the provisions of Section 2.7 of these Bylaws, the Chairperson of the Board shall have the power to preside at all meetings of the Board and shall have such other powers and duties as provided in these Bylaws and as the Board may from time to time prescribe. The Chairperson of the Board may or may not be an officer of the Corporation.

Section 4.4: Lead Independent Director. The Board may, in its discretion, elect a lead independent director from among its members that are Independent Directors (as defined below) (such director, the "***Lead Independent Director***"). The Lead Independent Director shall preside at all meetings at which the Chairperson of the Board is not present and shall exercise such other powers and duties as may from time to time be assigned to him or her by the Board or as prescribed by these Bylaws. For purposes of these Bylaws, "***Independent Director***" has the meaning ascribed to such term under the rules of the exchange upon which the Corporation's Common Stock is primarily traded.

Section 4.5: President. The person holding the office of Chief Executive Officer shall be the President of the Corporation unless the Board shall have designated one individual as the President and a different individual as the Chief Executive Officer of the Corporation. Subject to the provisions of these Bylaws and to the direction of the Board, and subject to the supervisory powers of the Chief Executive Officer (if the Chief Executive Officer is an officer other than the President), and subject to such supervisory powers and authority as may be given by the Board to the Chairperson of the Board, and/or to any other officer, the President shall have the responsibility for the general management and control of the business and affairs of the Corporation and the general supervision and direction of all of the officers, employees and agents of the Corporation (other than the Chief Executive Officer, if the Chief Executive Officer is an officer other than the President) and shall perform all duties and have all powers that are commonly incident to the office of President or that are delegated to the President by the Board.

Section 4.6: Chief Financial Officer. The person holding the office of Chief Financial Officer shall be the Treasurer of the Corporation unless the Board shall have designated another officer as the Treasurer of the Corporation. Subject to the direction of the Board and the Chief Executive Officer, the Chief Financial Officer shall perform all duties and have all powers that are commonly incident to the office of Chief Financial Officer, or as the Board or the Chief Executive Officer may from time to time prescribe.

Section 4.7: Treasurer. The person holding the office of Treasurer shall be the Chief Financial Officer of the Corporation unless the Board shall have designated another officer as the Chief Financial Officer of the Corporation. The Treasurer shall have custody of all monies and securities of the Corporation. The Treasurer shall make such disbursements of the funds of the Corporation as are authorized and shall render from time to time an account of all such transactions. The Treasurer shall also perform such other duties and have such other powers as are commonly incident to the office of Treasurer, or as the Board or the Chief Executive Officer may from time to time prescribe.

Section 4.8: Vice President. Each Vice President shall have all such powers and duties as are commonly incident to the office of Vice President or that are delegated to him or her by the Board or the Chief Executive Officer. A Vice President may be designated by the Board to perform the duties and exercise the powers of the Chief Executive Officer or President in the event of the Chief Executive Officer's or President's absence or disability.

Section 4.9: Secretary. The Secretary shall issue or cause to be issued all authorized notices for, and shall keep, or cause to be kept, minutes of all meetings of the stockholders and the Board. The Secretary shall have charge of the corporate minute books and similar records and shall perform such other duties and have such other powers as are commonly incident to the office of Secretary, or as the Board or the Chief Executive Officer may from time to time prescribe.

Section 4.10: Delegation of Authority. The Board may from time to time delegate the powers or duties of any officer of the Corporation to any other officers or agents of the Corporation, notwithstanding any provision hereof.

Section 4.11: Removal. Any officer of the Corporation shall serve at the pleasure of the Board and may be removed at any time, with or without cause, by the Board; *provided* that if the Board has empowered the Chief Executive Officer to appoint any officer of the Corporation, then such officer may also be removed by the Chief Executive Officer. Such removal shall be without prejudice to the contractual rights of such officer (if any) with the Corporation.

ARTICLE V: STOCK

Section 5.1: Certificates; Uncertificated Shares. The shares of capital stock of the Corporation shall be uncertificated shares; *provided*, *however*, that the resolution of the Board that the shares of capital stock of the Corporation shall be uncertificated shares shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation (or the transfer agent or registrar, as the case may be). Notwithstanding the foregoing, the Board may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be certificated shares. Every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of, the Corporation, by any two authorized officers of the Corporation (it being understood that each of the Chairperson of the Board, the Vice-Chairperson of the Board, the Chief Executive Officer, the President, any Vice President, the Treasurer, any Assistant Treasurer, the Secretary and any Assistant Secretary shall be an authorized officer for such purpose), representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were an officer, transfer agent or registrar at the date of issue.

Section 5.2: Lost, Stolen or Destroyed Stock Certificates; Issuance of New Certificates or Uncertificated Shares. The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate previously issued by it, alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to agree to indemnify the Corporation and/or to give the Corporation a bond sufficient to indemnify it, against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

Section 5.3: Other Regulations. Subject to applicable law, the Certificate of Incorporation and these Bylaws, the issue, transfer, conversion and registration of shares represented by certificates and of uncertificated shares shall be governed by such other regulations as the Board may establish.

ARTICLE VI: INDEMNIFICATION

Section 6.1: Indemnification of Officers and Directors. Each person who was or is made a party to, or is threatened to be made a party to, or is involved in any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative, legislative, investigative or any other type whatsoever, preliminary, informal or formal, including any arbitration or other alternative dispute resolution (including but not limited to giving testimony or responding to a subpoena) and including any appeal of any of the foregoing (a "***Proceeding***"), by reason of the fact that such person (or a person of whom such person is the legal representative), is or was a director or officer of the Corporation or a Reincorporated Predecessor (as defined below) or, while serving as a director or officer of the Corporation or a Reincorporated Predecessor, is or was serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise or non-profit entity, including service with respect to employee benefit plans (for purposes of this Article VI, an "***Indemnitee***"), shall be indemnified and held harmless by the Corporation to the fullest extent permitted by the DGCL as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), against all expenses, costs, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes and penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such Indemnitee in connection therewith. Such indemnification shall continue as to an Indemnitee who has ceased to be a director or officer of the Corporation or a Reincorporated Predecessor (as defined below) or, while serving as a director or officer of the Corporation or a Reincorporated Predecessor, is or was serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation, or of a partnership, joint venture, trust or other enterprise or non-profit entity, including service with respect to employee benefit plans and shall inure to the benefit of such Indemnitees' heirs, executors and administrators. Notwithstanding the foregoing, subject to Section 6.5 of this Article VI, the Corporation shall indemnify any such Indemnitee seeking indemnity in connection with a Proceeding (or part thereof) initiated by such Indemnitee only if such Proceeding (or part thereof) was authorized by the Board or such indemnification is authorized by an agreement approved by the Board. As used herein, the term the "***Reincorporated Predecessor***" means a corporation that is merged with and into the Corporation in a statutory merger where (a) the Corporation is the surviving corporation of such merger; or (b) the primary purpose of such merger is to change the corporate domicile of the Reincorporated Predecessor to Delaware.

Section 6.2: Advancement of Expenses. Notwithstanding any other provision of these Bylaws, the Corporation shall pay all reasonable expenses (including attorneys' fees) incurred by an Indemnitee in defending any Proceeding in advance of its final disposition; *provided*, *however*, that if the DGCL then so requires, the advancement of such expenses (i.e., payment of such expenses as incurred or otherwise in advance of the final disposition of the Proceeding) shall be made only upon delivery to the Corporation of

an undertaking, by or on behalf of such Indemnitee, to repay such amounts if it shall ultimately be determined by a court of competent jurisdiction in a final judgment not subject to appeal that such Indemnitee is not entitled to be indemnified under this Article VI or otherwise. Any advances of expenses or undertakings to repay pursuant to this Section 6.2 shall be unsecured, interest free and without regard to Indemnitee's ability to pay.

Section 6.3: Non-Exclusivity of Rights. The rights conferred on any person in this Article VI shall not be exclusive of any other right that such person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, Bylaws, agreement, vote or consent of stockholders or disinterested directors, or otherwise. Additionally, nothing in this Article VI shall limit the ability of the Corporation, in its discretion, to indemnify or advance expenses to persons whom the Corporation is not obligated to indemnify or advance expenses pursuant to this Article VI.

Section 6.4: Indemnification Contracts. The Board is authorized to cause the Corporation to enter into indemnification contracts with any director, officer, employee or agent of the Corporation, or any person serving at the request of the Corporation as a director, officer, employee, agent or trustee of another corporation, partnership, joint venture, trust or other enterprise or non-profit entity, including employee benefit plans, providing indemnification or advancement rights to such person. Such rights may be greater than those provided in this Article VI.

Section 6.5: Right of Indemnitee to Bring Suit.

6.5.1 Right to Bring Suit. If a claim under Section 6.1 or 6.2 of this Article VI is not paid in full by the Corporation within sixty (60) days after a written claim has been received by the Corporation, except in the case of a claim for an advancement of expenses, in which case the applicable period shall be twenty (20) days, the Indemnitee may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim. If the Indemnitee is successful in whole or in part in any such suit, or in a suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Indemnitee also shall be entitled to be paid, to the fullest extent permitted by law, the expense of prosecuting or defending such suit.

6.5.2 Effect of Determination. Neither the absence of a determination prior to the commencement of such suit that indemnification of or the providing of advancement to the Indemnitee is proper in the circumstances because the Indemnitee has met the applicable standard of conduct set forth in applicable law, nor an actual determination that the Indemnitee has not met such applicable standard of conduct, shall create a presumption that the Indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the Indemnitee, be a defense to such suit.

6.5.3 Burden of Proof. In any suit brought by the Indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the burden of proving that the Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article VI, or otherwise, shall be on the Corporation.

Section 6.6: Nature of Rights. The rights conferred upon Indemnitees in this Article VI shall be contract rights and such rights shall continue as to an Indemnitee who has ceased to be a director or officer and shall inure to the benefit of the Indemnitee's heirs, executors and administrators.

Section 6.7: Amendment or Repeal. Any amendment, repeal or modification of any provision of this Article VI that adversely affects any right of an Indemnitee or an Indemnitee's successors shall be prospective only, and shall not adversely affect any right or protection conferred on a person pursuant to this Article VI and existing at the time of such amendment, repeal or modification.

Section 6.8: Insurance. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise or non-profit entity against any expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

ARTICLE VII:NOTICES

Section 7.1: Notice.

7.1.1 Form and Delivery. Except as otherwise specifically required in these Bylaws (including, without limitation, Section 7.1.2 of these Bylaws) or by applicable law, all notices required to be given pursuant to these Bylaws may (a) in every instance in connection with any delivery to a member of the Board, be effectively given by hand delivery (including use of a delivery service), by depositing such notice in the mail, postage prepaid, or by sending such notice by overnight express courier, facsimile, electronic mail

or other form of electronic transmission and (b) be effectively delivered to a stockholder when given by hand delivery, by depositing such notice in the mail, postage prepaid, or, if specifically consented to by the stockholder as described in Section 7.1.2 of these Bylaws, by sending such notice by facsimile, electronic mail or other form of electronic transmission. Any such notice shall be addressed to the person to whom notice is to be given at such person's address as it appears on the records of the Corporation. The notice shall be deemed given (a) in the case of hand delivery, when received by the person to whom notice is to be given or by any person accepting such notice on behalf of such person, (b) in the case of delivery by mail, upon deposit in the mail, (c) in the case of delivery by overnight express courier, when dispatched, and (d) in the case of delivery via facsimile, electronic mail or other form of electronic transmission, at the time provided in Section 7.1.2 of these Bylaws.

7.1.2 Electronic Transmission. Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Corporation under any provision of the DGCL, the Certificate of Incorporation or these Bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given in accordance with Section 232 of the DGCL. Any such consent shall be revocable by the stockholder by written notice to the Corporation. Any such consent shall be deemed revoked if (a) the Corporation is unable to deliver by electronic transmission two consecutive notices given by the Corporation in accordance with such consent and (b) such inability becomes known to the Secretary or an Assistant Secretary of the Corporation or to the transfer agent, or other person responsible for the giving of notice; *provided*, *however*, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action. Notice given pursuant to this Section 7.1.2 shall be deemed given: (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice; (ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice; (iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of such posting and the giving of such separate notice; and (iv) if by any other form of electronic transmission, when directed to the stockholder.

7.1.3 Affidavit of Giving Notice. An affidavit of the Secretary or an Assistant Secretary or of the transfer agent or other agent of the Corporation that the notice has been given in writing or by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

Section 7.2: Waiver of Notice. Whenever notice is required to be given under any provision of the DGCL, the Certificate of Incorporation or these Bylaws, a written waiver of notice, signed by the person entitled to notice, or waiver by electronic transmission by such person, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders, directors or members of a committee of directors need be specified in any waiver of notice.

ARTICLE VIII: INTERESTED DIRECTORS

Section 8.1: Interested Directors. No contract or transaction between the Corporation and one or more of its members of the Board or officers, or between the Corporation and any other corporation, partnership, association or other organization in which one or more of its directors or officers are members of the board of directors or officers, or have a financial interest, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the Board or committee thereof that authorizes the contract or transaction, or solely because his, her or their votes are counted for such purpose, if: (a) the material facts as to his, her or their relationship or interest and as to the contract or transaction are disclosed or are known to the Board or the committee, and the Board or committee in good faith authorizes the contract or transaction by the affirmative votes of a majority of the disinterested directors, even though the disinterested directors be less than a quorum; (b) the material facts as to his, her or their relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon, and the contract or transaction is specifically approved in good faith by vote of the stockholders; or (c) the contract or transaction is fair as to the Corporation as of the time it is authorized, approved or ratified by the Board, a committee thereof, or the stockholders.

Section 8.2: Quorum. Interested directors may be counted in determining the presence of a quorum at a meeting of the Board or of a committee which authorizes the contract or transaction.

ARTICLE IX: MISCELLANEOUS

Section 9.1: Fiscal Year. The fiscal year of the Corporation shall be determined by resolution of the Board.

Section 9.2: Seal. The Board may provide for a corporate seal, which may have the name of the Corporation inscribed thereon and shall otherwise be in such form as may be approved from time to time by the Board.

Section 9.3: Form of Records. Any records administered by or on behalf of the Corporation in the regular course of its business, including its stock ledger, books of account and minute books, may be kept on or by means of, or be in the form of, any other information storage device, method or one or more electronic networks or databases (including one or more distributed electronic networks or databases), electronic or otherwise, *provided* that the records so kept can be converted into clearly legible paper form within a reasonable time and otherwise comply with the DGCL. The Corporation shall so convert any records so kept upon the request of any person entitled to inspect such records pursuant to any provision of the DGCL.

Section 9.4: Reliance Upon Books and Records. A member of the Board, or a member of any committee designated by the Board shall, in the performance of such person's duties, be fully protected in relying in good faith upon the books and records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of the Corporation's officers or employees, or committees of the Board, or by any other person as to matters the member reasonably believes are within such other person's professional or expert competence and who has been selected with reasonable care by or on behalf of the Corporation.

Section 9.5: Certificate of Incorporation Governs. In the event of any conflict between the provisions of the Certificate of Incorporation and these Bylaws, the provisions of the Certificate of Incorporation shall govern.

Section 9.6: Severability. If any provision of these Bylaws shall be held to be invalid, illegal, unenforceable or in conflict with the provisions of the Certificate of Incorporation, then such provision shall nonetheless be enforced to the maximum extent possible consistent with such holding and the remaining provisions of these Bylaws (including without limitation, all portions of any section of these Bylaws containing any such provision held to be invalid, illegal, unenforceable or in conflict with the Certificate of Incorporation, that are not themselves invalid, illegal, unenforceable or in conflict with the Certificate of Incorporation) shall remain in full force and effect.

Section 9.7: Time Periods. In applying any provision of these Bylaws which requires that an act be done or not be done a specified number of days prior to an event or that an act be done during a period of a specified number of days prior to an event, calendar days shall be used, the day of the doing of the act shall be excluded, and the day of the event shall be included.

ARTICLE X: AMENDMENT

Notwithstanding any other provision of these Bylaws, any alteration, amendment or repeal of these Bylaws, and any adoption of new Bylaws, shall require the approval of the Board or the stockholders of the Corporation as expressly provided in the Certificate of Incorporation.

ARTICLE XI: EXCLUSIVE FORUM

Unless the Corporation consents in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring or holding any interest in any security of the Corporation shall be deemed to have notice of and consented to the provisions of this Article XI.

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULE 13a-14(a) OR 15d-14(a) OF 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 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)) 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. 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

   c. 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.

5. The registrant's other certifying officer 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: November 12, 2020

Graybug Vision, Inc.

/s/ Frederic Guerard

Frederic Guerard
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULE 13a-14(a) OR 15d-14(a) OF 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 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)) 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. 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

   c. 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.

5. The registrant's other certifying officer 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: November 12, 2020

Graybug Vision, Inc.

/s/ Robert S. Breuil

Robert S. Breuil
Chief Financial Officer
(Principal Financial and 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

I, Frederic Guerard, Chief Executive Officer of Graybug Vision, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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: November 12, 2020

Graybug Vision, Inc.

/s/ Frederic Guerard

Frederic Guerard
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

I, Robert S. Breuil, Chief Financial Officer of Graybug Vision, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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: November 12, 2020

Graybug Vision, Inc.

/s/ Robert S. Breuil

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