UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 March 31, 2026

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: 001-43165

Generate Biomedicines, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-1630228**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
101 South Street, Suite 900 Somerville, MA	**02143**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (888) 469-0055

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, $0.001 par value per share	GENB	The Nasdaq Global Select 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 ☒

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of April 29, 2026, the registrant had 128,192,484 shares of common stock, $0.001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (the "Quarterly Report") contains forward-looking statements about us and our industry that involve substantial risks and uncertainties, and which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our future results of operations and financial position, business strategy, product candidates, preclinical studies and clinical trials, results of preclinical studies and clinical trials, research and development costs, regulatory approvals, commercial strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements.

Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials;
- the ability of clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results, and the ability of our preclinical studies and earlier clinical trials to predict later clinical trial results;
- the timing, scope and likelihood of regulatory filings and approvals of our product candidates;
- the implementation of our business model, and strategic plans for our business, programs, and current and future product candidates;
- our ability to effectively use artificial intelligence ("AI") in our drug discovery and development process, and to maintain and improve our Generate Platform;
- the acceptance of AI in the biotechnology industry, including market acceptance of products and product candidates discovered and developed using AI;
- our ability to obtain additional cash and the sufficiency of our existing cash, cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our potential and ability to successfully manufacture and supply our current and future product candidates for clinical trials and for commercial use, if approved;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- existing regulations and regulatory developments in the U.S. and other jurisdictions;
- expectations regarding future events under collaboration and licensing agreements, including potential future payments, as well as our plans and strategies for entering into further collaboration and licensing agreements;
- general economic, industry and market conditions, including fluctuating interest rates and rising inflation;
- our ability to attract and retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act ("ECG"); and
- our anticipated use of our existing cash, cash equivalents and marketable securities, including the proceeds from the initial public offering.

In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “Risk Factors” and elsewhere in this Quarterly Report. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed with the SEC as exhibits to this Quarterly Report and previous filings, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report represent our views as of the date of this Quarterly Report. We anticipate that subsequent events and developments will cause our views to change. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Quarterly Report, whether as a result of any new information, future events or otherwise. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report.

This Quarterly Report includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this Quarterly Report, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties, which include, but are not limited to, the following:

- We are a clinical-stage biotechnology company with a limited operating history and no products approved by regulators for commercial sale, which may make it difficult to evaluate our current and future business prospects.
- We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate programs, product candidates (including clinical trials), investments in our Generate Platform or future commercialization efforts.
- We are dependent on the success of our product candidates, including GB-0895, GB-4362 and GB-5267, and our ongoing and anticipated trials may not be successful.
- Our approach to the engineering and development of our programs is unproven, and we may not be successful in our efforts to identify and develop any programs and product candidates of commercial value by leveraging our Generate Platform.
- We are substantially dependent on the successful application of our Generate Platform to develop programs and product candidates that can be commercialized by us or our current or future collaboration partners.
- Issues relating to our use of AI in the identification of our programs and the engineering and development of our product candidates could adversely affect our business and operating results.
- Preclinical and clinical development is inherently lengthy and uncertain. Preclinical and clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which would have a material adverse impact on our Generate Platform or our business.
- We are currently enrolling patients in clinical trials for GB-0895 globally and may in the future conduct clinical trials for other product candidates outside the United States, and the U.S. Food and Drug Administration (the “FDA”), the Medicines and Healthcare products Regulatory Agency (the “MHRA”), the European Medicines Agency (the “EMA”), Pharmaceuticals and Medical Devices Agency and other comparable foreign regulatory authorities (collectively, the “Regulatory Authorities”) may not accept data from such trials.
- If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third-parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.
- Due to the significant resources required for drug development and depending on our ability to access capital, we intend to prioritize the development of GB-0895 for severe asthma. Moreover, we may fail to expend our limited resources on the development of GB-0895 for the treatment of other indications or for the development of other potential future product candidates that may have been more profitable or for which there is a greater likelihood of success.
- The regulatory approval processes of the Regulatory Authorities are lengthy, time-consuming and inherently unpredictable, and if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.
- We rely on third-parties for the supply and manufacture of our product candidates for our research, preclinical and clinical activities, and may do the same for commercial supplies of our products, if approved. As our pipeline increases and matures, the increased demand for supplies from our manufacturers may increase the risk that we will not have sufficient supply when needed or at an acceptable cost.
- We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with our suppliers, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

- The product candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of our contract development and manufacturing organizations encounter such difficulties, our ability to supply material for clinical trials or any approved product could be delayed or stopped.
- We have in the past entered into, and in the future may enter into, partnership, collaboration and licensing arrangements with third-parties to support development of programs and product candidates. If these partnership, collaboration and licensing arrangements are not successful, our business could be adversely affected.
- Our success is largely based upon our intellectual property and proprietary technologies, and we may be unable to adequately protect and/or enforce our intellectual property.
- If we do not obtain sufficient patent term for our product candidates, our business may be materially harmed.
- The biopharmaceutical market is intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to successfully commercialize any drugs that we develop.
- An active trading market for our common stock may not develop.
- The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for investors.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled “Risk Factors” and the other information set forth in this Quarterly Report, as well as in other documents that we file with the SEC. The risks summarized above or described in full elsewhere in this Quarterly Report are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

GENERATE BIOMEDICINES, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data) (unaudited)

	As of March 31, 2026	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 160,575	$ 121,650
Marketable securities	356,066	99,848
Restricted cash and cash equivalents (VIE)	-	339
Prepaid expenses and other current assets	18,749	12,528
Total current assets	535,390	234,365
Property and equipment, net	27,837	29,151
Operating lease right-of-use assets	57,765	59,860
Other assets	4,745	6,806
Total assets	$ 625,737	$ 330,182
Liabilities, convertible preferred stock, non-controlling interest and stockholders' deficit		
Current liabilities:		
Accounts payable[(1)]	$ 7,617	$ 3,837
Accrued expenses and other current liabilities	19,267	42,164
Deferred revenue – current	17,244	21,194
Current portion of finance lease liabilities	3,883	4,311
Operating lease liabilities – current	10,378	10,697
Total current liabilities	58,389	82,203
Non-current liabilities:		
Warrant to purchase convertible preferred stock	-	1,205
Finance lease liabilities, net of current portion	2,221	2,908
Deferred revenue – non-current	1,238	4,511
Operating lease liabilities – non-current	49,088	50,610
Other long term liabilities	-	116
Total liabilities	110,936	141,553
Commitments and contingencies (Note 13)		
Convertible preferred stock	-	811,826
Non-controlling interest	-	(7,232)
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 500,000,000 and 200,456,735 shares authorized as of March 31, 2026 and December 31, 2025 respectively; 128,192,484 and 33,116,957 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	128	33
Additional paid-in capital	1,252,388	60,189
Accumulated other comprehensive income	24	106
Accumulated deficit	(737,739)	(676,293)
Total stockholders' equity (deficit)	514,801	(615,965)
Total liabilities, convertible preferred stock, non-controlling interests and stockholders' equity (deficit)	$ 625,737	$ 330,182

(1) Includes related party amounts of $0.1 million for the three months ended March 31, 2026, and $0.2 million for the year ended December 31, 2025. See Note 14 for details of related party amounts.

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

GENERATE BIOMEDICINES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data) (unaudited)

	Three Months Ended March 31,	
	2026	2025
Collaboration revenue	$ 7,224	$ 8,818
Operating expenses:		
Research and development[1]	57,812	46,825
General and administrative[2]	13,524	10,147
Total operating expenses	71,336	56,972
Loss from operations	(64,112)	(48,154)
Other income (expense), net		
Change in fair value of convertible preferred stock warrant liability	(363)	—
Interest expense	(182)	(368)
Interest income	2,913	4,281
Foreign currency exchange loss	58	(17)
Total other income (expense), net	2,426	3,896
Loss before provision for income taxes	(61,686)	(44,258)
Provision for income taxes	(28)	(56)
Net loss	(61,714)	(44,314)
Net loss attributable to non-controlling interests	(268)	(2,629)
Net loss attributable to Generate Biomedicines, Inc. stockholders	(61,446)	(41,685)
Convertible preferred stock accrued dividends	(7,749)	(11,592)
Net loss attributable to Generate Biomedicines, Inc. common stockholders	$ (69,195)	$ (53,277)
Net loss per share, basic and diluted	$ (1.07)	$ (1.62)
Weighted average common shares outstanding, basic and diluted	64,871,295	32,791,905
Other comprehensive loss:		
Net loss	(61,714)	(44,314)
Unrealized loss on marketable securities	(82)	(71)
Comprehensive loss	$ (61,796)	$ (44,385)
Comprehensive loss attributable to non-controlling interest	(268)	(2,629)
Comprehensive loss attributable to Generate Biomedicines, Inc. stockholders	$ (61,528)	$ (41,756)

(1) Includes related party amounts of $0.1 million for the three months ended March 31, 2026, and $0.2 million for the three months ended March 31, 2025. See Note 14 for details of related party amounts.

(2) Includes related party amounts of $0.1 million for the three months ended March 31, 2026, and $0.2 million for the three months ended March 31, 2025. See Note 14 for details of related party amounts.

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

GENERATE BIOMEDICINES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK, NON-CONTROLLING INTEREST AND STOCKHOLDERS' EQUITY(DEFICIT)
(in thousands, except share data) (unaudited)

	Convertible Preferred Stock		Non-Controlling	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Interest	Shares	Amount	Capital	Income	Deficit	(Deficit)
Balance at December 31, 2025	105,317,255	811,826	(7,232)	33,116,957	33	60,189	106	(676,293)	(615,965)
Issuance of common stock from the initial public offering, net of underwriting discounts, commissions and offering expenses	—	—	—	25,000,000	25	369,264	—	—	369,289
Contributions from noncontrolling interests	—	—	7,500				—	—	
Conversion of convertible preferred stock into common stock upon initial public offering	(105,317,255)	(811,826)	—	69,333,244	69	811,756	—	—	811,825
Reclassification of warrant liability to equity upon initial public offering	—	—	—	—	—	1,568	—	—	1,568
Exercise of common stock warrants	—	—	—	86,423	—	—	—	—	—
Exercise of stock options	—	—	—	655,860	1	3,216	—	—	3,217
Stock-based compensation	—	—	—	—	—	6,395	—	—	6,395
Unrealized gain (loss) on marketable securities	—	—	—	—	—	—	(82)	—	(82)
Net loss attributable to Generate Biomedicines, Inc. stockholders	—	—	(268)	—	—	—	—	(61,446)	(61,446)
Balance at March 31, 2026	—	—	—	128,192,484	128	1,252,388	24	(737,739)	514,801

	Convertible Preferred Stock		Non-Controlling	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Interest	Shares	Amount	Capital	Income	Deficit	(Deficit)
Balance at December 31, 2024	103,460,716	$ 789,853	$ (571)	32,691,628	$ 33	$ 38,469	$ 118	$ (473,139)	$ (434,519)
Issuance of Series C convertible preferred stock (net of issuance costs of $28)	1,856,539	21,973	—	—	—	—	—	—	—
Contributions from non-controlling interests	—	—	750	—	—	—	—	—	—
Exercise of stock options	—	—	—	146,702	—	483	—	—	483
Stock-based compensation	—	—	—	—	—	4,744	—	—	4,744
Vesting of restricted stock	—	—	—	138,177	—	46	—	—	46
Unrealized gain (loss) on marketable securities	—	—	—	—	—	—	(71)	—	(71)
Net loss attributable to Generate Biomedicines, Inc. stockholders	—	—	(2,629)	—	—	—	—	(41,685)	(41,685)
Balance at March 31, 2025	105,317,255	$ 811,826	$ (2,450)	32,976,507	$ 33	$ 43,742	$ 47	$ (514,824)	$ (471,002)

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

GENERATE BIOMEDICINES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands) (unaudited)

	Three Months Ended March 31, 2026	2025
Operating activities		
Net loss	$ (61,714)	$ (44,314)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization and accretion on marketable securities	(146)	(919)
Non-cash stock-based compensation	6,395	4,744
Non-cash lease expense	2,094	1,339
Depreciation and amortization	3,273	3,414
Changes in fair value of convertible preferred stock warrant liability	363	—
Changes in operating assets and liabilities:		
Accounts receivable	—	(91)
Prepaid expenses and other current assets	(6,221)	(2,756)
Other assets	2,045	1,400
Accounts payable	3,754	(597)
Operating lease liabilities	(1,841)	(55)
Other long term liabilities	(117)	(117)
Accrued expenses and other liabilities	(21,049)	(6,405)
Deferred revenue	(7,224)	(8,819)
Net cash used in operating activities	(80,388)	(53,176)
Investing activities		
Purchase of marketable securities	(321,153)	(77,350)
Purchases of property and equipment	(3,781)	(751)
Proceeds from sales and maturities of marketable securities	65,000	153,633
Net cash used in investing activities	(259,934)	75,532
Financing activities		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	21,973
Proceeds from issuance of common stock from the initial public offering, net of underwriting discounts, commissions and offering expenses	369,289	—
Contributions from non-controlling interests	7,500	750
Proceeds from exercise of stock options	3,217	483
Payments on finance lease obligations	(1,115)	(2,646)
Net cash provided by financing activities	378,891	20,560
Net increase (decrease) in cash, cash equivalents and restricted cash	38,569	42,916
Cash, cash equivalents and restricted cash at beginning of period	126,038	181,831
Cash, cash equivalents and restricted cash at end of period	$ 164,607	$ 224,747
Cash and cash equivalents, end of period	160,575	220,607
Restricted cash and cash equivalents (VIE)	—	96
Long-term restricted cash	4,032	4,044
Cash, cash equivalents and restricted cash at end of period	164,607	$ 224,747
Supplemental disclosure of noncash investing and financing information:		
Purchase of property and equipment included in the accounts payable and accrued liabilities	$ 25	$ 59
Vesting of restricted stock	—	46
Reclassification of warrant liability to equity upon initial public offering	1,568	—
Conversion of convertible preferred stock to common stock	811,826	—

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

GENERATE BIOMEDICINES, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Nature of Business – Generate Biomedicines, Inc. (the "Company") is a clinical-stage generative biology company pioneering the AI revolution in biotechnology and drug design and development. The Company's vision is to program biology to generate optimal therapeutics for the greatest impact on human health. Central to its vision is the Generate Platform, designed to be a therapeutic area and protein modality agnostic system integrating computational innovation with scalable biohardware to address therapeutic challenges beyond the reach of traditional technologies. The Company has built its Generate Platform to be a tight and fully-integrated loop (design–build–test–learn) to create proprietary, therapeutically relevant data and differentiated molecular solutions for the biological challenges we aim to address.

Since inception, the Company has devoted substantially all of its resources to drug discovery, the development of the Generate Platform and the advancement of its programs and product candidates, including its ongoing Phase 3 clinical trials for GB-0895 and Phase 1 clinical trials for GB-4362, for which clinical trial sites have been activated and the first patient is expected to be dosed in mid-2026, and GB-5267, for which the first patient is expected to be dosed in the second half of 2026, along with multiple preclinical programs in immunology and oncology. In addition to its research and development efforts, the Company has invested in establishing and protecting its intellectual property portfolio, raising capital and obtaining financing, organizing and staffing the company, and providing general and administrative support for these operations. It does not have any products approved for sale.

Reverse Stock Split – In February 2026, the Company's board of directors and stockholders approved an amendment to the amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock on a one-for-1.5190 basis (the "Reverse Stock Split"), which was effected on February 20, 2026. The par value and authorized number of shares of common stock was not adjusted as a result of the Reverse Stock Split. All share data and per share data amounts for all periods presented in the unaudited condensed consolidated financial statements and notes thereto have been retrospectively adjusted to reflect the effect of the Reverse Stock Split.

Initial Public Offering ("IPO") – On March 2, 2026, the Company closed its IPO, pursuant to which it issued and sold an aggregate of 25,000,000 shares of its common stock at a public offering price of $16.00 to the underwriters of the IPO, resulting in net proceeds of approximately $369.3 million after deducting underwriting discounts and commissions and offering expenses payable by the Company, totaling $30.7 million. Following closing of the IPO, all of the Company's then-outstanding convertible preferred stock converted into an aggregate of 69,333,244 shares of common stock, and no shares of convertible preferred stock were thereafter outstanding.

In connection with the closing of its IPO, on March 2, 2026, the Company's certificate of incorporation was amended and restated to authorize 500,000,000 shares of common stock, par value $0.001 per share and 10,000,000 shares of preferred stock, par value $0.001 per share.

Liquidity and Managements Plan – As of March 31, 2026, the Company had cash, cash equivalents and marketable securities of $516.6 million. The Company has incurred recurring losses since its inception, including a net loss of $61.7 million for the three months ended March 31, 2026. As of March 31, 2026, the Company had an accumulated deficit of $737.7 million.

As of December 31, 2025, the Company had concluded that there was substantial doubt about its ability to continue as a going concern. Upon closing of the IPO and receipt of the associated cash proceeds, the Company has alleviated the substantial doubt that previously existed, and based on the Company's current capital resources, which consists of its cash, cash equivalents and marketable securities on hand at March 31, 2026, it expects to have sufficient cash to support current operating plans into the first half of 2028. The Company expects to require additional capital to support its long-term operations.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

There have been no significant changes from the significant accounting policies and estimates disclosed in Note 2 of the "Notes to Consolidated Financial Statements" in the audited consolidated financial statements for the year ended December 31, 2025 and notes thereto, included in the Company's final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on February 27, 2026, except as noted below.

Basis of Presentation - The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation – The accompanying unaudited condensed consolidated financial statements reflect the consolidated operations of the Company, including its wholly owned subsidiaries, Generate Biomedicines Securities Corporation, and Generate Golukibart Therapeutics, Inc. (formerly Pioneering Medicines 02, Inc. ("PMCo")), which was until February 26, 2026, a variable interest entity where the Company was the primary beneficiary. On February 26, 2026, the Company acquired all of the outstanding capital stock of PMCo. All intercompany accounts and transactions have been eliminated.

At the inception of a transaction, the Company identifies each entity involved in such transaction for which control is achieved by the Company through means other than voting rights (each a "variable interest entity" or "VIE") and determines if the Company is the primary beneficiary of such entity's operations. A VIE is broadly defined as an entity where either (i) the equity investors as a group, if any, do not have a controlling financial interest, or (ii) the equity investment at risk is insufficient to finance that entity's activities without additional subordinated financial support. The Company consolidates investments in a VIE when the Company is determined to be the primary beneficiary. ASC Topic 810, *Consolidations* ("ASC 810"), requires the Company to perform a qualitative approach to determining whether or not a VIE will need to be consolidated. This evaluation is based on the Company's ability to direct and influence the activities of a VIE that most significantly impact that entity's economic performance, whether the Company has the power to direct those activities, and if the Company's obligation to absorb losses or receive benefits from the VIE could potentially be significant to the VIE.

For consolidated entities with ownership interest or economic rights held by third-parties, the Company records net loss attributable to non-controlling interests in its consolidated statements of operations equal to the percentage of common stock ownership interest retained in the respective operations by the non-controlling parties. The Company presents non-controlling interests as a component of shareholders' equity or mezzanine equity on its consolidated balance sheets based on the redemption rights of the equity interest. The Company records the non-controlling interests' share of loss based on the percentage of ownership interest retained by the respective non-controlling interest holders.

Use of Estimates – The preparation of the unaudited condensed consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of expenses during the reporting period. The Company bases its estimates and assumptions on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, which include but are not limited to pre-paid and accrued research and development expenses, liquidity projections, stock-based compensation expense and the incremental borrowing rate for operating and finance lease right-of-use assets, and income taxes. Actual results could differ from those estimates. Changes in estimates are recorded in the period in which they become known.

Cash and Cash Equivalents – Cash and cash equivalents are short-term, highly liquid investments with original maturities of three months or less at the date of purchase. Investments qualifying as cash equivalents primarily consist of money market funds and government securities.

Recently Issued Accounting Pronouncements Not Yet Adopted – In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): *Disaggregation of Income Statement Expenses*. This update requires that at each interim and annual reporting period public entities disclose (1) the amounts of purchases of inventory, employee compensation, depreciation, amortization, and depletion in commonly presented expense captions; (2) certain amounts that are already required to be disclosed under current GAAP in the same disclosure as the other disaggregation requirements; (3) a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively; (4) the total amount of selling expenses and; (5) in annual reporting periods, the definition of selling expenses. In January 2025, the FASB issued ASU 2025-01, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): Clarifying the Effective Date. This update clarifies that ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact of adopting this guidance on its financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software* (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software. This update removes all references to prescriptive and sequential software development stages throughout Subtopic 350-40. The update requires an entity to start capitalizing software costs when management has authorized and committed to funding the software project, and it is probable that the project will be completed and the software will be used to perform the function intended. The update further specifies that the disclosures in Subtopic 360-10 are required for all capitalized internal-use software costs. This update is effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods. Early adoption is permitted. The guidance can be applied using a prospective transition approach, a modified transition approach that is based on the status of the project and whether software costs were capitalized before the date of adoption, or a retrospective transition approach. The Company is currently evaluating the impact of adopting this guidance on its financial statements.

3. CASH EQUIVALENTS AND MARKETABLE SECURITIES

The following tables summarize the amortized cost and fair value of the Company's cash equivalents and marketable securities (in thousands):

	March 31, 2026			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 51,130	$ —	$ —	$ 51,130
Government securities	5,957	—	(1)	5,956
	$ 57,087	$ —	$ (1)	$ 57,086
Marketable securities:				
Government securities	$ 156,041	$ 42	$ (17)	$ 156,066
Term Deposits	200,000	—	—	200,000
	$ 356,041	$ 42	$ (17)	$ 356,066

	December 31, 2025			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash equivalents:				
Money market funds	$ 92,788	$ —	$ —	$ 92,788
	$ 92,788	$ —	$ —	$ 92,788
Marketable securities:				
Government securities	$ 99,742	$ 106	$ —	$ 99,848
	$ 99,742	$ 106	$ —	$ 99,848

The Company did not record a provision for credit losses on any marketable securities for the three months ended March 31, 2026 and year ended December 31, 2025. No securities held by the Company were delinquent on contractual payments as of March 31, 2026 and December 31, 2025, nor were any securities placed on non-accrual status for the period then ended. Interest on investments is recognized as interest income in the unaudited condensed consolidated statements of operations and comprehensive loss.

Information pertaining to marketable securities with gross unrealized losses as of March 31, 2026, for which the Company did not recognize a provision for credit losses under the current expected credit loss methodology, aggregated by investment category and length of time that individual securities had been in a continuous loss position, is as follows (in thousands):

	March 31, 2026 - Less Than 12 Months		
	# of Holdings	Gross Unrealized Loss	Fair Value
Government securities	17	$ (17)	$ 46,116
	17	$ (17)	$ 46,116

As of December 31, 2025, the Company did not hold any securities with gross unrealized losses.

Maturity information based on fair value of the available-for-sale securities is as follows as of March 31, 2026:

Maturity Information	Fair Value as of March 31, 2026
Maturing in one year or less	$ 344,684
Maturing in one to five years	11,382
Total	$ 356,066

As of December 31, 2025, the Company's marketable securities all matured within one year or less.

4. FAIR VALUE MEASUREMENTS

The following table sets forth by level, within the fair value hierarchy, the assets and liabilities carried at fair value on a recurring basis (in thousands):

	Fair Value Measurement as of March 31, 2026			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 51,130	$ —	$ —	$ 51,130
Government securities	—	5,956	—	5,956
	$ 51,130	$ 5,956	$ —	$ 57,086
Marketable securities:				
Government securities	$ —	$ 156,066	$ —	$ 156,066
Term Deposits	—	200,000	—	200,000
	$ —	$ 356,066	$ —	$ 356,066

	Fair Value Measurement as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 92,788	$ —	$ —	$ 92,788
	$ 92,788	$ —	$ —	$ 92,788
Marketable securities:				
Government securities	$ —	$ 99,848	$ —	$ 99,848
	$ —	$ 99,848	$ —	$ 99,848
Liabilities:				
Warrant to purchase convertible preferred stock	$ —	$ —	$ 1,205	$ 1,205
	$ —	$ —	$ 1,205	$ 1,205

Valuation of the Warrant to Purchase Convertible Preferred Stock

The fair value of the convertible preferred stock warrant liabilities was determined using the Black-Scholes Option Pricing Model (the "Black-Scholes OPM") with the assumptions as disclosed in Note 8. These assumptions include significant judgments, including the fair value of the underlying convertible preferred stock.

The following table presents a roll-forward of the aggregate fair values of the Company's liabilities for which fair value is determined by Level 3 inputs (in thousands):

	Warrant to purchase convertible preferred stock
Balance as of December 31, 2025	$ 1,205
Change in fair value	363
Reclassification of warrant liability to equity	(1,568)
Balance as of March 31, 2026	$ -

There were no transfers among Level 1, Level 2, or Level 3 categories in the period presented.

Financial Instruments Not Recorded at Fair Value – The carrying value of accounts receivable, accounts payable and accrued expenses that are reported on the unaudited condensed consolidated balance sheet approximate their fair value because of the relatively short period of time between origination and expected realization or settlement.

5. COLLABORATION AGREEMENTS

Agreement with Novartis Pharma AG ("Novartis")

On September 19, 2024, the Company entered into a Collaboration and License Agreement with Novartis (the "Novartis Collaboration Agreement") to discover, develop, manufacture and commercialize protein therapeutics using the Generate Platform. The collaboration covers multiple collaboration targets, conducted under applicable research plans during defined research terms. As consideration for the collaboration, the Company received a $50.0 million upfront payment. Novartis also purchased 1,265,822 shares of our Series C convertible preferred stock for $15.0 million. The Company is eligible to receive up to $1.0 billion across all programs upon the achievement of certain performance-based milestones, inclusive of $130.0 million in development and regulatory milestones and $210.0 million in commercial milestones associated with each research

program. Novartis is also obligated to pay, on a licensed product-by-licensed product and on a country-by-country basis, tiered royalties ranging from a mid-single digit to a low tens percentage on worldwide net sales of any licensed product, subject to specified reductions and offsets.

The Company concluded that the per share purchase price, paid by Novartis, was equal to the per share fair value of Series C convertible preferred stock. As such, there is no impact to the transaction price related to the investment in Series C convertible preferred stock by Novartis.

The Company concluded that the arrangement contemplated by the Novartis Collaboration Agreement represents a contract with a customer within the scope of ASC 606. The Company determined that for each research program, the research services and related research license granted under the Novartis Collaboration Agreement are not distinct and should be a combined performance obligation. The transaction price at inception was $50.0 million, representing the nonrefundable upfront fee. All contingent payments represent variable consideration that are constrained at inception as the achievement of the milestones underlying such contingent payments is based on either the Company or Novartis's ability to execute under the respective research program plans which is not certain at contract inception. The Company allocated the transaction price to each of the distinct research program performance obligations on a relative stand-alone selling price basis.

The Company recognizes revenue related to each distinct performance obligation over time using the costs incurred input method, such that revenue is recognized based on the Company's efforts or inputs to the satisfaction of a performance obligation.

The Company allocated the $50.0 million transaction price equally to the performance obligations based on the relative selling price.

The Company recognized $6.5 million and $6.7 million of revenue under the Novartis Collaboration Agreement during the three months ended March 31, 2026 and 2025, respectively. The remaining transaction price of $16.1 million is expected to be recognized by the Company as revenue through 2027. As of March 31, 2026, all contingent payments were constrained. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

Agreement with Amgen Inc. ("Amgen")

On December 24, 2021, the Company entered into a Collaboration and License Agreement, as amended by the First Amendment dated October 5, 2022 and the Second Amendment dated December 12, 2023 (as amended from time to time, the "Amgen Collaboration Agreement"), with Amgen to identify biologic proteins and antibodies directed against specified targets. The Amgen Collaboration Agreement initially covered five collaboration targets. In addition, Amgen has the option to nominate up to five additional collaboration targets, at additional cost, the first of which was exercised in December 2023 related to the sixth target. As consideration for the collaboration, the Company received a $50.0 million upfront payment. In connection with the Second Amendment, which added an additional collaboration target, the Company received an additional payment of $5.0 million. The Company is eligible to receive up to $370.0 million for each program upon the achievement of certain milestones, including $160.0 million in development and regulatory milestones and $210.0 million in commercial milestones per program. Amgen is also obligated to pay, on a licensed product-by-licensed product and on a country-by-country basis, tiered royalties ranging from a mid-single digit up to a low tens percentage on worldwide net sales of any licensed product, subject to customary reductions and offsets. Additionally, the Amgen Collaboration Agreement included an investment by Amgen of $25.0 million in equity, at the offering price, if the Company consummated certain future equity offerings. Amgen purchased 2,109,704 shares of the Company's Series C convertible preferred stock for approximately $25.0 million on May 9, 2023.

The per share purchase price that would be paid by Amgen, if the Company were to engage in a future equity offering, is equal to the per share fair value of the Company's other investors at the time, therefore would not impact the transaction price under the Amgen Collaboration Agreement.

The Company assessed this arrangement in accordance with ASC 606 and concluded that Amgen is a customer. The Company determined that the research activities and the exclusive license granted under the Amgen Collaboration Agreement are not individually distinct and should be combined for each target program, and each target program was considered as a distinct performance obligation. Therefore, the transaction price was allocated to each target program on a relative stand-alone selling price basis.

In connection with the modification in 2023, the Company allocated the transaction price to the performance obligations on a relative selling price basis as follows: (i) $9.2 million to the first target program; (ii) $10.4 million to the second target program; (iii) $9.2 million to the third target program; (iv) $9.0 million to the fourth target program; (v) $9.5 million to the fifth target program and (vi) $7.7 million to the sixth target program.

The Company recognizes revenue related to each performance obligation over time using the costs incurred input method, such that revenue is recognized based on the Company's efforts or inputs to the satisfaction of a performance obligation.

During the year ended December 31, 2024, a development milestone related to an initial collaboration target was achieved which triggered a $5.0 million milestone payment to the Company. The $5.0 million milestone payment was fully recognized during the year ended December 31, 2024 as this variable consideration was allocated to a distinct performance obligation and the Company had completed its related performance obligation related to the collaboration target. All other milestones and royalties were constrained as of March 31, 2026. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

On July 21, 2025, the Company and Amgen executed an amendment to the Amgen Collaboration Agreement that effectively eliminated the remaining service obligation related to a collaboration target. The Company determined the amendment represented a modification of the arrangement under ASC 606 and that the remaining fixed transaction price at the modification date of $4.3 million should be re-allocated to the remaining performance obligations based on their updated standalone selling prices. Accordingly, the Company recorded a cumulative adjustment to revenue of approximately $1.3 million on the partially satisfied remaining performance obligations, as the remaining services to be performed under each of the performance obligations are not distinct from the services prior to the modification.

The Company recognized $0.7 million and $2.1 million of revenue during the three months ended March 31, 2026 and 2025, respectively. The remaining transaction price of $2.4 million is expected to be recognized as revenue through 2026.

Agreement with The University of Texas M.D. Anderson Cancer Center ("MD Anderson")

In April 2023, the Company entered into a co-development and commercialization collaboration agreement with MD Anderson to discover and develop protein therapeutics for up to five oncology targets. Under the agreement, the Company and MD Anderson agreed to share research and development expenses as well as profits generated through commercialization of jointly developed products. The arrangement is considered a collaboration agreement under ASC 808 and the Company recognizes costs as incurred and reimbursements as a reduction of research and development expense. As of March 31, 2026, the Company had a net reimbursement payable to MD Anderson of $0.1 million.

Agreement with Roswell Park Comprehensive Cancer Center ("Roswell Park")

In October 2023, the Company entered into a collaboration agreement with Roswell Park to discover and develop chimeric antigen receptors T-cell therapies and armoring technologies for up to three oncology targets. Under the agreement, the Company and Roswell Park agreed to share research and development expenses as well as profits generated through commercialization of jointly developed products. The arrangement is considered a collaboration agreement under ASC 808 and the Company recognizes costs as incurred and reimbursements as a reduction of research and development expense. During the three months ended March 31, 2026 Roswell Park reimbursed the Company $0.1 million, which was recorded as a reduction of research and development expense.

6. PROPERTY AND EQUIPMENT

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

	Period Ended	
	March 31, 2026	December 31, 2025
Finance lease right of use assets	$ 21,978	$ 20,722
Lab equipment	39,740	37,384
Computers and software	3,513	3,513
Furniture and fixtures	2,023	2,023
Leasehold improvements	9,661	9,661
Construction in process	2,452	4,105
Total property and equipment	79,367	77,408
Less accumulated depreciation	(51,530)	(48,257)
Property and equipment, net	$ 27,837	$ 29,151

The Company leases equipment under agreements which are classified as finance lease liabilities in the accompanying unaudited condensed consolidated balance sheet. The equipment and obligations related to the leases are recorded at the present value of the lease payments. Depreciation is computed on a straight-line basis over the shorter of the estimated useful lives of the assets or remaining lease term. Depreciation expense related to leased equipment totaled $2.2 million and $2.1 million for the three months ended March 31, 2026 and 2025.

Depreciation and amortization expense for the three months ended March 31, 2026 and 2025 was $3.3 million and $3.4 million, respectively, including the depreciation expense related to the leased equipment.

7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31, 2026	December 31, 2025
Compensation and benefit	$ 4,347	$ 13,798
Research and development	11,463	23,414
Legal and professional	1,040	2,324
Other current liabilities	2,417	2,628
Total accrued expenses and other current liabilities	$ 19,267	$ 42,164

8. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss attributable to the Company's common stockholders by the weighted average number of shares of the Company's common stock outstanding during the period. Diluted net loss per share is computed similarly to basic net loss per share except that it also includes potential shares of common stock only if they are dilutive. When participating securities exist, earnings or losses are allocated between common and participating securities under the two-class method before calculating earnings per share. For the period presented, basic and diluted net loss per share are the same as any potential shares of common stock would be anti-dilutive and the participating securities do not share in losses of the Company.

The following securities are common stock equivalents, but were excluded in the computation of diluted net loss per common stock because to do so would have been anti-dilutive:

	Period Ended	
	March 31, 2026	March 31, 2025
Series A convertible preferred stock	—	26,398,943
Series B convertible preferred stock	—	20,745,628
Series C convertible preferred stock	—	22,188,673
Warrant to purchase Series A convertible preferred stock		98,749
Stock options outstanding	24,591,567	21,970,006
Total	24,591,567	91,401,999

9. WARRANT LIABILITY

On July 10, 2020, the Company issued a warrant to purchase up to 150,000 shares of Series A convertible preferred stock with an exercise price of $1.00 per share (the "Warrant"). The Warrant had an original term to maturity of 10 years, expiring on July 10, 2030. On March 2, 2026, the warrant was reclassified to a warrant to purchase 98,749 shares of common stock due to the automatic conversion of convertible preferred stock upon the closing of the IPO. Upon the automatic conversion of the convertible preferred stock (see Note 10), the Company remeasured the warrant liability to its fair market value and reclassified the total carrying value of the warrant liability into additional paid-in capital. In March 2026, the warrant was exercised by the warrant holder under the warrant's cashless (net) exercise provisions, resulting in the issuance of 86,423 shares of common stock to the warrant holder.

The assumptions that the Company used to determine the fair value of the Warrant are as follows:

	Period Ended	
	March 2, 2026	December 31, 2025
Expected term (years)	0.1	0.9
Expected volatility	73.0%	86.8%
Risk-free interest rate	3.7%	3.6%
Expected dividend yield	0.0%	0.0%
Fair value of Series A convertible preferred stock per share	$ 11.44	$ 9.29

10. CONVERTIBLE PREFERRED STOCK

Immediately prior to the closing of the IPO, the Company had an aggregate of 105,317,255 shares of redeemable convertible and convertible preferred stock issued and outstanding which automatically converted into 69,333,244 shares of common stock. Subsequent to the closing of the IPO, no shares of convertible preferred stock were issued or outstanding.

As of December 31, 2025, the Company's convertible preferred stock consisted of the following (in thousands, except share data):

	December 31, 2025				
	Convertible Preferred Stock Authorized	Convertible Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A convertible preferred stock	40,250,000	40,100,000	$ 40,053	$ 40,100	26,398,943
Series B convertible preferred stock	31,512,642	31,512,642	373,133	469,660	20,745,628
Series C convertible preferred stock	42,194,093	33,704,613	398,640	450,689	22,188,673
	113,956,735	105,317,255	$ 811,826	$ 960,449	69,333,244

11. COMMON STOCK

As of March 31, 2026, the Company had authorized 500,000,000 shares of common stock.

As of March 31, 2026, the Company had reserved 31,686,348 shares for the exercise of outstanding stock options and the number of shares remaining available for grant under the 2026 Equity Incentive Plan (see Note 12).

	March 31, 2026	December 31, 2025
Series A convertible preferred stock outstanding	—	26,398,943
Series B convertible preferred stock outstanding	—	20,745,628
Series C convertible preferred stock outstanding	—	22,188,673
Stock options outstanding	24,591,567	20,422,301
Shares reserved for future issuance under the 2019 Plan	—	3,404,855
Shares reserved for exercise of outstanding Warrant	—	98,749
Shares reserved for future issuance under the 2026 Plan	7,094,781	-
Total shares of common stock reserved for issuance	31,686,348	93,259,149

12. STOCK-BASED COMPENSATION

2019 Equity Incentive Plan

During 2019, the Company adopted the 2019 Equity Incentive Plan, as amended (the "2019 Plan"). The 2019 Plan provided for the issuance of up to 19,801,227 shares of common stock as of March 31, 2026, to employees, officers, directors, consultants, and advisors in the form of non-qualified and incentive stock options, restricted stock awards, and other stock-based awards. Options typically vest over four years and have a maximum term of 10 years. Concurrent with the IPO in February 2026, all shares available for issuance under the 2019 Plan ceased to be available for issuance as the 2026 Equity Incentive Plan became effective.

2026 Equity Incentive Plan

During the three months ended March 31, 2026, in connection with the Company's IPO, the Company adopted the 2026 Equity Incentive Plan, as amended (the "2026 Plan"). The 2026 Plan initially provided for the issuance of up to 11,852,719 shares of common stock, and will be increased annually at 4% of the outstanding number of shares of common stock outstanding per year, or a lesser amount determined by the board of directors, as well as for forfeitures and cancellations under the 2019 Plan. As of March 31, 2026, there were 7,094,781 shares of common stock available for issuance to employees, officers, directors, consultants, and advisors in the form of non-qualified and incentive stock options, restricted stock awards, and other stock-based awards. Options typically vest over four years and have a maximum term of 10 years.

Stock Option Valuation

The Company typically grants stock options to employees and non-employees at exercise prices deemed by the Board to be equal to the fair value of the common stock at the time of grant.

The Company utilized the Black-Scholes OPM to estimate the fair value of stock options awarded to employees, officers, directors, consultants and advisors. The Black-Scholes OPM requires several key assumptions. The assumptions that the Company used to determine the grant-date fair value of options granted to employees, non-employees and directors were as follows, presented on a weighted-average basis:

	Three Months Ended March 31, 2026
Expected term (in years)	6.2
Expected volatility	82.4%
Risk-free interest rate	3.7%
Expected dividend yield	—

As of March 31, 2026, there was $95.3 million of unrecognized compensation expense, related to unvested time-based stock options that will be recognized over a weighted-average remaining term of 3.0 years.

Prior to January 1, 2024, the Company issued stock options covering shares 631,665 of common stock subject to the performance condition of entering into one or more strategic transactions pursuant to which the Company has the right to receive, in the aggregate, at least $200.0 million in specified payments. During the year ended December 31, 2022, the vesting of stock options covering 157,916 shares of stock with this performance condition was accelerated following the signing of the Amgen Collaboration Agreement in recognition of performance that did not otherwise achieve the performance condition. During the year ended December 31, 2025, the vesting of stock options covering 157,916 shares of common stock with this performance condition was accelerated following the signing of the Novartis Collaboration Agreement in recognition of performance that did not otherwise achieve the performance condition. The balance of 315,833 shares of common stock underlying these stock options remains outstanding. No stock-based compensation expense has been recorded on the remaining unvested stock options as the performance conditions are not deemed probable of occurrence.

During the year ended December 31, 2024, the Company issued stock options covering 65,832 shares of common stock subject to the performance condition of entering into one or more strategic transactions pursuant to which the Company has the right to receive, in the aggregate, at least $50.0 million in specified payments. Additionally, the Company issued stock options covering 65,832 shares of common stock subject to the performance condition of entering into one or more strategic transactions pursuant to which the Company has the right to receive, in the aggregate, at least $100.0 million in specified payments. Any unvested shares underlying both stock option grants lapsed and were forfeited as of January 1, 2026. During the three months ended March 31, 2026, the stock options covering 131,664 shares of common stock expired.

The following table summarizes the option activity under the 2019 Plan and the 2026 Plan:

	Options	Weighted Average Exercise Price per Unit	Weighted Average Remaining Life (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	20,422,301	$ 5.91	7.3	$ 119,435
Granted	5,240,236	15.64		
Exercised	(655,860)	4.92		
Forfeited/Expired	(415,110)	7.34		
Outstanding at March 31, 2026	24,591,567	$ 7.98	7.7	$ 127,956
Exercisable at March 31, 2026	12,438,020	$ 4.86	6.5	$ 122,042

During the three months ended March 31, 2026, the Company granted stock options to purchase an aggregate of 5,240,236 shares at weighted average grant date fair value per option share of $15.64.

The Company recorded stock-based compensation expense in the following expense categories of its unaudited condensed consolidated statement of operations and comprehensive loss:

	Three Months Ended March 31,	
	2026	2025
Research and development	$ 2,703	$ 2,453
General and administrative	3,692	2,291
	$ 6,395	$ 4,744

13. COMMITMENTS AND CONTINGENCIES

Legal Proceedings – The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

14. RELATED-PARTY TRANSACTIONS

In August 2018, the Company entered into a ten-year management service agreement with Flagship Pioneering, Inc. (“Flagship Pioneering”) to provide management services, including accounting, human resources, information technology, legal, and consultation services. The Company also agreed to reimburse Flagship Pioneering for certain expenses, including insurance and benefits, partner and related fees, software licenses, supplies, and administration consulting services incurred on the Company’s behalf. Upon the effectiveness of the Company's Registration Statement on Form S-1 (File No. 333-293204), as amended, filed in connection with the Company's IPO (the "Registration Statement") on February 26, 2026, the Flagship Managerial Agreement was terminated. The Company recorded general and administrative expense totaling $0.1 million and $0.2 million related to these services and the termination of the agreement for the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026 and December 31, 2025, the Company owed $0.1 million and $0.1 million, respectively, to Flagship.

In July 2022, the Company entered into a Vivarium Shared Space Operating Agreement, as amended in May 2024, with Cellarity, Inc. (“Cellarity”), an affiliate of Flagship, to use a vivarium space, along with other companies affiliated with Flagship. The Company pays Cellarity a monthly operating fee for using the vivarium and obtaining various services; the shared cost is variable depending on the actual usage. The Company recognized less than $0.1 million and $0.2 million of expense paid to Cellarity during the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026 and December 31, 2025, the Company had less than $0.1 million and $0.1 million in accounts payable to Cellarity, respectively.

In August 2021, the Company entered into an agreement (the “Flagship Agreement”), with Flagship Pioneering Innovations VI, LLC (“Flagship”), pursuant to which it (i) irrevocably and unconditionally assigned to Flagship all of the Company’s right, title and interest in and to certain foundational patent rights conceived prior to the Company’s launch, which is defined as the closing of its Series B financing, and its improvements to such patent rights that cannot be practiced without infringing the foregoing patent rights (such patent rights and improvements, the “Foundational IP”), and (ii) obtained an exclusive, worldwide, royalty-bearing, sublicensable, transferable license from Flagship under such Foundational IP to develop, manufacture and commercialize any product or process or component thereof in the licensed field of human therapeutics and vaccines that would, absent the license granted to the Company by Flagship, infringe at least one valid claim of the Foundational IP. Pursuant to the Flagship Agreement, the Company is obligated to use commercially reasonable efforts to diligently exploit licensed products in the licensed field and maintain such efforts during the term of the Flagship Agreement. To satisfy the due diligence requirements, the Company must spend at least $1.0 million each year on its own development and commercialization activities with respect to licensed products during the term of the Flagship Agreement and at least $10.0 million on such activities until August 2026, which may include internal or external research and development costs. The research and development costs are expensed as incurred. The Company's only financial obligation to Flagship is to pay Flagship, on a licensed product-by-licensed product and jurisdiction-by-jurisdiction basis, royalties equal to a low single-digit percentage on net sales of licensed products by the Company or its sublicensees until the expiration of the last valid claim of any Foundational IP covering such licensed product in such jurisdiction. To date, there have been no amounts paid or received by the Company under the Flagship Agreement.

In June 2023, the Company entered into a collaboration agreement with PMCo, a company newly formed and controlled by Flagship Labs VII, LLC and Flagship Pioneering Fund VII, L.P., each of which are affiliated with Flagship Pioneering (the "Prior PMCo Agreement"). This collaboration agreement was terminated on February 26, 2026. See Note 15.

15. VARIABLE INTEREST ENTITIES

Prior PMCo Agreement

On June 22, 2023, the Company entered into the Prior PMCo Agreement with PMCo, an affiliate of Flagship Pioneering, pursuant to which PMCo was granted an exclusive, worldwide, royalty-free, sublicensable license under certain of the Company’s patent rights and know-how to develop, manufacture and commercialize licensed products containing certain antibodies against TSLP and/or IL-4Rα, including GB-0895, in all fields. The Prior PMCo Agreement was terminated on February 26, 2026.

During the period from the effective date until June 2030, neither the Company nor any of its affiliates were permitted to develop or commercialize, nor collaborate with, enable or otherwise authorize, license or grant any right to any third-party to develop or commercialize, any antibody that (i) binds to TSLP, (ii) binds to both TSLP and IL-4Rα (but no other target), or (iii) binds to IL-4Rα (and no other target, including TSLP) in the territory. Subject to the license to PMCo, as between the parties, the Company solely owned and retained all right, title and interest in and to all technology, know-how and materials conceived, discovered, developed or otherwise made by or on behalf of PMCo or any of its affiliates or sublicensees in the course of performing activities under or in connection with the Prior PMCo Agreement, and any patents or patent applications claiming any of the developed know-how.

Under the terms of the Prior PMCo Agreement, the Company and PMCo were to collaborate on research and development activities with respect to the licensed products and will share research and development costs, with the Company bearing 65% and PMCo bearing 35% of all fully-burdened research costs and development expenses, which percentage commitments are subject to adjustment if the Company or PMCo failed to pay or wished to reduce their respective percentage commitments prior to the consummation of a business combination of PMCo or a license transaction

of all commercial rights for all licensed products. In addition, the Company was entitled to 70% and PMCo was entitled to 30% of the proceeds of a business combination of PMCo or an exclusive license transaction with a third-party; provided, however, that the failure by any party to bear their agreed portion of the fully-burdened research costs and development expenses would have resulted in an automatic *pro rata* adjustment of such party's interest in any such proceeds and that such failure would not automatically have been deemed to constitute a breach of the Prior PMCo Agreement.

Subject to the terms and conditions of the Prior PMCo Agreement, the Company was obligated to use commercially reasonable efforts to develop licensed products in the licensed field in the territory, including by way of directing PMCo under the Prior PMCo Agreement, and upon receipt of regulatory approval for a licensed product in a country, PMCo would have been obligated to use commercially reasonable efforts to commercialize such licensed product in such country.

Following the first achievement of a specified regulatory milestone, and prior to a business combination of PMCo or a license transaction of all commercial rights for all licensed products, (i) the Company had the right to acquire all of the securities of PMCo for a price equal to a low tens percentage of the fair market value of such securities on terms and conditions to be negotiated between the Company and PMCo, and if the Company does not exercise such right, the Company had the right to initiate a business combination of PMCo or an exclusive license transaction with a third party; and (ii) PMCo had the right to have us acquire all of the securities of PMCo in exchange for royalties equal to a mid-to-high single-digit percentage on net sales of licensed products on a country-by-country and licensed product-by-licensed product basis until the later of (a) the expiration of the last valid claim of any patent right controlled by us or PMCo covering the use or sale of such licensed product in such country, (b) expiration of regulatory exclusivity for such product in such country, and ten years following the first commercial sale of such licensed product in such country (such transactions in (i) and (ii), collectively, the "Subject Transactions"). Concurrently with the Prior PMCo Agreement, the Company, PMCo and Pioneering Medicines 02, LLC ("PM LLC"), the sole stockholder of PMCo, entered into a drag-along agreement (the "Drag-Along Agreement"), pursuant to which PM LLC agreed to, among other things, vote in favor of a Subject Transaction.

The Company consolidated PMCo, which, prior to the termination of the Prior PMCo Agreement and acquisition by Generate of all of the issued and outstanding capital stock of PMCo on February 26, 2026, was deemed to be VIE and of which the Company was the primary beneficiary based on a combination of the decision-making power over the activities that most significantly impact the economic performance of PMCo and an obligation to absorb losses or receive benefits from PMCo. These decisions and significant activities included, but were not limited to, research and development activities under the research plan and the development plan and other operational and strategic matters. The terms of the agreements governing PMCo prohibited the Company from using the assets of PMCo to satisfy the obligations of other entities.

The Prior PMCo Agreement was treated as an asset acquisition as PMCo's assets transferred do not meet the definition of a business. Prior to the acquisition, PMCo's majority stockholder was the same as the Company's majority stockholder and there was common ownership and control, including common members of the Board. As such, the Company accounted for the asset acquisition as a transaction between entities under common control. The Company initially measured and recognized the assets and liabilities transferred at their carrying amounts in the accounts of PMCo at the date of transfer. Accordingly, the Company recognized non-controlling interest ("NCI") based on the net assets held by PMCo. As a result of PMCo's preferred stock being redeemable upon a deemed liquidation event and its put right, the NCI in PMCo is presented in mezzanine equity.

The net assets acquired on June 30, 2023, included cash totaling $0.6 million and liabilities totaling $2.1 million, comprised primarily of accounts payable and accrued liabilities.

Non-Controlling Interest Acquisition

On February 4, 2026, the Company entered into a stock purchase agreement ("Stock Purchase Agreement") with the stockholder of PMCo, PM LLC, pursuant to which the Company agreed to purchase, and PM LLC agreed to sell, all of the issued and outstanding capital stock in PMCo. In consideration for such sale, PMCo, PM LLC and the Company agreed to terminate the Prior PMCo Agreement, and the Company agreed to pay PM LLC a portion of the net sales, if any, arising from the sale of certain products covered by certain patents or containing certain know-how ("Generate Products") developed under the Prior PMCo Agreement. The closing of the transactions contemplated by the Stock Purchase Agreement and the termination of the Prior PMCo Agreement occurred on February 26, 2026.

The Company is obligated to make net sales payments equal to a high-single digit percentage of net sales of Generate Products, including any Generate Product that contains GB-0895. However, if a Generate Product (i) does not contain GB-0895, (ii) binds to at least one of TSLP or IL-4Rα, and (iii) binds to other proteins in addition to TSLP or IL-4Rα, then the sales payment is reduced based on the composition of the product. Further, if the Company exclusively license its rights to exploit a Generate Product in one or more countries to a third party, and the royalties on net sales of such Generate Product to be paid by such third party are subject to certain specified reductions, then the Company may be allowed to further proportionally reduce the sales payment due to PM LLC, depending on the relative value of the future royalties due to the Company from such third party as compared to the total deal consideration.

Both PM LLC and the Company have the ability to trigger a buy-out of all future net sales payments under the Stock Purchase Agreement in certain instances, which would require the Company to make a single payment to PM LLC that is equivalent to the fair market value of the projected future net sales payments due to PM LLC based upon the projected future

net sales of the applicable and then-existing Generate Products (the “Buy-Out Amount”). Both PM LLC and the Company have this right following the Company entering into an exclusive license to the Company's rights to exploit a Generate Product in one or more countries with a third party (or transaction approximating an exclusive license). In addition, in the event the Company is acquired by a qualified acquirer, the Company has the right to trigger a buy-out of all future sales payments under the Stock Purchase Agreement in exchange for the Buy-Out Amount. Following payment of the Buy-Out Amount with respect to a Generate Product in a country, the Company's diligence obligations and the Company's obligations to make net sales payments with respect to the applicable Generate Products in the applicable countries shall immediately terminate, as do the Company's exclusivity restrictions with respect to the protein targeted by such Generate Products in such countries.

The transaction represents the acquisition of a non-controlling interest in a consolidated subsidiary. The Company accounts for the acquisition of the non-controlling interest as an equity transaction with no gain or loss recognized in net income (loss). The consideration payable by the Company is contingent upon the successful commercialization of licensed products. The contingent consideration will be recognized when the contingency is resolved and the consideration is paid or becomes payable.

As a result of the acquisition of the non-controlling interest, the Company will no longer allocate losses to the non-controlling interest. The net loss allocated to the non-controlling interest, was $0.3 million and $2.6 million during the three months ended March 31, 2026 and 2025, respectively, primarily represented amounts that PMCo had paid to the Company under the cost sharing arrangement.

16. SEGMENT INFORMATION

The Company has one operating segment. The Company’s operating segment is engaged in the field of generative biology by using machine learning for drug discovery and development through the programming of novel protein therapeutics. The Company’s chief operating decision maker, its Chief Executive Officer, manages the Company’s operations on a consolidated basis for the purposes of assessing performance and allocating resources based on net loss attributable to Generate Biomedicines, Inc. stockholders that also is reported on the consolidated statement of operations as consolidated net loss to Generate Biomedicines, Inc. stockholders. This financial metric is used by the chief operating decision maker ("CODM") to make key operating decisions such as the allocation of capital between program expenses, early-stage discovery expenses, and general and administrative expense, including headcount and facilities decisions. The operating segment’s revenue is derived from multiple collaboration agreements from which the segment licenses certain development or product candidates and performs research and development services. The measure of segment assets is reported on the balance sheet as total consolidated assets. All of the Company’s long-lived assets are held in the United States. The following table presents selected financial information about the Company’s single operating segment. The significant expense categories and amounts align with the segment-level information that is regularly provided to the CODM for the three months ended March 31, 2026 and 2025 (amounts in thousands):

	Three Months Ended March 31,	
	2026	2025
Revenue:		
Collaboration revenue	$ 7,224	$ 8,818
Operating Expenses:		
Research and development personnel-related (excluding stock-based compensation)	19,813	18,011
External research and development costs - GB-0895	15,586	3,794
External - discovery related costs and other	16,458	19,170
General and administrative personnel-related (excluding stock-based compensation)	4,640	4,431
External - General and administrative	5,171	3,408
Stock-based compensation	6,395	4,744
Depreciation expense	3,273	3,414
Other segment expenses [(a)]	305	17
Interest income	(2,913)	(4,281)
Interest expense	182	368
Provision for income tax	28	56
Consolidated net loss	$ 61,714	$ 44,314
Net loss attributable to non-controlling interests	268	2,629
Consolidated net loss attributable to Generate Biomedicines, Inc. stockholders	$ 61,446	$ 41,685

(a) Other segment expenses include change in fair value of convertible preferred stock warrant liability and foreign currency exchange loss.

17. SUBSEQUENT EVENTS

The Company evaluated subsequent events through the date on which these financial statements were issued to ensure that these condensed consolidated financial statements include appropriate disclosure of events both recognized in the financial statements as of March 31, 2026 and events which occurred subsequently but not recognized in the financial statements. No subsequent events have occurred that require disclosure.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q (this "Quarterly Report") and with our audited financial statements and the notes thereto for the year ended December 31, 2025 included in our final prospectus dated February 27, 2026 filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended. This discussion and analysis and other parts of this Quarterly Report contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, strategies, objectives, expectations, intentions and beliefs. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this Quarterly Report. You should carefully read the "Risk Factors" section of this Quarterly Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see "Cautionary Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage generative biology company pioneering the AI revolution in biotechnology and drug design and development. Our vision is to program biology to generate optimal therapeutics for the greatest impact on human health. Central to our vision is the Generate Platform, designed to be a therapeutic area and protein modality agnostic system integrating computational innovation with scalable biohardware to address therapeutic challenges beyond the reach of traditional technologies. We have built our Generate Platform to be a tight and fully-integrated loop (design–build–test–learn) to create proprietary, therapeutically relevant data and differentiated molecular solutions for the biological challenges we aim to address. In addressing these challenges, the Generate Platform can engineer solutions against therapeutic targets starting from either existing reference proteins or by suggesting completely novel ones without a reference starting point, also known as *de novo* design. The Generate Platform's therapeutic potential has been demonstrated by successfully progressing three computationally engineered proteins into human clinical testing, the most advanced of which is GB-0895, an investigational long-acting anti-thymic stromal lymphopoietin ("TSLP") monoclonal antibody, which is enrolling patients in pivotal Phase 3 clinical trials for severe asthma. Also, in connection with our Phase 1 clinical trial for GB-4362, an investigational Monomethyl Auristatin E ("MMAE") neutralizer, we have activated clinical trial sites and expect to dose the first patient in mid-2026, and, in connection with our planned Phase 1 clinical trial for GB-5267, an investigational armored CAR-T therapy in collaboration with Roswell Park Comprehensive Cancer Center ("Roswell Park"), we expect to dose the first patient in the second half of 2026.

Since our inception, we have devoted substantially all of our resources to drug discovery, the development of our Generate Platform and the advancement of GB-0895 and our other product candidates, along with multiple preclinical programs in immunology and oncology. In addition to our research and development efforts, we have invested in establishing and protecting our intellectual property portfolio, raising capital and obtaining financing, organizing and staffing our company, and providing general and administrative support for these operations. We do not have any products approved for sale.

To date, we have not generated any revenue from product sales. On March 2, 2026, we closed our initial public offering ("IPO"), pursuant to which we issued and sold 25,000,000 shares of common stock, resulting in net proceeds of $369.3 million. Prior to our IPO, we had principally raised capital through the private placement of our Series A, Series B and Series C convertible preferred stock, par value $0.001 per share (collectively, the "convertible preferred stock"), the issuance of convertible notes, payments from Amgen Inc. ("Amgen") and Novartis Pharma AG ("Novartis"), and cost-sharing payments from our other partnership, collaboration or licensing arrangements which resulted in aggregate gross cash proceeds in excess of $934.0 million. We also have benefited from cost-sharing arrangements in our collaboration arrangements with The University of Texas M.D. Anderson Cancer Center ("MD Anderson"), Roswell Park and Pioneering Medicines 02, Inc. ("PMCo"). During the period ended March 31, 2026, we acquired the non-controlling interest in PMCo. At that time, our collaboration, including our cost-sharing arrangements, terminated and we became obligated to make certain payments to PMCo's parent based on net sales.

As needed, we will seek additional funding through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches. We may not be able to obtain funding on acceptable terms, or at all. The terms of any future financing may adversely affect the holdings or the rights of our current stockholders.

If we are unable to obtain funding, we could be forced to delay, limit, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all.

We have incurred significant operating losses since inception, and we expect to continue to incur substantial losses for the foreseeable future. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the

successful development and eventual commercialization of one or more of our product candidates and any additional product candidates we may develop. Our net losses were $61.7 million and $44.3 million, of which $0.3 million and $2.6 million were attributable to a non-controlling interest for the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026, we had an accumulated deficit of $737.7 million.

We anticipate that our expenses and operating losses will increase substantially for the foreseeable future if and as we:

- expand the number of our research and development programs;
- continue or expand our scope of research or development of our current programs and product candidates in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical or other studies for our programs and product candidates, including pursuant to some of our partnership, collaboration and licensing arrangements;
- change or add additional manufacturers or suppliers;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts;
- seek marketing approvals and reimbursement for our product candidates and products;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- acquire or in-license technologies;
- make payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We do not expect to generate revenue from product sales unless and until we or our collaboration partners successfully complete the clinical development or future clinical development of, and obtain regulatory approval for, one or more of our current or future product candidates, including any jointly-developed product candidates, which will not be for several years, if ever. If we obtain regulatory approval for any of our product candidates and do not enter into a commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, manufacturing, marketing, market access and distribution.

Our net losses may fluctuate significantly from period to period, depending on the timing of our current and potential future clinical trials and expenditures related to our research and developmental activities. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant audit, legal and regulatory expenses, as well as director and officer insurance premiums and investor relations costs. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such a time when we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. Our failure to raise capital or enter into such agreements or arrangements as, and when needed, could have a material adverse effect on our business, results of operations and financial condition, including potentially requiring us to delay, limit, reduce or eliminate product development or future commercialization efforts, or grant rights to develop and market current or future development product candidates that we would otherwise prefer to develop and market ourselves.

As there are numerous risks and uncertainties associated with 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 or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As a result, we will need substantial additional capital to support our continuing operations and pursue our strategy. As of March 31, 2026, we had cash, cash equivalents and marketable securities of $516.6 million. We believe, based upon our

current operating plan, that these amounts will be sufficient to fund our operations into the first half of 2028. We expect to require additional capital to support our long-term operations.

Components of Results of Operations

Revenues

We have not generated any revenues from the sale of products to date and do not expect to generate any revenues from the sale of products for the next several years, if at all. If our development efforts for our current or future product candidates are successful and result in regulatory approval, we may generate revenues in the future from product sales. For the foreseeable future, we expect substantially all of our revenues to be generated from our current collaboration arrangements with Novartis and Amgen. For more information on our collaboration agreements with Novartis and Amgen, please see "License, *Collaboration and Other Agreements"* below and Note 5 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expenses

Research and development expenses consist primarily of external and internal costs incurred for our research and development activities, including development of our platform, our product discovery efforts and the development of our future product candidates. These expenses include:

- external expenses, including expenses incurred under arrangements with third-parties, such as contract development and manufacturing organizations ("CDMOs"), contract research organizations ("CROs"), providers of sponsored research, consultants and our scientific advisors;
- costs related to compliance with regulatory authorities;
- direct costs of conducting internal research and development for our internal preclinical programs;
- intellectual property and related future payments should certain development and regulatory milestones be achieved;
- personnel-related costs, including salaries, bonuses, benefits and stock-based compensation for employees engaged in research and development functions;
- expenses incurred for the procurement of materials, third-party license fees, laboratory supplies and non-capital equipment used in the research and development process; and
- depreciation, amortization and other direct and allocated expenses, including rent, insurance, maintenance of facilities and other operating costs, incurred as a result of our research and development activities.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

We record accruals for estimated ongoing research costs and receive updated estimates of costs and amounts owed on a monthly basis from our third-party service providers. When evaluating the adequacy of the prepaid expenses and accrued liabilities, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted cost estimates from its third-party service providers. Estimates are made in determining the balances at the end of any reporting period.

We use our personnel and infrastructure resources for our research and development efforts, including the advancement and development of our platform, product candidates and managing external research and development efforts. A significant portion of our research and development costs have been, and will continue to be, external costs. External expenses, which are specific to a program, are tracked on a program-by-program basis for partner programs or upon development candidate nomination. Due to our ability to use certain resources across several programs, personnel-related expenses and indirect or shared operating costs incurred for our research and development programs are not recorded or maintained on a program-by-program basis.

We anticipate that our research and development expenses will increase substantially for the foreseeable future in connection with our ongoing clinical trials and our planned clinical development activities in the near term and in the future. However, we cannot reasonably estimate the costs or timing of the efforts that will be necessary to complete the development of any of our product candidates due to the numerous risks and uncertainties associated with their development, including the uncertainty of:

- the scope, timing, costs and progress of clinical development activities related to GB-0895, including expansion into other indications, and our other product candidates;
- the number and scope of additional preclinical and clinical programs we decide to pursue, and the number of product candidates we decide to develop further;
- our successful enrollment in and completion of clinical trials;
- our ability to commercialize products, if and when approved, whether alone or in collaboration with others;
- third-party maintaining existing, or arranging for new CDMOs, to support clinical trials of our product candidates;
- seeking regulatory approvals for any of our product candidates that successfully complete clinical trials;
- securing access rights to external products, technologies or intellectual property;
- hiring additional clinical, quality control, manufacturing and other scientific personnel;
- the terms and timing of any partnership, collaboration, or license arrangement, including the terms and timing of any milestone or royalty payments thereunder, if any; and
- general economic conditions, including inflation.

Any changes in the outcome of any of these variables with respect to the development of our programs and product candidates or any future programs and product candidates that we may identify could result in a significant change in the costs and timing associated with the development of that program or product candidate. For example, if the U.S. Food and Drug Administration (the “FDA”), the Medicines and Healthcare products Regulatory Agency (the “MHRA”), the European Medicines Agency (the “EMA”), Pharmaceuticals and Medical Devices Agency and other comparable foreign regulatory authorities (collectively, the “Regulatory Authorities”) were to require us to conduct clinical trials beyond those that we anticipate would be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never succeed in achieving regulatory approval for any of our product candidates or any future product candidates that we may identify.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits and stock-based compensation expenses for employees in executive, accounting and finance, business development, human resources, legal and other administrative functions. Other significant general and administrative expenses include allocated facility related costs including depreciation, legal fees relating to corporate and intellectual property matters and other corporate matters, professional fees for accounting, auditing and tax services, consulting fees and insurance costs.

We anticipate that our general and administrative expenses will increase as we increase our headcount to support our research and development activities and the potential commercialization of our product candidates, if approved. Additionally, these increases will likely include increased costs related to the hiring of additional personnel, among other expenses. We also expect to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and the Securities and Exchange Commission's (the “SEC”) requirements, director and officer insurance costs, and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Other Income (Expense), Net

Other income (expense), net primarily consists of interest income generated from interest bearing cash, cash equivalents and marketable securities, change in fair value associated with the convertible preferred stock warrant liability, realized and unrealized gains and losses on foreign currency transactions and interest expense associated with our finance lease of lab equipment.

Income Taxes

Income tax expenses (benefit) consists of U.S. federal and state income taxes. As of December 31, 2025, we had $331.8 million and $287.6 million of U.S. federal and state net operating loss ("NOL") carryforwards, respectively. The federal NOL carryforwards are not subject to expiration and the state NOL carryforwards begin to expire in 2042. These loss carryforwards are available to reduce future federal and state taxable income, if any.

Utilization of our NOL carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state provisions. These "ownership changes," as defined by Section 382 of the Code, may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 of the Code results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. In the third quarter of 2021, we had an ownership change as defined by Sections 382 and 383 of the Code. In addition, in connection with our IPO and other equity transactions, we may have experienced, or may in the future experience, additional ownership changes that could further limit our ability to utilize our NOL carryforwards and other tax attributes.

We have not yet completed a comprehensive analysis to determine whether ownership changes as defined by Sections 382 and 383 of the Code have occurred as a result of our initial public offering or the extent of any resulting limitations. Accordingly, we may be subject to additional limitations that could be material and could significantly reduce or potentially eliminate our ability to utilize a portion of our NOL carryforwards and other tax attributes in the future.

As a result, if we earn net taxable income, our ability to use our pre-ownership change NOL carryforwards and other pre-change tax attributes to offset such taxable income may be subject to limitations, which could result in increased future tax liability to us and could have an adverse effect on our future results of operations.

Income taxes are determined at the applicable tax rates adjusted for non-deductible expenses and other permanent differences. Our income tax provision may be significantly affected by changes to our estimates.

Loss attributable to non-controlling interest

In connection with our agreement with PMCo prior to its termination and our acquisition of all of the outstanding capital stock of PMCo on February 26, 2026, we determined that we were the primary beneficiary of PMCo, and therefore we consolidated PMCo. However, prior to such acquisition, we did not have any equity interest in PMCo, therefore all net losses associated with PMCo were attributable to the non-controlling interest holders. The net losses attributable to non-controlling interest holders is the loss absorbed by the previous holders of the ownership interest of PMCo, which consist primarily of research and development costs that were reimbursed by PMCo under our collaboration agreement with PMCo. On February 4, 2026, we entered into the Stock Purchase Agreement to acquire the non-controlling interest of PMCo, contingent upon the execution of the underwriting agreement relating to our IPO. Upon the closing of the transactions contemplated by the Stock Purchase Agreement on February 26, 2026, we no longer allocated net income (loss) to the non-controlling interest, as we thereafter owned 100% of the equity of PMCo.

Results of Operations

Comparison of the Three Months Ended March 31, 2026 and 2025

The following table summarizes our results of operations for the periods presented (in thousands):

	Period Ended		
	March 31, 2026	March 31, 2025	Change
Revenue:			
Collaboration revenue	$ 7,224	$ 8,818	$ (1,594)
Operating expenses:			
Research and development	57,812	46,825	10,987
General and administrative	13,524	10,147	3,377
Total operating expenses	71,336	56,972	14,364
Loss from operations	(64,112)	(48,154)	(15,958)
Other income (expense), net			
Change in fair value of convertible preferred stock warrant liability	(363)	—	(363)
Interest expense	(182)	(368)	186
Interest income	2,913	4,281	(1,368)
Foreign currency exchange loss	58	(17)	75
Total other income (expense), net	2,426	3,896	(1,470)
Loss before provision for income taxes	(61,686)	(44,258)	(17,428)
Provision for income taxes	(28)	(56)	28
Net loss	$ (61,714)	$ (44,314)	$ (17,400)
Net loss attributable to non-controlling interests	(268)	(2,629)	2,361
Net loss attributable to Generate Biomedicines, Inc. stockholders	$ (61,446)	$ (41,685)	$ (19,761)

Collaboration Revenue

Collaboration revenue consists entirely of revenue from the Novartis Collaboration Agreement and Amgen Collaboration Agreement. Revenue under these agreements is recognized as we conduct research activities related to the research program or target program within the respective agreements based on costs incurred to conduct those activities relative to the total estimated costs. Collaboration revenue decreased to $7.2 million for the three months ended March 31, 2026 compared to $8.8 million for the three months ended March 31, 2025. Total revenue recognized under the Novartis Agreement was $6.5 million during the three months ended March 31, 2026 compared to $6.7 million during the three months ended March 31, 2025. Additionally, under the Amgen Agreement we recognized revenue of $0.7 million from Amgen during the three months ended March 31, 2026 compared to $2.1 million during the three months ended March 31, 2025. The decrease was due to us nearing completion of our performance obligations under the Amgen Agreement, which we expect will be completed in 2026.

Research and Development Expense

The following table summarizes our research and development expenses for the periods presented (in thousands):

	Period Ended		
	March 31, 2026	March 31, 2025	Change
External research and development costs by program:			
GB-0895	$ 15,586	$ 3,794	$ 11,792
Discovery and other programs	$ 2,439	$ 4,612	(2,173)
Other research and development costs:			
External - early research and infrastructure	14,020	14,558	(538)
Personnel-related (excluding stock-based compensation)	19,813	18,011	1,802
Stock-based compensation	2,703	2,453	250
Depreciation expense	3,251	3,396	(145)
Total research and development expense	$ 57,812	$ 46,825	$ 10,988

Research and development expenses increased to $57.8 million for the three months ended March 31, 2026 compared to $46.8 million for the three months ended March 31, 2025. The $11.0 million increase in research and development expenses for the three months ended March 31, 2026 compared to the three months ended March 31, 2025 was primarily due to an increase of $11.8 million in spending on GB-0895 and an increase in personnel-related costs of $1.8 million offset by a decrease in external discovery and other program related costs of $2.2 million.

External research and development expenses related to the GB-0895 program for the three months ended March 31, 2026 and 2025 were $15.6 million and $3.8 million, respectively. The increase of $11.8 million for the three months ended March 31, 2026 compared to the three months ended March 31, 2025 was primarily driven by the continued advancement of our GB-0895 program, including our Phase 1b clinical trial in chronic obstructive pulmonary disease ("COPD") and the commencement of our global Phase 3 clinical trial in severe asthma during the three months ended March 31, 2026, including related CMC costs.

External discovery and other program costs in the three months ended March 31, 2026 decreased by $2.2 million from the three months ended March 31, 2025, primarily driven by an decrease in Chemistry, Manufacturing and Controls ("CMC") and toxicology activities for development candidates.

Personnel-related expenses and stock-based compensation increased by $1.8 million and $0.3 million in the three months ended March 31, 2026, respectively, compared to the three months ended March 31, 2025, related to salaries, benefits and other compensation costs related to the hiring of additional full-time employees in order to support the growth of our research and development programs. Depreciation expense decreased by $0.1 million for the three months ended March 31, 2026 compared to the three months ended March 31, 2025, primarily due to certain property and equipment becoming fully depreciated and a decrease in purchases of property and equipment during the period.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods presented (in thousands):

	Period Ended		
	March 31, 2026	March 31, 2025	Change
Personnel-related (excluding stock-based compensation)	$ 4,639	$ 4,431	$ 208
Stock-based compensation	3,692	2,291	1,401
Professional fees	3,998	2,142	1,856
Other costs	1,195	1,283	(88)
Total general and administrative expense	$ 13,524	$ 10,147	$ 3,377

General and administrative expenses increased to $13.5 million for the three months ended March 31, 2026, from $10.1 million for the three months ended March 31, 2025. The $3.4 million increase in general and administrative expenses for the three months ended March 31, 2026, compared to the three months ended March 31, 2025, was primarily due to an increase of stock-based compensation of $1.4 million and an increase in professional fees of $1.9 million, which was offset by a $0.1 million decrease in other costs.

Other Income (Expense), Net

Other income (expense), net decreased to $2.4 million for the three months ended March 31, 2026 from $3.9 million for the three months ended March 31, 2025. The $1.5 million decrease for the three months ended March 31, 2026 compared to the three months ended March 31, 2025 in other income (expense), net was primarily related to a decrease in interest income of $1.4 million due to decreases in our average cash, cash equivalents and marketable securities balance, which was offset by a $0.2 million decrease in interest expense due to the expiration of certain financing leases during the three months ended March 31, 2026.

Loss Attributable to Non-Controlling Interest

Loss attributable to non-controlling interest decreased to $0.3 million for the three months ended March 31, 2026, from $2.6 million for the three months ended March 31, 2025. The $2.4 million decrease for the three months ended March 31, 2026 compared to the three months ended March 31, 2025, was a result of no longer allocating net income (loss) to the non-controlling interest as we own 100% of the equity of PMCo upon the closing of the transactions contemplated by the Stock Purchase Agreement in February 2026.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses and negative cash flows from operations. We have not yet commercialized any of our product candidates, which are in clinical or preclinical development, and we do not expect to generate revenue from sales of any products for several years, if at all. On March 2, 2026, we closed our IPO, pursuant to which we issued and sold 25,000,000 shares of common stock, resulting in net proceeds of $369.3 million. Prior to our IPO, we had principally raised capital through the private placement of our convertible preferred stock, par value $0.001 per share, the issuance of convertible notes, payments from Amgen and Novartis, and cost-sharing payments from our other partnership, collaboration or licensing arrangements which resulted in aggregate gross cash proceeds in excess of $934.0 million. In addition, we have benefited from cost-sharing arrangements in our collaboration arrangements with MD Anderson,

Roswell Park and PMCo. During the period ended March 31, 2026, we acquired the non-controlling interest in PMCo. At that time, our collaboration, including our cost-sharing arrangements, terminated and we became obligated to make certain payments to PMCo's parent based on net sales.

Cash Flows

The following table provides information regarding our cash flows for the periods presented (in thousands):

	Period Ended		
	March 31, 2026	March 31, 2025	Change
Net cash provided by (used in):			
Operating activities	$ (80,388)	$ (53,176)	$ (27,212)
Investing activities	(259,934)	75,532	(335,466)
Financing activities	378,891	20,560	358,331
Net increase (decrease) in cash and cash equivalents	$ 38,569	$ 42,916	$ (4,347)

Operating Activities

Our cash flows from operating activities are greatly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we invested in research and development of our platform, product candidates, including preclinical studies, clinical trials, manufacturing and manufacturing process development. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges, which are generally due to stock-based compensation, depreciation and amortization and non-cash lease expense, as well as changes in components of operating assets and liabilities, which are generally due to deferred revenue, increased expenses and timing of vendor payments.

For the three months ended March 31, 2026, operating activities used $80.4 million of cash, primarily resulting from a net loss of $61.7 million and changes in operating assets and liabilities that used $30.7 million in cash partially offset by changes in net non-cash expenses of $12.0 million.

For the three months ended March 31, 2025, operating activities used $53.2 million of cash, primarily resulting from a net loss of $44.3 million and changes in operating assets and liabilities of $17.4 million, which was partially offset by changes in net non-cash expenses of $8.6 million.

Investing Activities

During the three months ended March 31, 2026, net cash used in investing activities was $259.9 million, which primarily consisted of purchases of marketable securities with the net proceeds of our IPO as well as purchases of equipment, offset by sales of marketable securities.

During the three months ended March 31, 2025, net cash provided by investing activities was $75.5 million, which primarily consisted of sales and maturities of marketable securities, offset by purchases of marketable securities and equipment.

Financing Activities

During the three months ended March 31, 2026, net cash provided by financing activities of $378.9 million primarily related to proceeds received from issuance of our common stock, net of issuance costs and contributions from our non-controlling interest, offset by payments on finance lease obligations.

During the three months ended March 31, 2025, net cash provided by financing activities of $20.6 million primarily related to proceeds received from issuance of our Series C convertible preferred stock, net of issuance costs and contributions from our non-controlling interest, offset by payments on finance lease obligations.

Future Funding Requirements

We expect our future capital requirements to increase substantially over time in connection with our ongoing research and development activities, particularly as we advance our current and planned clinical development of our product candidates and maintain the research efforts and preclinical activities associated with our other existing programs and discovery platform. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant expenses related to product sales, marketing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Further, we expect to incur additional costs associated with operating as a public company. As a result, we expect to incur substantial operating losses and negative operating cash flows for the foreseeable future.

Inflation generally affects us by increasing our cost of labor and certain services. We do not believe that inflation had a material effect on our unaudited condensed consolidated financial statements. However, the United States has recently experienced historically high levels of inflation. If the inflation rate continues to increase, it may affect our expenses, such as employee compensation and research and development charges due to, for example, increases in the costs of labor and supplies.

As of March 31, 2026, we had total cash, cash equivalents and marketable securities of $516.6 million. We believe, based on our current operating plan, our cash, cash equivalents and marketable securities will be sufficient to fund our operations into the first half of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. However, our forecast for the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties and actual results could vary materially. Additionally, the process of conducting preclinical studies and testing product candidates in clinical trials is costly, and the timing of progress and expenses in these studies and trials is uncertain. We will need to raise substantial additional capital in the future.

Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may enter into collaborations with third-parties for the development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including, but not limited to:

- the progress, results and costs of, discovery and preclinical studies for our programs and development candidates;
- our ability to advance our clinical-stage product candidates into later-stage trials, which we expect will be required in order to seek marketing approval of our product candidates;
- the costs associated with maintaining and improving our Generate Platform;
- our ability to scale up our manufacturing processes and capabilities, or arrange for a third-party to do so on our behalf, to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- our ability to seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- the costs associated with acquiring or in-licensing products, product candidates or technologies or intellectual property;
- the costs associated with maintaining, expanding, enforcing, defending and protecting our intellectual property;
- the costs associated with hiring additional clinical, quality control, manufacturing and other scientific personnel;
- the costs and timing of establishing or securing sales and marketing capabilities if any current or future product candidate is approved; and
- the costs associated with making any milestone, royalty or other payments under any collaboration or license agreements that we enter into.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Our expectation with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, and we may need to seek additional funds sooner than planned. If we are unable to raise this capital when needed, we may be forced to delay, limit, reduce or eliminate one or more of our research and development programs or other operations.

Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or issuance of convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as common stockholders. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute our stockholders' ownership interest. If we raise additional funds through partnership, collaboration or licensing arrangements with third-parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or development product candidates or grant licenses on terms that may not be favorable to us. Our failure to raise capital or

enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. For instance, if we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market development product candidates to third-parties that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Other Commitments

Leases

We lease office space in Somerville, Massachusetts under a non-cancelable operating lease that expires in June 2032 and lease office and laboratory space in Andover, Massachusetts under a non-cancelable operating lease, as amended, that expires in December 2034. Our operating lease in Andover, Massachusetts includes an option of early termination allowing us to terminate the lease on or after December 31, 2031. We also entered into a finance lease agreement for the purchase of lab equipment. Additionally, we have entered into a service agreement with a CRO in relation to the conduct of our phase 3 clinical studies for GB-0895, which contains embedded leases for certain equipment. Future minimum commitments under these leases are $90.7 million as of March 31, 2026. These commitments are also recognized as operating lease liabilities and finance lease liabilities on our balance sheet as of March 31, 2026.

Purchase and Other Obligations

We enter into contracts in the normal course of business with third-party CROs, CDMOs and other third-party vendors for preclinical, clinical trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation generally consist of payments for services provided or expenses incurred up to the date of cancellation, including non-cancelable obligations of our service providers and, in some cases, wind-down costs. For further information regarding certain of our license agreements and amounts that could become payable in the future under those agreements, please see Note 5 in our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

License, Collaboration and Other Agreements

Below is a summary of the key terms for certain of our license and collaboration agreements. For a more detailed description of these agreements, see Note 5 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Agreement with Novartis

On September 19, 2024, we entered into the Novartis Collaboration Agreement to discover, develop, manufacture and commercialize protein therapeutics using our Generate Platform. The collaboration covers multiple collaboration targets, conducted under applicable research plans during defined research terms. As consideration for the collaboration, we received a $50.0 million upfront payment. Novartis also purchased 1,265,822 shares of our Series C convertible preferred stock for $15.0 million. We are eligible to receive up to $1.0 billion across all programs upon the achievement of certain performance-based milestones, including $130.0 million in development and regulatory milestones and $210.0 million in commercial milestones per research program. None of such milestones have been achieved to date. Novartis is also obligated to pay, on a licensed product-by-licensed product and on a country-by-country basis, tiered royalties ranging from a mid-single digit to a low tens percentage on worldwide net sales of any licensed product, subject to specified reductions and offsets.

Agreement with Amgen

On December 24, 2021, we entered into the Amgen Collaboration Agreement, with Amgen to identify biologic proteins and antibodies directed against specified targets. The Amgen Collaboration Agreement initially covered five collaboration targets. In addition, Amgen has the option to nominate up to five additional collaboration targets, at additional cost, the first of which was exercised in December 2023 related to the sixth target. As consideration for the collaboration, we received a $50.0 million upfront payment. In connection with the Second Amendment, which added an additional collaboration target, we received an additional payment of $5.0 million. We are eligible to receive up to $370.0 million for each program upon the achievement of certain milestones, including $160.0 million in development and regulatory milestones and $210.0 million in commercial milestones per program. Amgen is also obligated to pay, on a licensed product-by-licensed product and on a country-by-country basis, tiered royalties ranging from a mid-single digit up to a low tens percentage on worldwide net sales of any licensed product, subject to customary reductions and offsets.

Agreements with PMCo and Pioneering Medicines 02, LLC ("PM LLC")

On June 22, 2023, we entered into a collaboration agreement (the "Prior PMCo Agreement") with PMCo, an affiliate of Flagship Pioneering and a wholly owned subsidiary of PM LLC, pursuant to which the parties agreed to collaborate on research and development activities with respect to the licensed products containing certain antibodies against TSLP and/or IL-4Rα and share research and development costs, with us bearing 65% and PMCo bearing 35% of all fully-burdened research costs and development expenses, which percentage commitments were subject to adjustment. In addition, concurrently with the Prior PMCo Agreement, we and PM LLC entered into a Drag-Along Agreement pursuant to which PM LLC agreed to, among other things, vote in favor of certain transactions with respect to PMCo.

On February 4, 2026, we entered into a stock purchase agreement (“Stock Purchase Agreement”) with PM LLC, pursuant to which we agreed to purchase, and PM LLC agreed to sell, all of the issued and outstanding capital stock in PMCo. In consideration for such sale, PMCo, PM LLC and we agreed to terminate the Prior PMCo Agreement and the Drag-Along Agreement, and we agreed to pay PM LLC a portion of our net sales, if any, arising from the sale of certain products covered by certain patents or containing certain know-how (“Generate Products”) developed under the Prior PMCo Agreement. The termination of the Prior PMCo Agreement and the closing of the transactions contemplated by the Stock Purchase Agreement occurred on February 26, 2026.

We will generally be obligated to make payments equal to a high-single digit percentage of net sales of Generate Products, including any Generate Product that contains GB-0895. However, if a Generate Product (i) does not contain GB-0895, (ii) binds to at least one of TSLP or IL-4Rα, and (iii) binds to other proteins in addition to TSLP or IL-4Rα, then the sales payment is reduced based on the composition of the product. Further, if we exclusively license our rights to exploit a Generate Product in one or more countries to a third party, and the royalties on net sales of such Generate Product to be paid by such third party are subject to certain specified reductions, then we may be allowed to further proportionally reduce the sales payment due to PM LLC, depending on the relative value of the future royalties due to us from such third party as compared to the total deal consideration.

Critical Accounting Policies, Estimates and Significant Judgments

Our management’s discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses and the disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated 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 values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes from the significant accounting policies and estimates disclosed in Note 2 of the “Notes to Consolidated Financial Statements” in the audited consolidated financial statements for the year ended December 31, 2025, and notes thereto, included in the Company’s final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on February 27, 2026.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and President and Chief Financial Officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2026.

Based on this evaluation, our Chief Executive Officer and President and Chief Financial Officer concluded that, as of March 31, 2026, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

As a recently public company, we are continuing to develop and enhance our internal control environment, including our financial reporting systems and processes, to meet the standards expected of a public company. While our controls and procedures are not yet fully mature, we believe that they are appropriately designed and operating effectively to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements in accordance with generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

In connection with our transition to a public company, we have continued to implement and refine internal controls over financial reporting. These efforts include the formalization and documentation of policies and procedures, the enhancement of our information technology systems and controls, and the expansion of our finance and accounting personnel.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Emerging Growth Company Status

We are an “emerging growth company,” (ECG) as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), as modified by the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”), and we have elected to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002.

We expect to continue to qualify as an ECG as defined in Section 2(a)(19) of the Securities Act and Section 3(a)(80) of the Exchange Act, until the earliest of (i) the last day of the fiscal year in which our total annual gross revenues equal or exceed $1.235 billion, subject to inflation adjustment, (ii) the date on which we become a “large accelerated filer” under Exchange Act Rule 12b-2, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt over a three-year period, and (iv) the last day of the fiscal year following the fifth anniversary of the closing of our IPO.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. As of the date of this Quarterly Report, we are not a party to any legal proceedings that we believe will have, individually or in the aggregate, a material adverse effect on our business, financial condition or results of operations.

Item 1A. Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all other information in this Quarterly Report, including our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before investing in our common stock. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations. The market price of our common stock could decline if one or more of these risks or uncertainties actually occur, causing you to lose all or part of the money you paid to buy our common stock. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business. Certain statements below are forward-looking statements. See the section titled "Cautionary Note Regarding Forward-Looking Statements" appearing elsewhere in this Quarterly Report.

Risks Related to Our Business, Financial Position and Capital Needs

We are a clinical-stage biotechnology company with a limited operating history and no products approved by regulators for commercial sale, which may make it difficult to evaluate our current and future business prospects.

Since our inception in 2018, we have focused substantially all of our efforts and financial resources on developing our Generate Platform and researching and developing programs and product candidates. All of our programs and product candidates are still in the research, preclinical development or clinical development stages. We have not yet demonstrated our ability to successfully complete Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third-party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, 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.

We have no products approved for commercial sale and we can provide no assurance that we will obtain regulatory approvals to market and sell any products in the future. We therefore have never generated any revenue from product sales, and we do not expect to generate any revenue from product sales in the foreseeable future. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. If we do not address these risks and difficulties successfully, our business will suffer.

We will require substantial additional capital to finance our operations in the future. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate programs, product candidates (including clinical trials), investment in our Generate Platform, or future commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete. We expect to spend substantial amounts to (i) continue our research and development activities, perform preclinical studies, and conduct clinical trials of our current and future programs and product candidates, (ii) continue to develop our Generate Platform, (iii) seek regulatory approvals for our product candidates, including GB-0895 and (iv) launch and commercialize any product candidates for which we receive regulatory approval, including potentially building our own commercial sales, marketing and distribution organization.

As of March 31, 2026, we had approximately $516.6 million in cash, cash equivalents, and marketable securities. We believe, based on our current operating plan, that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations for at least twelve months from the date of issuance of the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, royalty financings, government or other third-party grants, asset sales, partnership, collaboration or licensing arrangements such as our collaborations with Amgen and Novartis, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing research and development and corporate activities. Because the length of time and activities associated with research and development of our programs and product candidates are highly uncertain, we are unable to estimate the actual

funds we will require for research, development, marketing and commercialization activities. Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to the:

- number of programs that result in product candidates we chose develop further;
- initiation, progress, timing, costs and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- resources required to further develop Generate Platform;
- clinical development plans we establish for these product candidates;
- terms of any agreements with our current or future collaboration partners;
- outcome, timing and cost of meeting regulatory requirements established by the Regulatory Authorities;
- cost of filing, prosecuting, maintaining, defending and enforcing our patent claims and other intellectual property rights,
- effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future product candidates; and
- cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

To date, we have financed our operations primarily through private placements of our convertible preferred stock, the issuance of convertible notes, payments from Amgen and Novartis, and cost-sharing payments from other partnership, collaboration or licensing arrangements. In December 2021, we entered into the Amgen Collaboration Agreement, and, in connection therewith, we received a non-refundable upfront payment of $50.0 million in January 2022, an equity investment of $25.0 million in October 2023 from the sale to Amgen of our Series C convertible preferred stock, an additional upfront payment of $5.0 million in December 2023 in connection with an amendment to the Amgen Collaboration Agreement, and a $5.0 million development milestone payment in August 2024. In September 2024, we entered into the “Novartis Collaboration Agreement, and, in connection therewith, we received a non-refundable upfront payment of $50.0 million in October 2024 and an equity investment of $15.0 million from the sale of our Series C convertible preferred stock. In addition, we have benefited from cost-sharing arrangements in our collaboration arrangements with MD Anderson, Roswell Park and PMCo. Upon execution of the underwriting agreement relating to our IPO on February 26, 2026, we acquired PMCo. At that time, our collaboration, including our cost-sharing arrangements, terminated and we became obligated to make certain payments to PMCo’s parent based on net sales. We cannot be certain that additional funding will be available on favorable terms, or at all. Until we can generate sufficient product, milestone or royalty revenue to finance our operations, which we may never do, we expect to finance our future cash needs through a combination of public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, and partnership, collaboration or licensing arrangements. Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop our programs, develop and commercialize our product candidates or develop our Generate Platform. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms or at all. Among other possibilities, negative clinical trial data or setbacks, or perceived setbacks, in our programs or product candidates, or with respect to our Generate Platform, could impair our ability to raise additional financing or grants, or our ability to enter into partnership, collaboration and licensing arrangements, in each case, on favorable terms, or at all. Moreover, the terms of any equity or debt financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, or the possibility of such issuance, may cause the market price of our shares to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our stockholders’ rights.

Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and 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. If we raise additional capital from third-parties through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches, we may have to relinquish certain valuable rights to our programs or product candidates, technologies or future revenue streams. We also could be required to seek collaboration partners for one or more of our current or future programs and product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to programs and product candidates, or intellectual property that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, we may have to significantly delay, scale back or discontinue the development of one or more of our programs, or the development and commercialization of one or more of our product candidates, or one or more of our other research and development initiatives. Any of the above events

could significantly harm our business, prospects, financial condition and results of operations, cause the price of our common stock to decline, and negatively impact our ability to fund operations.

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. We will continue to incur significant research and development and other expenses related to our programs, product candidates, Generate Platform, and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital. We have incurred net losses in each year since our inception in 2018, including net losses of $61.7 million and $44.3 million for the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026, we had an accumulated deficit of $737.7 million.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities and the development of our Generate Platform. To date, we have financed our operations primarily through private placements of our convertible preferred stock, the issuance of convertible notes, payments from Amgen and Novartis, and cost-sharing payments from other partnership, collaboration or licensing arrangements. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches. We have not completed pivotal clinical trials for any of our product candidates, and it will be several years, if ever, before we or our collaboration partners have a product candidate ready for commercialization. Even if we or our collaboration partners obtain regulatory approval to market a product, our future revenues will depend upon the size of any markets in which such product have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. We may never achieve profitability.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- expand the number of our research and development programs;
- continue or expand our scope of research or development of our current programs and product candidates in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical or other studies or trials for our programs and product candidates, including pursuant to some of our partnership, collaboration and licensing arrangements;
- change or add additional manufacturers or suppliers;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our product candidates toward commercialization;
- attract and retain skilled personnel;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts;
- seek marketing approvals and reimbursement for our product candidates and products;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- acquire or in-license technologies;
- make payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any program or product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical-stage biotechnology companies such as ours, should be carefully considered. Any predictions about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

The development of our programs and the development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We have entered into collaboration agreements for certain programs and product candidates and may decide to collaborate for the future development and potential commercialization of other product candidates. For example, we are party to cost-sharing arrangements in our collaboration arrangements with MD Anderson and Roswell Park, pursuant to which we will collaborate to jointly discover and co-develop protein therapeutics. However, we cannot guarantee that either we or our collaboration partners will have the available funds to fund the research and development activities contemplated by such agreements. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our programs and product candidates or bring them to market and generate product revenue.

Additionally, our expenses could increase beyond our expectations if we are required by the Regulatory Authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in the development of GB-0895 and our other product candidates such as delays in establishing appropriate manufacturing arrangements or delays in completing clinical trials.

We are dependent on the success of our product candidates, including GB-0895, GB-4362 and GB-5267, and our ongoing and anticipated trials may not be successful.

Our future success is dependent on our ability to timely obtain marketing approval for, and then successfully commercialize, our product candidates, including GB-0895, GB-4362 and GB-5267. We are investing a majority of our financial resources into the research and development of these product candidates including our ongoing Phase 3 clinical trials for GB-0895 and Phase 1 clinical trials for GB-4362 for which clinical trial sites have been activated and the first patient expected to be dosed in mid-2026, and GB-5267, for which the first patient is expected to be dosed in the second half of 2026.

Our product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote these product candidates, or any other product candidates, before we receive marketing approval from the applicable Regulatory Authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on a variety of factors. We do not have control over many of these factors, including certain aspects of clinical development and the regulatory submission and review process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts of those of any current or future collaborator. In addition, we do not have control over whether products that target the same indications as our product candidates are introduced, which could impact the competitiveness of our product candidates. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of these product candidates, even if approved. If we are not successful in commercializing GB-0895, GB-4362 or GB-5267, or any other product candidate, or are significantly delayed in doing so, our business will be materially harmed.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our product candidates may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives, such as the expected timing for the topline data from our Phase 3 clinical trials of GB-0895 for the treatment of severe asthma or Phase 1b clinical trial of GB-0895 in moderate-to-severe COPD. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, in some cases for reasons beyond our control, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;

- our substantial reliance on third-party CROs to engage, qualify and prepare clinical trial sites, complete these trials successfully, in compliance with regulatory requirements, and on schedule;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the Regulatory Authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our substantial reliance on third-party CDMOs to manufacture our product candidates;
- our CDMOs access to sufficient, reliable and affordable supplies of materials used to manufacture our product candidates;
- the efforts of our collaborators with respect to the manufacturing and commercialization of our product candidates;
- the ability to commercialize our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

Any inability to meet milestones as publicly announced, or at all, may delay the commercialization of our product candidates or commercialization may never be achieved and, as a result, our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones, and may decrease the attractiveness of our product candidates relative to competitive products expected to be approved by the applicable Regulatory Authorities prior to our product candidates.

Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability as well as negatively impact our ability to exist as a standalone company.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this Quarterly Report:

- inability to develop promising programs;
- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- the feasibility of developing, manufacturing and commercializing our product candidates;
- our ability to manage our growth;
- the outcomes of research programs, clinical trials or other product development or approval processes conducted by us and our collaboration partners;
- our ability to develop or successfully commercialize product candidates;
- the ability of our collaboration partners to develop and successfully commercialize product candidates;
- our relationships, and any associated exclusivity terms, with collaboration partners, including Amgen and Novartis;
- our contractual or other obligations to provide resources to fund our programs and product candidates;
- our operation in a net loss position for the foreseeable future;
- risks associated with the international aspects of our business, including manufacturing of our product candidates, the conduct of clinical trials in multiple international locations and potential commercialization in such locations; our ability to consistently arrange for manufacture of our product candidates by third-parties;
- our ability to accurately report our financial results in a timely manner; our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain and enforce our intellectual property (“IP”) rights; our ability to prevent the theft or misappropriation of our IP and know-how or proprietary technologies; potential advantages that our competitors and potential competitors may have in securing funding, obtaining and maintaining the rights to critical IP or developing competing technologies or products;

- our ability to obtain additional capital that may be necessary to expand our business; our collaboration partners' ability to obtain additional capital that may be necessary to develop programs and develop and commercialize product candidates pursuant to our partnership, collaboration and licensing arrangements;
- the effect of changes in government regulation;
- cybersecurity breaches and other business interruptions such as power outages, strikes, acts of terrorism or natural disasters; and
- our ability to use our NOL carryforwards to offset future taxable income.

Risks Related to Our Generate Platform and Our Use of Artificial Intelligence

Our approach to the engineering and development of our programs is unproven, and we may not be successful in our efforts to identify and develop any programs and product candidates of commercial value by leveraging our Generate Platform.

The Generate Platform and our approach to drug engineering and development utilizes, among other things, our proprietary AI and machine learning solutions to create a pipeline of product candidates. Because our approach is both proprietary and pioneering, the cost and time needed to develop our programs and product candidates can be difficult to predict, and our efforts may not result in the engineering and development of commercially viable human therapeutics.

Any drug engineering and development that we are conducting with our Generate Platform may not be successful in identifying programs and product candidates that have commercial value or therapeutic utility. The Generate Platform may initially show promise in identifying potential programs and product candidates, yet fail to yield viable programs and product candidates for clinical development or potential commercialization for a number of reasons, including:

- research programs to identify new programs and product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new programs and product candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop programs and product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;
- programs and product candidates engineered with our Generate Platform may not demonstrate efficacy, safety or tolerability, including because they may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies, or otherwise may interact with human biological systems in unforeseen, ineffective or possibly harmful ways;
- programs and product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;
- competitors may develop alternative therapies that render our programs and product candidates non-competitive or less attractive; or
- a potential product candidate may not be capable of being produced at an acceptable cost.

In addition, we may in the future seek to identify and develop programs and engineer and develop product candidates that are based on novel targets and technologies that are unproven. If our activities fail to identify novel targets or technologies for drug engineering and development, or such targets prove to be unsuitable for treating human disease, we may not be able to develop viable additional programs and product candidates. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. If the product candidates resulting from our programs prove to be ineffective, unsafe or commercially unviable, our programs and product candidates would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

We are substantially dependent on the successful application of our Generate Platform to develop programs and product candidates that can be commercialized by us or our current or future collaboration partners.

Since our formation, we have focused on investing in our Generate Platform to unlock a new way of developing programs and product candidates for development and, if approved, potential commercialization by us and our collaboration partners. The biotechnology industry is capital intensive, and our success depends significantly on our ability to apply our Generate Platform to develop programs and engineer and develop product candidates that can be further developed by us or our current or future collaboration partners. Our ability to engineer and develop product candidates and increase revenue depends in large part on our ability to continue to enhance and improve our Generate Platform. We have invested, and expect to continue to invest, in research and development efforts, acquisitions and licensing agreements that further enhance our Generate Platform. These investments may involve significant time, risks and uncertainties, including the risks that any new software or hardware enhancement or the integration of software or hardware from an acquired company or third-party

licensor may not be introduced in a timely or cost-effective manner; may not keep pace with technological developments; or may not achieve the functionality necessary to generate significant revenues. The success of any enhancement to our Generate Platform depends on several factors, including (i) the development of more advanced models and algorithms; (ii) the generation of additional high quality and relevant data; (iii) high quality and high-throughput biohardware, including laboratory analysis and structural solutions from our cryogenic electron microscopy ("Cryo-EM") core; (iv) innovation in other experimental, computational and/or infrastructure technologies; and (v) increased computational storage and processing capacity.

The Generate Platform depends upon the continuous, effective and reliable operation of our biohardware, including our laboratory systems, Cryo-EM core and AI solutions, including software, hardware, databases and related tools and functions, as well as the integrity of our data. We have from time to time found defects, vulnerabilities or other errors in such tools, functions and data, and new errors may be detected in the future. The risk of errors is particularly significant when new software code or hardware is first introduced or when new versions or enhancements of existing software code or hardware are implemented. Errors may also result from the interface of our proprietary software and hardware tools with our data or with third-party systems and data.

Further, the price of new equipment and hardware, including graphics processing units ("GPUs"), is subject to market fluctuations. Such fluctuations are influenced by factors, including supply and demand for such equipment. In the case of GPUs for AI services, current demand for certain types of GPUs and networking equipment far exceeds supply, impacting the price and availability of such hardware. As a result, the cost of new equipment has been and may in the future be unpredictable, and may also be significantly higher than our historical costs.

If we are unable to successfully enhance our Generate Platform, or if there are any defects or disruptions in our Generate Platform that are not timely resolved, our ability to develop new innovations and ultimately gain market acceptance of our products and our Generate Platform, could be materially and adversely impacted, and our reputation, business, operating results and prospects could be materially harmed.

We have limited clinical data on product candidates that were computationally engineered with our Generate Platform demonstrating whether they are safe or effective for long-term treatment in humans. The long-term safety and efficacy of product candidates computationally engineered with our Generate Platform is unknown. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new product candidates as quickly or cost effectively as expected and we therefore may not be able to execute on our strategic approach as originally expected.

Product candidates engineered with our Generate Platform require substantial technical, financial and human resources to develop and potentially commercialize. We may not be able to maintain sufficient resources and expertise to discover additional programs and product candidates. If we are unable to identify successful programs and product candidates for preclinical and clinical development and regulatory approval in a timely matter or at all, we could experience significant delays or an inability to successfully pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our product candidates, which could harm our business.

Issues relating to our use of AI in the identification of our programs and the engineering and development of our product candidates could adversely affect our business and operating results.

We incorporate AI solutions, among other technologies and capabilities, into our Generate Platform. There are risks involved in utilizing AI, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. If our AI systems fail to achieve their intended purposes – such as identifying viable therapeutic candidates or targets, predicting biological outcomes, producing reproducible results, and other similar or related purposes – our product development efforts may be delayed or unsuccessful. If we are unable to successfully integrate and manage AI within our business, or if AI fails to deliver the expected benefits, our ability to develop our programs and product candidates could be materially adversely affected.

Issues relating to the use of new and evolving technologies such as AI may cause us to experience brand or reputational harm, competitive harm, legal liability and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. Known risks of AI generally include inaccuracy, hallucinations, bias, intellectual property infringement or misappropriation, data privacy and cybersecurity issues and data provenance disputes. Perceived or actual technical, legal, compliance, privacy, security, ethical or other issues relating to the use of AI in biopharmaceutical development may cause public confidence in AI to be undermined, which could slow market acceptance of product candidates discovered and developed using AI. In addition, litigation or government regulation related to the use of AI may also adversely impact our ability to identify programs and engineer and develop product candidates using AI, as well as increase the cost and complexity of doing so. For example, regulators may limit our ability to develop or implement our proprietary AI models and algorithms and/or may eliminate or restrict the confidentiality of our proprietary technology, or may limit our ability to secure intellectual property rights to technologies created with the assistance of our proprietary AI models and algorithms, which could have an adverse effect on our business, results of operations and financial condition.

We also face increased competition from other companies that claim to use AI and related methods for drug engineering and development, some of which have more resources than we do and may have developed more effective methods than we and any third-party collaborators have, which may reduce our and any third-party collaborators' effectiveness in identifying potential product candidates and attracting additional collaborators to work with us. In particular, biotechnology companies based in China present both known and emerging competitive threats to our business. Many of these companies operate within innovation ecosystems characterized by substantial government investment, access to large and rapidly expanding biological and clinical datasets, and accelerated regulatory or funding pathways. These factors may allow Chinese biotechnology companies to develop, train and deploy advanced computational models, drug discovery platforms or biologic design technologies more rapidly or at lower cost than we can. If our competitors are able to utilize new technologies more effectively (including but not limited to those that may involve AI or be created using AI) to discover, develop and commercialize products that compete with any of our programs and product candidates, such technologies could adversely impact our ability to compete.

Further, AI may have or produce errors or inadequacies that are not easily detectable. The quality of AI outputs depends heavily on the quality and quantity of input data. If the data used to train AI or the content, analyses or recommendations that AI applications assist in producing are or are alleged to be deficient, inaccurate, incomplete, hallucinatory, overbroad or biased, our business, financial condition and results of operations may be adversely affected. Developing, testing and deploying AI systems may also increase the cost profile of our product offerings due to the nature of the computing costs involved in such systems, which could impact our project margin and adversely affect our business and operating results.

The legal landscape and subsequent legal protection for the use of AI remains uncertain, and the increasing use of AI in drug discovery and development introduces new and evolving risks related to ownership, inventorship and protection of intellectual property generated by or with the assistance of AI technologies. For example, generative AI may be used improperly or inappropriately, which could lead to the tainting of our proprietary information and render us unable to qualify for certain patent or trade secret protection. Moreover, if our vendors, employees, suppliers or contractors with access to our proprietary and confidential information and know-how were to disclose such information as inputs to third-party AI tools this could lead to loss of trade secret protection and otherwise impact our ability to realize the benefit of our intellectual property. If we do not have sufficient rights to collect or use the data on which our AI relies or to the outputs produced by our Generate Platform, we may incur liability through the alleged violation of certain laws, third-party privacy rights, online terms of service or other contracts to which we or our data providers are a party. In addition, we rely on third-party software and hardware for our Generate Platform. If the relevant software or hardware, or updates to such software or hardware, were to become unavailable to us in the future on reasonable commercial terms, or if they became the subject of allegations of intellectual property infringement, our ability to continue to use our Generate Platform could be affected. We also rely on public sources of data, such as the Protein Data Bank, which, if they became unavailable to us on reasonable terms, could affect our Generate Platform. Regulatory and legal frameworks governing inventions created with or using AI are still developing and may create uncertainty regarding our ability to secure and enforce rights in such inventions.

AI presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of AI, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, AI presents risks and challenges that could impact our business. In addition to our Generate Platform, we have adopted and integrated, and in the future may adopt and integrate additional generative AI tools into our systems for specific use cases reviewed by our legal department and information technology department. Our vendors may incorporate generative AI tools into their offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Our use of AI may also lead to novel and urgent cybersecurity and privacy risks, which may adversely affect our operations and reputation, as well as the operations of any third-party collaborators. Emerging ethical issues surround the use of AI, and we may be subject to reputational and legal risk if our deployment or use of AI becomes controversial. Our use of AI may also, in the future, result in cybersecurity incidents that implicate personal data of customers or patients. Any such cybersecurity incidents related to our use of AI could adversely affect our reputation and results of operations.

A growing number of federal, state, and international legislators, agencies and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI, and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU's Artificial Intelligence Act ("AI Act") entered into force on August 1, 2024, with most provisions becoming effective on August 2, 2026. This legislation imposes

significant obligations on providers and deployers of AI systems and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The recently enacted United States Department of Justice Data Security Program (also known as the Bulk Data Transfer Rules), effective April 8, 2025, imposes complex additional restrictions on international data transfers, which may affect our ability to do business in manufacturing and clinical research in foreign countries. Likewise, in the U.S., several states, including Colorado and California, passed laws to regulate various AI uses, including on deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued draft guidance on the use of AI in regulatory decision-making for drug and biological products that centers on the context of use while establishing a credibility assessment framework for establishing and evaluating AI model outputs intended to support regulatory decision-making. If we develop or use AI systems governed by these laws or regulations, including as informed by regulatory guidance, we would need to meet higher standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance. We expect other jurisdictions will adopt similar laws. Uncertainty in the legal regulatory regime may require significant resources to modify and maintain business practices to comply with U.S. and non-U.S. laws, the nature of which cannot be determined at this time. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines or significant restrictions on our ability to conduct our business activities.

We utilize third-party open-source software ("OSS"), which presents risks that could adversely affect our business and subject us to possible litigation.

We utilize software that is licensed from third-parties under open-source licenses, and we expect to continue to use such OSS in the future. We cannot ensure that we have effectively monitored our use of OSS, validated the quality or source of such software, or are in compliance with the terms of the applicable open-source licenses or our policies and procedures. Use of OSS may entail greater risks than use of third-party commercial software because open-source licensors generally do not provide support, updates or warranties or other contractual protections regarding infringement claims or the quality of the code. OSS may also be more susceptible to security vulnerabilities. The availability of OSS could be adversely affected by service outages, data loss, privacy breaches, cyber-attacks and other events relating to the availability of these applications and services they provide, which could diminish the utility of these services and harm our business. We also could be subject to lawsuits by third-parties alleging that what we believe to be licensed OSS infringes such parties' intellectual property rights, which could be costly for us to defend and require us to devote additional research and development resources to change our solutions. Some OSS licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of OSS we use. If we combine our proprietary software with OSS in a certain manner, we could, under certain of the OSS licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of OSS, the terms of many OSS licenses have not been interpreted by U.S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our product candidates. We could be required to seek licenses from third-parties in order to continue using our software, to re-engineer our software or to discontinue use of our software in the event re-engineering cannot be accomplished on a timely basis, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Research, Development, Regulatory Review and Approval of Our Product Candidates

Preclinical and clinical development is inherently lengthy and uncertain. Preclinical and clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which would have a material adverse impact on our Generate Platform or our business.

Preclinical and clinical testing is expensive and complex and can take many years to complete, and its outcome is inherently uncertain. We and our collaboration partners may not be able to initiate, may experience delays in or may have to discontinue preclinical studies and clinical trials for our product candidates.

Before we can initiate clinical trials for a product candidate, we must first complete extensive preclinical studies, including IND-enabling good laboratory practices ("GLP") toxicology testing, which support our planned INDs in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of our preclinical testing and studies. For example, while regulators like the FDA have signaled through draft guidance a movement away from animal testing for monoclonal antibodies, we have thus far depended on the availability of non-human primates ("NHPs") to conduct certain preclinical studies that we are required to complete prior to submitting an IND or foreign equivalent prior to initiating clinical development, and prior to submitting a marketing application. During the past several years, there was a global shortage of NHPs available for drug development. If the shortages in NHPs or other laboratory animals occur in the future, this could significantly increase the costs of obtaining, or decrease the availability of, NHPs or other laboratory animals for our future preclinical studies if regulators continue to require NHP data, or we require other

laboratory animals, to support our preclinical and clinical development programs. This could also result in delays in our development and approval timelines.

We must also complete extensive work on CMC activities (including yield, purity and stability data) to be included in the IND filing. CMC activities require extensive manufacturing processes and analytical development, which is uncertain and lengthy. For instance, batch failures as we scale up our manufacturing may occur. In addition, we may have difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our preclinical or clinical product candidates. If we are required to produce new batches of our product candidates due to insufficient shelf life, it may delay the commencement or completion of preclinical or clinical trials of such product candidates.

We cannot predict if the Regulatory Authorities will accept the results of our preclinical testing or our proposed clinical programs or if the outcome of our preclinical testing, studies and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the Regulatory Authorities allowing clinical trials to begin.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would also significantly harm our business. Our development costs will also increase if we experience delays in testing or regulatory approvals, and we may be required to obtain additional funds to complete clinical trials. There can be no assurance that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Regulatory Authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We and our collaboration partners also may experience numerous unforeseen events during, or as a result of, any clinical trials that we or our collaboration partners conduct that could delay or prevent us or our collaboration partners from successfully developing our product candidates, including:

- the Regulatory Authorities, institutional review boards (“IRBs”) or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site for any number of reasons, including concerns regarding safety and aspects of the clinical trial design;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges in manufacturing sufficient quantities of our product candidates, or obtaining sufficient quantities of combination therapies for use in clinical trials;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- we may experience limitations or shortages in our ability to obtain or supply necessary medical equipment to conduct clinical trials; for example, there are current supply constraints on the ability to obtain certain volumes of equipment for testing airway inflammation measures;
- we may continue to optimize our manufacturing processes, including through changes to the scale and site of manufacturing, which may lead to potentially significant changes in our clinical trial designs, requiring additional cost and time, and, as a consequence, lead to a delay in plans for progressing one or more product candidates;
- the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies or add additional cohorts to reflect changes in regulatory requirements or guidance, which may be required to resubmit to an IRB, ethics committee and regulatory authorities for re-examination;
- in an effort to optimize product features, we plan to make in the future changes to our product candidates after we commence clinical trials, which may require us to repeat earlier stages of clinical testing or delay later stage testing of the product candidate;
- clinical trials of any product candidates may fail to show safety or efficacy, or produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon development programs;

- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- differences in clinical trial design between early-stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials; preclinical and clinical data are often susceptible to varying interpretations and analyses, and many product candidates believed to have performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of our CDMOs, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- product candidates may have undesirable side effects or degradation products, any of which could lead to serious adverse events ("SAEs") or other unexpected characteristics;
- occurrence of SAEs in trials of the same class of product candidates conducted by other companies that could be considered similar to our product candidates; and
- the potential for approval policies or regulations of the Regulatory Authorities to significantly change in a manner rendering our clinical data insufficient for approval.

For example, we are developing a biologic-device combination for the administration of GB-0895 with an autoinjector and pre-filled syringe ("PFS") for ease of administration. Earlier clinical trials have used a syringe and vial presentation, and we intend to transition to the PFS presentation for our pivotal Phase 3 trials in severe asthma via protocol and regulatory amendments. Regulatory Authorities may require us to conduct, among other things, pharmacokinetics compatibility studies to bridge the vial and syringe presentation to these new planned devices and human factors testing to support self-administration of these devices. There is no assurance that we will be successful in demonstrating the safety of either of these biologic-device combinations in clinical trials, any other studies or at all, and any such failure would impede our development and commercialization strategy for GB-0895. In addition, Regulatory Authorities could require additional preclinical studies or clinical trials to support introduction of a biologic-device combination, which could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase our clinical trial costs, delay marketing approval of GB-0895 and jeopardize our ability to commence product sales and generate revenue from GB-0895, if approved.

We could also encounter delays if a clinical trial is suspended or terminated by us, the Regulatory Authorities, ethics committees or the IRBs of the institutions in which such trials are being conducted, or if such trial is recommended for suspension or termination by the Data Safety Monitoring Board ("DSMB") for such trial. We may experience delays in gaining clearance from Regulatory Authorities to initiate clinical trials through the imposition of a clinical hold in order to address comments from such regulators on our clinical trial design or other elements of our clinical trials. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the Regulatory Authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit or adequate benefit risk ratio from using a product candidate, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Further, conducting clinical trials in foreign countries, as we intend to do for GB-0895 and as we may in the future conduct for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to Regulatory Authorities. A Regulatory Authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The Regulatory Authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the Regulatory Authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize GB-0895 or any other product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business, financial condition, results of operations and growth prospects. In addition, many of the factors that cause, or lead to, delays of clinical

trials may ultimately lead to the denial of regulatory approval of our product candidates. Any delays in the development of our product candidates may harm our business, financial condition and prospects significantly.

We are currently enrolling patients in clinical trials for GB-0895 globally and may in the future conduct clinical trials for other product candidates outside the United States, and the Regulatory Authorities may not accept data from such trials.

We are currently enrolling patients in two global Phase 3 clinical trials for GB-0895 in patients with severe asthma across more than 50 countries in North America, Europe, Latin America and Asia Pacific, and we expect to continue to conduct trials for our current and future product candidates internationally in the future. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the Regulatory Authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, regardless of whether such trials were conducted under an IND, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice, the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice ("GCP") regulations, and the FDA can validate the data through on-site inspections or other appropriate means. Many foreign regulatory authorities have similar approval requirements, including in relation to the use of data from clinical trials conducted in foreign jurisdictions. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the Regulatory Authorities will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the Regulatory Authorities do not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in any product candidates that we develop being delayed or halted in development or not receiving approval for commercialization in the applicable jurisdiction. Additionally, recent policy proposals in the United States may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third-parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.

The results observed from preclinical studies or early-stage clinical trials of GB-0895 or any other product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For instance, results seen in our Phase 1 clinical trial for GB-0895 in patients with mild-to-moderate asthma may not translate to similar results in our Phase 3 clinical trials in patients with severe asthma. While a dose-ranging trial in the target patient population or studying multiple doses in the Phase 3 clinical trials for GB-0895 in patients with severe asthma was recommended by the FDA and EMA, and proceeding directly to Phase 3 with a single dose carries higher risk of failure and uncertainty, we did not conduct a dose-ranging trial prior to proceeding into Phase 3 clinical trials in severe asthma. Based on the results of our Phase 1 clinical trial and other scientific considerations, we are evaluating GB-0895 at a single 300 mg subcutaneous dose every six months ("Q26W") in our Phase 3 clinical trials in severe asthma. However, there is no guarantee that the positive results generated at such dose in the completed Phase 1 clinical trial in mild-to-moderate asthma will demonstrate similar results in our Phase 3 clinical trials in patients with severe asthma, and we may be required to conduct additional trials before we can submit a marketing application for the approval of GB-0895. Furthermore, our product candidates may not be able to demonstrate similar activity or adverse event profiles as those observed in earlier studies and trials, and we may not have generated sufficient safety data to support a marketing application by the time of our targeted submission as other third-party products or product candidates that we believe may have similar profiles. In addition, in our planned future clinical trials, we may utilize clinical trial designs or dosing regimens that have not been tested in prior clinical trials.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of GB-0895 or any other product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, adverse safety or efficacy observations made in clinical trials.

Additionally, we intend to utilize an "open-label" clinical trial design for certain of our clinical trials, such as our Phase 1 clinical trial of GB-5267 for the treatment of platinum-resistant ovarian cancer. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results of a product candidate when studied in a controlled environment with a placebo or active control.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain approval from the Regulatory Authorities.

Interim, initial, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular preclinical study or clinical trial. We may also make assumptions, estimations, calculations and conclusions as part of our analyses of preliminary or topline data, and we may not have received or had the opportunity to evaluate all data fully and carefully. As a result, the topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. As a result, topline data should be viewed with caution until the final data is available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participants enrollment continues and more participants' data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between interim data and final data could significantly harm our business prospects.

Further, others, including Regulatory Authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions, study population size, safety database size, interpretations of data or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular product candidate, the approvability or commercialization of the particular product candidate and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or trial is based on what is typically extensive information, and investors may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline or preliminary data that we report differ from actual results, or if others, including Regulatory Authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and growth prospects. Further, disclosure of interim, topline or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

If we encounter difficulties identifying and enrolling participants in our clinical trials, including participants with the required or desired characteristics to achieve diversity in a trial, our clinical development activities could be delayed or otherwise adversely affected.

We depend on enrollment of participants in our clinical trials for our product candidates. We may find it difficult to enroll trial participants in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Delays or difficulties in enrollment may result in increased costs or otherwise affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates, or result in termination of the clinical trials altogether. For example, in order to enroll a sufficient number of participants in our Phase 3 clinical trials for GB-0895 in patients with severe asthma, we plan to contract with sites across more than 50 countries in North America, Europe, Latin America and Asia Pacific.

Identifying and qualifying trial participants to participate in clinical trials of our product candidates is critical to our success. Patient and subject enrollment is affected by factors including: severity of the disease under investigation; complexity and design of the trial protocol; size of the targeted patient population; eligibility criteria for the trial in question; proximity and availability of clinical trial for the disease or condition under investigation; available sites for prospective trial participants; availability of competing therapies and clinical trials, including between our own clinical trials; efforts to facilitate timely enrollment in clinical trials; patient referral practices of physicians; ability to monitor trial participants adequately during and after treatment; ability to recruit clinical trial investigators with the appropriate competencies and experience; clinicians' and trial participants' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating; our ability to obtain and maintain participant informed consent; and the risk that trial participants enrolled in clinical trials will not complete a clinical trial.

The timing of our clinical trials depends on the speed at which we can recruit trial participants to participate in testing our product candidates. If trial participants are unwilling to participate in our studies because of negative publicity from adverse events in our trials or other trials of similar products, or those related to specific therapeutic area, or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting trial participants, conducting studies and obtaining regulatory approval of potential products may be delayed, which could also have significant commercial competitive impacts in the future.

In particular, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition may reduce the number and types of trial participants available to us, because some trial participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a third-party. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which may reduce the number of trial participants who are available for our clinical trials at such clinical trial sites. Additionally, if new product candidates show encouraging results, potential trial participants and their doctors may be inclined to enroll trial participants in clinical trials using those product candidates. If such new product candidates show discouraging results or other adverse safety indications, potential trial participants and their doctors may be less inclined to enroll trial participants in our clinical trials.

Due to the significant resources required for drug development and depending on our ability to access capital, we intend to prioritize the development of GB-0895 for severe asthma. Moreover, we may fail to expend our limited resources on the development of GB-0895 for the treatment of other indications or for the development of other potential future product candidates that may have been more profitable or for which there is a greater likelihood of success.

Due to the significant resources required for drug development, we must decide which indications to pursue and advance and the amount of resources to allocate to each product candidate. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. For example, our current strategy is to pursue regulatory approval of GB-0895 for the treatment of severe asthma and to evaluate a potential label expansion into COPD and other indications. If we make incorrect determinations regarding the viability or market potential of GB-0895, or misread trends in the biotechnology industry, our business, financial condition, results of operations and growth prospects could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to our product candidates through collaboration, licensing or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

Our product candidates may face competition from biosimilars approved through an abbreviated regulatory pathway, including biosimilars of competitive products.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”), includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (the “BPCIA”), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a Biologics License Application (“BLA”) for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company’s product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing, including the potential for sponsors under FDA draft guidance issued in 2024 to demonstrate interchangeability without conducting so-called “switching” studies and the potential for sponsors under FDA draft guidance issued in 2025 to demonstrate biosimilarity without conducting comparative efficacy studies. Although the FDA has yet to finalize these draft guidance documents, these or similar efforts may increase the risk of competition for our biologic product candidates, if approved.

In the European Union, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for diverse types of biological product.

In addition to the risk associated with biosimilars of our product candidates, the launch of biosimilars to products that compete with our product candidates may intensify competition in the therapeutic areas we target by lowering the overall price point and expanding access to alternative treatments. As these lower-cost biosimilars gain market share, payors may preferentially encourage their use or impose access restrictions that make it more difficult for our product candidates to obtain

favorable coverage, reimbursement or formulary placement. These dynamics could materially limit our market opportunity and adversely affect our commercial prospects.

The regulatory approval processes of the Regulatory Authorities are lengthy, time-consuming and inherently unpredictable, and if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, product candidates we may develop, and our ability to generate revenue will be materially impaired.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain, and may prevent us from obtaining approvals for the commercialization of any product candidates we may develop. Any product candidate we may develop and the activities associated with its development and commercialization, including design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by Regulatory Authorities. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we and our collaboration partners must demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure and potent or effective in humans, including the target population. Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA, a Marketing Authorization Application ("MAA") to the EMA, and similar marketing applications to other Regulatory Authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. The general approach for FDA approval of a new drug is dispositive data from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population. In February 2026, the FDA publicly indicated that a single adequate and well-controlled pivotal clinical trial supported by confirmatory evidence will be the FDA's default standard moving forward for novel products, rather than two such trials, but the scope, implementation and durability of this policy position remain uncertain and the FDA retains broad discretion to require additional clinical data for any product candidate, including a second adequate and well-controlled clinical trial. Regulatory Authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to regulatory approval. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from Regulatory Authorities or those that have been used for the approval of similar drugs, will be acceptable for future approvals. The clinical development of our product candidates is also susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate purity, potency or efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the Regulatory Authorities that a product candidate may not continue development or is not approvable. It is possible that even if our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the Regulatory Authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the Regulatory Authorities that a product candidate is safe and effective for any of its proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the Regulatory Authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the Regulatory Authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the Regulatory Authorities may not file or accept our BLA or marketing application for substantive review;
- the Regulatory Authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of our CDMOs;
- staffing changes and backlogs at the Regulatory Authorities may create unexpected delays in the review and approval of any applications we may submit; and

- the approval policies or regulations of the Regulatory Authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We have no experience as an organization in filing and supporting the applications necessary to gain marketing approvals and will need to rely on CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

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

In addition, if our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply, or ensure that our third-party providers comply, with current Good Manufacturing Practices ("cGMPs"), Quality Management System Regulation ("QMSR") and GCPs for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third-party might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidate's post-approval could adversely affect our business, financial condition, results of operations and growth prospects.

Regulatory Authorities also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies, may not approve the price we intend to charge for our product candidates, may grant approval contingent on the performance of costly post-marketing clinical trials or may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

The Regulatory Authorities review the CMC section of regulatory filings. Any aspects found unsatisfactory by Regulatory Authorities may result in delays in clinical trials and commercialization. In addition, the Regulatory Authorities conduct pre-approval inspections ("PAIs") of clinical sites and manufacturing sites at the time of a BLA. Any findings by Regulatory Authorities and failure to comply with requirements may lead to delay in approval and failure to commercialize the product candidate.

Additional time may be required to obtain marketing authorizations for any product candidates that we develop as biologic-device combination products.

We intend to develop GB-0895 as a biologic-device combination product for administration with an autoinjector and PFS for ease of administration. Development of a product candidate as a combination product candidate requires close coordination with the Regulatory Authorities for review of each of the biologic and device components that comprise the product and would typically be reviewed by different centers within the Regulatory Authorities if offered for use as standalone products. For example, the FDA's review of a marketing application for a biologic-device combination that has a primary mode of action as a biologic would likely be subject to a biologics license application with the Center for Biologics Evaluation and Research as the lead center, with coordination with the Center for Devices and Radiological Health for the review of the device component. Although the Regulatory Authorities have or may have systems in place for the review and approval of such combination products, we may experience additional delays in the development and commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

For example, we currently plan to begin our pivotal Phase 3 trials of GB-0895 using a syringe and vial presentation, similar to the presentation used in prior trials of GB-0895. We intend to submit the PFS presentation to Regulatory Authorities in our marketing submissions, including our BLA submission to the FDA. During the course of the Phase 3 trials, we also intend to conduct trials of a separate autoinjector pen device using GB-0895; it is our intention to amend our BLA submission at some point in the future to include the future autoinjector pen presentation; as a result, we may be required to gather additional data before we are able to submit a marketing application for GB-0895 or any of our other current or future product candidates, if ever. Any delay of clinical trials, the repetition of one or more clinical trials, or any Regulatory Authority's need for additional data to support a combination biologic-device presentation could cause delays in approval of our product candidates, increase our costs, and could jeopardize our ability to commence sales and generate revenue.

If we fail to expand our development of GB-0895 into additional indications, or engineer and subsequently develop and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although we are initially focused on developing and commercializing GB-0895 for the treatment of severe asthma, we also plan to evaluate developing GB-0895 for the treatment of COPD, such evaluation to take into account expected clinical timelines, regulatory feedback, costs and the clinical data from our Phase 1b trial. Expansion into new indications will require additional, time-consuming development efforts and significant additional expense prior to commercial sale, including preclinical studies, clinical trials and approval by the Regulatory Authorities. In addition, we plan to focus on continuing to develop and commercialize GB-4362 and GB-5267. All product candidates are prone to the risks of failure that are inherent in biopharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, there can be no assurance that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, other Regulatory Authorities must also approve the manufacturing and marketing of the product candidate in non-U.S. jurisdictions. In order to eventually market any of our product candidates in any particular foreign jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve product testing and validation and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign regulatory approval could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

Our current and future clinical trials or those of our future collaborators may reveal significant adverse events or undesirable side effects not seen in our preclinical studies and may result in a safety profile that could halt clinical development, inhibit regulatory approval, limit commercial potential, or market acceptance of any of our product candidates.

There is typically an extremely high rate of attrition for product candidates across categories of medicines proceeding through clinical trials. These product candidates may fail to show the desired safety and efficacy or safety, purity and potency profile in later stages of clinical trials despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Undesirable side effects caused by our product candidates, whether used alone or in combination with other therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the Regulatory Authorities. We may observe unexpected and undesirable safety or tolerability issues with our product candidates in ongoing or future clinical trials. For example, GB-0895 is a biologic developed to be injected subcutaneously. There are risks inherent in subcutaneous injections, such as injection-site reactions (including redness, itching, swelling, pain and tenderness) and other side effects.

If significant adverse events or unacceptable side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting trial participants to any of our clinical trials, trial participants may withdraw from trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the Regulatory Authorities or an IRB, may impose a clinical hold, suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of any of our product candidates could result in harm to patients that are administered any of our product candidates. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, unfavorable benefit risk ratio may inhibit market acceptance of the approved product due to its tolerability versus other therapies. In addition, an extended half-life could prolong the duration of undesirable side effects, which could also inhibit market acceptance. Any of these developments could materially harm our business, financial condition and prospects.

Moreover, clinical trials are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

In addition, even if we successfully advance our product candidates or any future product candidates through clinical trials, such trials will only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate after approval. Further, any clinical trials may not be sufficient to determine the effect and safety consequences of using our product candidates over a multi-year period.

If any of the foregoing events occur or if one or more of our product candidates prove to be unsafe, our entire pipeline or our Generate Platform could be affected, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Even if we obtain regulatory approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Even if our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP, QMSR, as applicable, and GCP requirements for any clinical trials that we conduct post-approval. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may: issue a warning letter asserting that we are in violation of the law and potentially restricting our ability to sell, manufacture, import or export our products; seek an injunction or impose civil or criminal penalties or monetary fines; suspend or withdraw regulatory approval or revoke a license; suspend any ongoing clinical trials; refuse to approve a pending BLA or supplements to a BLA submitted by us; seize product; or refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved products and generate revenues.

If we are successful in gaining approval for any of our product candidates, we and our CDMOs, which manufacture our products under contract, will continue to face significant regulatory oversight of the manufacturing and distribution of our products. Product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the Regulatory Authorities for compliance with cGMP, QMSR, as applicable, and adherence to commitments made in the BLA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory

agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a Risk Evaluation and Mitigation Strategy ("REMS") as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Comparable requirements may apply in foreign countries. In addition, if the Regulatory Authorities approves any of our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information, reports and registration.

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

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary product recalls;
- fines, FDA Form 483s, warning letters or holds on clinical trials;
- refusal by Regulatory Authorities to approve pending applications or supplements to approved applications filed by us or suspension, variation or withdrawal of approvals;
- product seizure, detention or refusal to permit the import or export of our product candidates;
- total or partial suspension of production, distribution, manufacturing or clinical trials;
- operating restrictions;
- suspension of licenses; and
- injunctions, fines or the imposition of civil or criminal penalties.

Additionally, Regulatory Authorities strictly regulate marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label.

The policies of the Regulatory Authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to Regulatory Authorities' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays and/or changes. 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 marketing approval that we may have obtained and we may not achieve or sustain profitability.

We may develop certain of our product candidates in combination with other therapies or as add-ons to the standard of care. Developing combination treatments increases complexity and risk, including risks of drug-drug interactions, unforeseen side effects or failures in our clinical trials that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

We have activated clinical trial sites and expect to dose the first patient in mid-2026 as part of our Phase 1 clinical trial of GB-4362 in patients receiving enfortumab vedotin plus pembrolizumab to assess GB-4362's potential as an adjunct therapy for reduction in peripheral neuropathy, while preserving antibody-drug conjugate ("ADC") anti-tumor efficacy. The use of our product candidates in combination with each other and/or in patients already receiving other companies' treatments may subject us to risks that we would not face if our product candidates were to be administered as monotherapies.

For example, either the combination of our product candidates with each other, or when used in patients already receiving other companies' products or product candidates, may result in unexpected adverse side effects or toxicities that the product candidates or other therapy do not produce when used alone. In addition, the product candidates may interact with each other, or with other companies' products or product candidates that patients receiving our product candidates may also be receiving, in undesirable ways that could negatively impact the potency or efficacy and safety of our product candidates, or of the other companies' products or product candidates. Testing product candidates in patients already receiving other treatments may increase the risk of significant adverse effects or failed clinical trials. The timing, outcome and cost of the potential adverse effects of developing products to be used in patients already receiving other therapies is difficult to predict and dependent on a number of factors that are outside our reasonable control. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidates, or the result of drug-drug interactions between our product candidate and any of the concomitant therapies given to the trial subjects, we, the Regulatory Authorities, or IRBs and other reviewing entities, could interrupt, delay, or halt clinical trials and could result in a more restrictive label or particularly narrow product indication (substantially limiting the product's commercial opportunities), a REMS or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

In addition, to the extent we choose to develop and commercialize a product candidate for use in patients receiving an already approved therapy, as is the case with GB-4362, any safety, efficacy, regulatory, manufacturing or supply issues that could arise with respect to the approved therapy could have an adverse impact on us. Prescribing information for the approved therapy, such as risk information like a boxed warning, or limitations of use, could negatively impact our ability to develop and commercialize a product as an add-on or as further supportive care to the approved therapy. If the approved therapy is replaced as the standard of care, the Regulatory Authorities may require us to conduct additional clinical trials, or we may not be able to obtain adequate reimbursement from third-party payors. Further, the Regulatory Authorities could revoke approval of the therapy patients in our clinical trials are receiving. The occurrence of any of these risks could result in an add-on product candidate being developed as further supportive care, if successfully developed and approved, being removed from the market or being less successful commercially. If the Regulatory Authorities revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with respect to, therapies we choose to evaluate in conjunction with or as background or standard of care therapy for any of our product candidates, we may be unable to obtain regulatory approval of or to commercialize such product candidates in combination with these therapies. If we experience safety, tolerability or toxicity issues in any of our ongoing or planned clinical trials that allow patients to remain on other therapies, or if the efficacy data from these trials of our candidates administered to patients on other therapies are not favorable, our clinical development plans could be materially negatively affected or delayed, or we may not receive regulatory approval for our product candidates, which would materially harm our business and likely cause the market price of our common stock to decline.

In addition, because GB-4362 is expected to be administered in combination with other therapies, payors may assess the overall cost of the treatment regimen, not solely the cost or value proposition of our licensed product. Combination regimens are subject to heightened reimbursement risk, as payors may:

- decline to cover the full regimen based on the aggregated cost of the component therapies;
- require step-through use of lower-cost or single-agent treatments before approving the combination;
- assign the combination to a more restrictive formulary tier, resulting in higher patient cost-sharing or reduced utilization;
- impose prior authorization, clinical criteria or other restrictions that limit prescribing; or
- negotiate price concessions with us based on the cost structure or formulary status of the companion therapy.

Even if our product candidate demonstrates clinical benefit as part of a combination regimen, payors may determine that the incremental value is insufficient to justify the overall cost and may refuse to reimburse at levels that are acceptable to us or that support commercial viability. In addition, we do not control the pricing, contracting strategy or reimbursement profile of the companion therapy, which may change over time and adversely impact the attractiveness or economics of the combination. If coverage for the companion therapy is reduced, withdrawn, or made more restrictive, the value proposition for our product candidate could be materially weakened.

While we may in the future seek designations for our product candidates with the Regulatory Authorities that are intended to confer benefits such as a faster development process, a streamlined review or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The Regulatory Authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address serious conditions. These designations may confer benefits such as additional interaction with regulatory authorities, streamlined development pathways and expedited review procedures. We have received Fast Track Designation for GB-4362, an investigational MMAE neutralizer, and may seek Fast Track Designation for certain of our other product candidates. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. While we have received Fast Track Designation for GB-4362, there can be no assurance that we will successfully obtain such designations for our other or future product

candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even with such designation for GB-4362 and if we obtain such designations for our other or future product candidates, there can be no assurance that we will realize their intended benefits.

Fast Track Designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A BLA submitted for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. The FDA has broad discretion whether or not to grant this designation, so even if we believe one of our other or future product candidates is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even with Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind any Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

Even in the absence of obtaining certain designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate an application for priority review if the product is intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for acting on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

Where appropriate, we may secure approval from Regulatory Authorities through the use of expedited approval pathways, such as accelerated approval or comparable foreign abbreviated pathways. If we are unable to obtain such approvals, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or approval following comparable foreign abbreviated pathways by foreign Regulatory Authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or such Regulatory Authorities may seek to withdraw the accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our potential future product candidates from the Regulatory Authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send status updates on such studies to the FDA every 180 days to be publicly posted by the agency, or if such post-approval studies fail to verify the drug's predicted clinical benefit. The FDA is empowered to act, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

Prior to seeking accelerated approval, or approval following comparable foreign abbreviated pathways, we would seek feedback from the Regulatory Authorities and would otherwise evaluate our ability to seek and receive such accelerated approval or approval following comparable foreign abbreviated pathways. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent feedback from Regulatory Authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to apply for accelerated approval, or comparable foreign abbreviated pathways, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The Regulatory Authorities could also require us to conduct

further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway, or comparable foreign abbreviated pathway, and subsequently converted by the Regulatory Authorities to full approval. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Disruptions at the FDA and other government agencies caused by, funding shortages, staffing limitations, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, review, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other Regulatory Authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign Regulatory Authorities' ability to perform routine functions. Average review times at the FDA and foreign Regulatory Authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain Regulatory Authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations hinder or 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 such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to the Manufacturing of Our Product Candidates and Our Future Pipeline

We rely on third-parties for the supply and manufacture of our product candidates for our research, preclinical and clinical activities, and may do the same for commercial supplies of our products, if approved. As our pipeline increases and matures, the increased demand for supplies from our manufacturers may increase the risk that we will not have sufficient supply when needed or at an acceptable cost.

We currently utilize, and expect to continue to utilize, CDMOs to, among other things, supply and manufacture raw materials, components, parts and consumables, and to perform quality testing for our preclinical and clinical supply for all of our product candidates. For example, we are party to agreements with Lonza AG ("Lonza"), which is currently our sole provider of drug product for GB-0895, and WuXi Biologics (Cayman) Inc. ("WuXi"), which is currently our sole provider of drug product for GB-4362. In addition, given the specialized expertise required to manufacture CAR-T therapies, we intend to rely upon Roswell Park to manufacture GB-5267. In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our CDMOs will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates, as applicable. The transition to larger scale production could prove difficult. If our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality, then we may not be able to meet the demands of clinical trials or market demands, which could adversely impact our ability to timely conduct our clinical trials or commercialize our product candidates, if approved, and have a material adverse impact on our business and results of operations. Furthermore, with the increase of companies developing monoclonal antibodies and other therapeutic proteins, there may be increased competition for the supply of the raw materials that are necessary to make our monoclonal antibodies and therapeutic proteins, which could severely impact the manufacturing of our product candidates.

Even if we are able to maintain arrangements with our CDMOs, reliance on CDMOs entails additional risks, including:

- the failure of the CDMO to comply with applicable regulatory requirements and reliance on third-parties for manufacturing process development, regulatory compliance and quality assurance;
- manufacturing delays if our CDMOs give greater priority to the supply of other products over our product candidates or otherwise do not perform satisfactorily according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third-parties;
- the possible breach of manufacturing agreements by our CDMOs because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by our CDMOs, at a time that is costly or inconvenient to us; and

- the possible misappropriation of our proprietary technology and IP, including our know-how.

If we are unable to maintain our key manufacturing relationships, we may fail to find replacement CDMOs, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement CDMOs, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the Regulatory Authorities.

We do not currently have long-term supply contracts with all of our suppliers and they are not obligated to supply materials to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term master supply agreements with certain of our suppliers and manufacturers in the future as we advance our clinical trials or commercialization plans, we may not be successful in negotiating such agreements on favorable terms or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the materials that we are required to purchase.

Additionally, if CDMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CDMO. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to the original CDMO and we may have difficulty, or there may be contractual restrictions prohibiting us from transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CDMOs for any reason, we will be required to verify that the new CDMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to the specifications previously submitted to the Regulatory Authorities. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new CDMO could negatively affect our ability to develop or commercialize our product candidates in a timely manner or within budget. Furthermore, a CDMO may possess technology related to the manufacture of our product candidates that such third-party owns independently. This would increase our reliance on such CDMO or require us to obtain a license from such CDMO in order to have another third-party manufacture our product candidates.

If any of our product candidates are approved by any Regulatory Authority, we will likely utilize arrangements with CDMOs for the commercial production of such product. This process is difficult and time-consuming and we may face competition for access to manufacturing facilities as there are a limited number of CDMOs operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with CDMOs on satisfactory terms, which could delay our commercialization.

The operations of our suppliers and CDMOs, some of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects. As a result of our global suppliers, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and CDMOs' compliance with cGMPs or status acceptable to the Regulatory Authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional or local public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our CDMOs or suppliers are located.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, including China, with respect to trade policies, treaties, government regulations and tariffs. It is possible further tariffs may be imposed that could affect imports of active pharmaceutical ingredients ("APIs") used in our product candidates, or our business may be adversely impacted by retaliatory trade measures taken by China or other

countries, including restricted access to such raw materials used in our product candidates. Given the unpredictable regulatory environment in China and the United States and uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements and policies, further governmental action related to tariffs, additional taxes, contracting matters, regulatory changes or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business, financial condition, results of operations and growth prospects. These and other factors beyond our control could interrupt our suppliers and CDMOs' production, influence their ability to export and manufacture our clinical supplies, cost-effectively or at all, and inhibit their ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with our suppliers, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

We depend on sole source and limited source suppliers for certain raw materials, APIs, drug products, drug substances and other materials used in our product candidates. For example, we are party to agreements with WuXi, which is currently our sole provider of drug product for GB-4362, and Lonza, which is currently our sole provider of drug product for GB-0895. Any change in our relationships with such suppliers or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects. Moreover, there may be difficulties in scaling up the clinical or commercial quantities of our product candidates despite such agreements, and the costs of manufacturing could become prohibitive.

Furthermore, any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. In addition, geopolitical tensions may impact our suppliers. For example, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from "biotechnology companies of concern," or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from "biotechnology companies of concern." The BIOSECURE Act defines "biotechnology companies of concern" to include (i) entities on the U.S. Department of Defense's 1260H (the "DoD 1260H list") list of Chinese military companies operating in the United States and (ii) entities separately designated by OMB as subject to foreign adversary control and posing a national security risk based on factors including multiomic data collection. While the U.S. BIOSECURE Act provides a five-year grandfathering period (measured from the date the Federal Acquisition Regulation is revised with respect to a particular biotechnology company of concern), for certain contracts entered into before the applicable effective date, and including a provision protecting manufacturers' eligibility for federal drug rebate agreements under the Medicaid program from being precluded solely as a result of BIOSECURE-driven disruptions to Department of Veterans Affairs contracting, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain. This and similar laws could have the potential to restrict the ability of companies to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. It is possible some of our contractual counterparties, could be designated as biotechnology companies of concern in the future. While neither WuXi nor Lonza are currently on the DoD 1260H list or otherwise designated as a biotechnology company of concern at this time, either company could be impacted by such future legislation or government policies. If WuXi, Lonza or any of the other third-parties that we engage to supply any materials or manufacture products for our preclinical studies and clinical trials should cease to continue to do so, or if we are prevented or restricted from using their services for any reason, we could experience delays in advancing these studies and trials while we identify and qualify replacement suppliers.

Establishing additional or replacement suppliers, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of sole source or limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

The product candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of our CDMOs encounter such difficulties, our ability to supply material for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our product candidates are complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management or shipping. These difficulties could be due to any number of reasons, including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology and product instability. Moreover, we are currently conducting, and will in the future conduct, our clinical trials internationally. For example, we are currently enrolling patients in two global clinical trials for GB-0895 in patients with severe asthma, which are expected to include clinical trials across more

than 50 countries. Logistical issues associated with shipping our product candidates and other materials globally from manufacturing sites to clinical sites, such as errors or improper handling by third-party carriers, transportation restrictions, or interruptions caused by natural disasters or force majeure events, could result in loss or destruction of, or damage to, our clinical supply, which may in turn cause delays in initiating or completing clinical trials.

As our product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Our rate of innovation is high, which has caused, and will continue to cause, a high degree of technological change. As we scale the manufacturing output for particular product candidates, we plan to continuously improve yield, purity and the pharmaceutical properties of our product candidates from IND-enabling studies through commercial launch, including shelf-life stability, and solubility properties of product and drug substance. Because of continuous improvement in manufacturing processes, we may switch processes for a particular product candidate during development. However, after a change in process, additional time is required for pharmaceutical property testing, such as 6- or 12-month stability testing. Such testing may require resupplying clinical material, or making additional cGMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.

Such technological changes can negatively impact product comparability during and after clinical development. Furthermore, technological changes may drive the need for changes in, modification to or the sourcing of new manufacturing infrastructure or may adversely affect third-party relationships. Such technological changes also carry the risk that they will not achieve these intended objectives. Any of these technological changes could cause our product candidates to perform differently and affect the results of planned or future clinical trials conducted with the materials manufactured using altered processes, such as impacting the specification and stability of the product. For example, we intend to develop a biologic-device combination for administration of GB-0895 with an autoinjector and PFS for ease of administration. Such changes may also require additional testing, notification or approval by the Regulatory Authorities. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trials. Our product candidates may also prove to have a stability profile that leads to a lower than desired shelf life of the final approved product. This poses risk in supply requirements, wasted stock and higher cost of goods.

We have established a number of analytical assays, and may have to establish several more, to assess the quality of our product candidates. We may subsequently identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy or stability. This may lead to an inability to release product candidates until the manufacturing or testing process is rectified.

Moreover, there are risks inherent in biopharmaceutical manufacturing operations that could affect our ability and the ability of the CDMOs or contract manufacturing organizations to meet our delivery requirements or provide adequate amounts of material. The convergence of process and analytical technology, raw materials, consumables, equipment, physical infrastructure, including a clean room environment, and air handling and other utilities, results in complex procedures and systems that must work effectively to manufacture our product candidates. Failure or process defects in any of the interrelated systems at either our manufacturing facilities or those of our third-party providers could adversely impact our ability to manufacture and supply our product candidates.

Certain of our product candidates require specific shipping, storage, handling and administration, which in some cases, may require cold-chain logistics and subject our product candidates to risk of loss or damage if failures occur.

Certain of our product candidates are sensitive to temperature, storage and handling conditions. They must be stored at very low temperatures in specialized freezers or specialized shipping containers until immediately prior to use. The handling and administration of our product candidates may need to be performed according to specific instructions and in some steps within specific time periods. Failure to correctly handle our product candidates could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of product candidates. In addition, because it is necessary to ship our product candidates and other materials globally from manufacturing sites to clinical sites, our product candidates will need to be frozen using specialized equipment and maintained following specific procedures in order to be shipped and stored without damage in a cost-efficient manner and without degradation. For administration, the cryopreserved product container must be carefully removed from storage, and rapidly thawed under controlled temperature conditions in an area proximal to the patient's bedside and administered into the patient. The handling, thawing and administration of the cryopreserved therapy product must be performed according to specific instructions, typically using specific disposables, specific bags and in some steps within specific time periods. Failure to correctly handle our product candidates, including the potential breakage of the cryopreservation bags or to follow the instructions for thawing and administration and or failure to administer our product candidates within the specified period post-thaw could negatively impact the efficacy and/or safety of our product candidates, or cause a loss of our clinical supply.

If any of our product candidates are approved, we will need to scale-up a cost-effective and reliable cold-chain distribution and logistics network, which we may be unable to accomplish. Failure to effectively scale-up our cold-chain supply logistics, by us or third-parties, could in the future lead to additional manufacturing costs and delays in our ability to

supply required quantities for our commercial supply, if approved. For these and other reasons, we may not be able to manufacture our current or future product candidates at commercial scale or in a cost-effective manner. Even if we or our CDMOs are able to manufacture and distribute the products, if our products require specific procedures to maintain and use them, we may be limited in commercial opportunity.

We are subject to significant regulatory oversight with respect to manufacturing our product candidates. The manufacturing facilities of our CDMOs or suppliers may not meet regulatory requirements. Failure to meet cGMP requirements set forth in regulations promulgated by the Regulatory Authorities could result in significant delays in and costs of our products.

The manufacturing of therapeutics for clinical trials or commercial sale is subject to extensive regulation. Components of a finished product approved for commercial use or used in clinical trials must be manufactured in accordance with cGMP and QMSR, as applicable, requirements. These regulations govern manufacturing processes and procedures, including recordkeeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in clinical trials. Poor control of the cGMP and QMSR production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, which could be extensive.

Such production process issues include, but are not limited to: critical deviations in the manufacturing process; facility and equipment failures; contamination of the product due to an ineffective quality control strategy; facility contamination as assessed by the facility and utility environmental monitoring program; ineffective process, equipment or analytical change management, resulting in failed lot release criteria; raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers; ineffective product stability; failed lot release or facility and utility QC testing; ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and failed or defective components or consumables.

We must supply all necessary documentation in support of a BLA or other marketing authorization application on a timely basis and must adhere to the cGMP requirements of the Regulatory Authorities which are enforced, in the case of the FDA, in part through its facilities inspection program.

Regulatory authorities typically require representative manufacturing site inspections to assess adequate compliance with cGMPs and manufacturing controls as described in the filing. If either we or one of our third-party manufacturing sites fails to provide sufficient quality assurance or control, the product approval to commercialize may not be granted. Inspections by regulatory authorities may occur at any time during the development or commercialization phase of products. The inspections may be product specific or facility specific for broader cGMP inspections or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may influence the ability of our CDMOs or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying product candidates.

The manufacturing process for any products that we may develop is subject to the approval process of the Regulatory Authorities, and we will need to contract with CDMOs who we believe can meet such requirements on an ongoing basis. If we or our CDMOs are unable to reliably produce product candidates to specifications acceptable to the Regulatory Authorities, we or our collaboration partners may not obtain or maintain the approvals we or they need to commercialize such products. Even if we or our collaboration partners obtain regulatory approval for any of our product candidates, there is no assurance that either we or our contract manufacturing organizations will be able to manufacture the approved product to specifications acceptable to the Regulatory Authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods. The occurrence of any of the foregoing could have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have limited control over the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMPs. If our CDMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the Regulatory Authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have limited control over the ability of our CDMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our CDMOs are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our CDMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of our CDMOs' facility. Our failure, or the failure of our CDMOs, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates (including those of our collaboration partners) and our overall business operations. Our dependence upon others for the manufacture of our product candidates and raw materials 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 Regulatory Authorities may require us to submit product samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the Regulatory Authorities may

require that we do not distribute a lot or lots until the relevant agency authorizes such release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls with respect to products produced by either our own facilities or those of our CDMOs could cause us and our collaboration partners to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and operations, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. While we will train and qualify all personnel around the appropriate handling of our products and materials, we may not be able to control or ultimately detect intentional sabotage or negligence by any employee or contractor.

Risks Related to Our Reliance on Third-Parties

We rely on and expect to continue to rely on third-parties to conduct aspects of our research, preclinical studies, clinical protocol development and clinical trials for our programs and product candidates. If these third-parties do not perform satisfactorily, comply with regulatory requirements or meet expected deadlines, we may not be able to develop product candidates in a timely or cost-effective manner, or obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We currently rely and expect to continue to rely on third-parties, such as CROs clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials, including our Phase 3 clinical trials for GB-0895 in patients with severe asthma. We currently rely and expect to continue to rely on third-parties to conduct certain research and preclinical testing activities. In some cases, these third-parties may terminate their engagements with us. If we need to enter into alternative arrangements, it could delay our product development activities or increase our costs.

Our reliance on these third-parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory or contractual responsibilities. We will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, we will 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 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 also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs will be required to comply with regulations, including GCPs, for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial participants are adequately informed, among other things, of the potential risks of participating in clinical trials. We are also responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by the Regulatory Authorities for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the Regulatory Authorities may require us to perform additional clinical trials before approving our marketing applications. There is no assurance that the FDA or other Regulatory Authorities, upon inspection, will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements in cGMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we intend to design the clinical trials for certain of our product candidates, our collaboration partners may design the clinical trials that they are managing (in some cases, with our input) and in the case of clinical trials controlled by us, we expect that CROs will perform many of the activities required to conduct clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will, in many respects, be outside of our direct control. Our reliance on third-parties to conduct future preclinical studies and clinical trials will also result in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also potentially lead to mistakes as well as difficulties in coordinating activities. Outside parties may: have staffing difficulties; fail to comply with contractual obligations; experience regulatory compliance issues; undergo changes in priorities or become financially distressed; form relationships with other entities, some of which may be our competitors; have human errors or be subject to cyber-attacks.

These factors may materially adversely affect the willingness or ability of third-parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform preclinical studies and clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory

requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs, we could be required to repeat, extend the duration of or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

We also expect to rely on other third-parties to transport, store and distribute the required materials for our clinical trials. In the past, certain of our third-party vendors have mishandled our materials, resulting in loss of full or partial lots of material. Any further performance failure on the part of these third-parties could result in damaged products and could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue, causing us to default on our contractual commitments, result in losses that are not covered by insurance, and damage our reputation and overall perception of our products in the marketplace.

Any of the third-party organizations we utilize may terminate their engagements with us under certain circumstances. The replacement of an existing CRO or other third-party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates. For example, although we believe there are a number of other CROs we could engage, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, while we believe there may be suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition, results of operations and growth prospects.

We have in the past entered into, and in the future may enter into, partnership, collaboration and licensing arrangements with third-parties to support development of programs and product candidates. If these partnership, collaboration and licensing arrangements are not successful, our business could be adversely affected.

We have entered into or sought to enter into partnership, collaboration and licensing arrangements with third-parties, which we refer to generally as our “collaboration partners” for strategic purposes, including for purposes of collaborating with collaboration partners with distinctive capabilities or experience with different modalities, working with collaboration partners capable of advancing the development and commercialization of our product candidates, and providing access to additional capital.

For example, we are party to collaboration arrangements with Amgen, Novartis, MD Anderson and Roswell Park, pursuant to which we agreed to collaborate to discover and develop protein therapeutics. We expect to enter into additional partnership, collaboration and licensing arrangements to take advantage of our Generate Platform, including for purposes of accessing additional capabilities, expertise and funding in the future. Our existing partnership, collaboration and licensing arrangements, and any future partnership, collaboration and licensing arrangements we may enter into, could pose a number of risks, including the following:

- collaboration partners may not perform their obligations as expected;
- the clinical trials conducted as part of such partnership, collaboration and licensing arrangement may not be successful;
- collaboration partners may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the strategic collaborators’ focus or available funding, or external factors, such as an acquisition, which divert resources or create competing priorities;
- collaboration partners may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaboration partners could independently develop, or develop with third-parties, products that compete directly or indirectly with our product candidates if the strategic 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 developed in partnership, collaboration and licensing arrangements with us may be viewed by our collaboration partners as competitive with their own candidates or products, which may cause collaboration partners to cease to devote resources to the development of our programs or the development or commercialization of our product candidates;
- a collaboration partner 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 any such product;
- disagreements with collaboration partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for

us with respect to such product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaboration partners may not properly maintain or defend our IP 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;
- disputes may arise with respect to the interpretation of key terms regarding control, economic rights, or the ownership of intellectual property developed pursuant to our partnership, collaboration and licensing arrangements;
- collaboration partners may infringe the intellectual property rights of third-parties, which may expose us to litigation and potential liability;
- partnership, collaboration and licensing arrangements may, in certain instances, be terminated for the convenience of the collaboration partner and, if terminated, the development of our programs and product candidates may be delayed, or we may lose rights to IP or expertise related to such programs and products candidates, and we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- future relationships may require us to incur non-recurring and other charges, assume indebtedness or contingent liabilities, increase our near- and long-term expenditures, acquire intangible assets, issue securities that dilute our existing stockholders, disrupt our management and business, or otherwise impact our ability to generate revenue from acquired intellectual property, technology and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs;
- we could face significant competition in seeking appropriate collaboration partners and the negotiation process and diligence process is time-consuming and complex; and
- our international operations, through any future partnerships, collaborations, acquisitions or joint ventures, may expose us to certain operating, legal, and other risks not encountered in the United States.

Whether we reach a definitive agreement for a partnership, collaboration or licensing arrangement will depend, among other things, on our assessment of the collaboration partner's resources and expertise, the terms and conditions of the proposed partnership, collaboration or licensing arrangement, and the potential collaboration partner's evaluation of a number of factors. Those factors may include, among others: (i) our technologies and capabilities, including our Generate Platform; (ii) our intellectual property position with respect to the subject program or product candidate; (iii) the design or results of clinical trials; (iv) the likelihood of approval by the Regulatory Authorities; (v) the potential market for the subject product candidate; (vi) potential competing products; and (vii) industry and market conditions generally. In addition, the significant number of business combinations among large pharmaceutical and biotechnology companies has reduced the number of potential future collaboration partners with whom we can partner.

Partnership, collaborations and licensing arrangements are complex and time-consuming to negotiate and document. We may have to relinquish valuable rights to our programs and product candidates, intellectual property or future revenue streams, or grant licenses on terms that are not favorable to us or in instances where it would have been more advantageous for us to retain sole development and commercialization rights. For some programs and product candidates, we depend on collaboration partners to design and conduct the clinical trials. As a result, we may not control the manner or time schedule in which these clinical trials are conducted, which may negatively impact our business operations. In addition, if any of our collaboration partners withdraws support for one or more of our programs or product candidates or otherwise impairs their development, our business could be negatively affected. In addition, management of our relationships with collaboration partners requires (i) significant time and effort from our management team; (ii) coordination of our marketing and research and development programs with the marketing and research and development priorities of our collaborators and (iii) effective allocation of our resources across multiple projects.

Partnerships, collaborations and licensing arrangements may never result in the successful development of programs or development and commercialization of product candidates or the generation of sales revenue. The success of these arrangements will depend heavily on the efforts and activities of our collaboration partners. Collaboration partners generally have significant discretion in determining the efforts and resources that they will apply to the development of programs and the development and commercialization of product candidates, and they may not pursue or prioritize the development and commercialization of such programs and product candidates in a manner that is in our best interests. Product revenues arising from partnership, collaboration and licensing arrangements are likely to be lower than if we directly marketed and sold products. Disagreements with collaboration partners regarding clinical development or commercialization matters can lead to delays in the development process or commercialization of the applicable product candidate and, in some cases, the termination of the partnership, collaboration or licensing arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Partnership, collaboration and licensing arrangements are often terminable by the collaboration partner, and any such termination or expiration would adversely affect us financially and could harm our business reputation. If we were to become involved in arbitration or litigation with any of our collaboration partners, it would consume time and divert management resources away from operations, damage our reputation, impact our ability to enter into future partnership, collaboration and licensing arrangements and may further result in substantial payments from us to our collaboration partners to settle those disputes.

We may not be able to establish additional partnership, collaboration and licensing arrangements on a timely basis, on acceptable terms, or at all, and to maintain and successfully conclude them. Such arrangements with third-parties could cause us to expend significant resources and incur substantial business risk with no assurance of financial return. If we are unable to establish or maintain partnership, collaboration and licensing arrangements on terms favorable to us and realize the intended benefits of those arrangements, our research and development efforts and potential to generate revenue may be limited and our business and operating results could be materially and adversely impacted.

Given the nature of our relationships with our collaboration partners, we often do not fully control the progression, clinical development, regulatory strategy or eventual commercialization, if approved, of our jointly-developed product candidates. As a result, our future success and the potential to receive revenues under these partnership, collaboration and licensing arrangements are significantly dependent on our collaboration partners' efforts, over which we have little control. If our partnership, collaboration and licensing arrangements do not result in the successful development and commercialization of product candidates, a collaboration partner determines not to proceed with the future development of a program or product candidate initially engineered or developed utilizing our Generate Platform, a collaboration partner implements a clinical or regulatory strategy that ultimately does not enable the further development, approval or commercialization of the product candidate, or a collaboration partner terminates its arrangement with us, we may not receive any future research funding or milestone, earnout, royalty or other contingent payments under such arrangement, which may have a material and adverse effect on our business and revenues. In addition, our ability to monitor the achievement of clinical, regulatory and commercial milestones by our collaboration partners and enforce the payment of any corresponding fees is limited. If we do not receive the funding we expect under these agreements, the development of our and our other collaboration partners' product candidates could be delayed and we may need additional resources to develop such product candidates.

In addition, in certain instances, our collaboration partners have the right to terminate their agreement with us for convenience. If one of our collaboration partners terminates its arrangement with us, we may find it more difficult to attract new partnership, collaboration and licensing arrangements and the perception of us in the business and financial communities could be adversely affected. We cannot assure investors that we will be able to maintain or expand our existing collaboration partners or that our Generate Platform will achieve adequate market acceptance among new collaboration partners. Any failure to increase penetration in our existing markets or new markets would adversely affect our ability to improve our operating results from our collaboration, partnership and licensing strategy.

All of the risks relating to product development, regulatory approval and commercialization described in this Quarterly Report apply to the activities of our collaboration partners. If we and our collaboration partners do not receive regulatory approval for a sufficient number of product candidates originating from our Generate Platform, we may not be able sustain our business model.

We may seek to establish additional partnership, collaboration and licensing arrangements and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Certain of our partnership, collaboration and licensing arrangement may restrict our ability to develop certain products.

Our development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaboration partners. Whether we reach a definitive agreement for any additional partnership, collaboration and licensing arrangements will depend, among other things, upon our assessment of the collaboration partner's resources and expertise, the terms and conditions of the proposed partnership, collaboration or licensing arrangement and the proposed collaboration partner's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the Regulatory Authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to trial participants, the potential of competing drugs, 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 collaboration partner 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. The terms of any additional partnership, collaboration and licensing arrangements or other arrangements that we may establish may not be favorable to us.

We are also restricted under certain of our existing partnership, collaboration and licensing arrangement from entering into certain future agreements on certain terms with potential collaboration partners to pursue other targets on our own. These restrictions on working with targets could limit our ability to enter into partnership, collaboration and licensing arrangements with future collaboration partners or to pursue certain potentially valuable product candidates.

We may not be able to negotiate additional partnership, collaboration and licensing arrangements on a timely basis, on favorable terms or at all. Strategic alliances are complex and time-consuming to negotiate and document. If we are unable to negotiate and enter into new partnership, collaboration and licensing arrangements, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we

elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on favorable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Our revenue under our partnership, collaboration and licensing arrangements for any particular period, or on an absolute basis, can be difficult to forecast.

Because of the complexities and long development timelines inherent in the drug development business, it is difficult to predict the timing of payments under our partnership, collaboration and licensing arrangements. In particular, payments under our partnership, collaboration and licensing arrangements are, in some cases, subject to the achievement of milestones and royalties, and our collaboration partner's decisions to initiate or continue the drug creation work, and any future downstream payments with respect to product candidates generated using our Generate Platform will be subject to our collaboration partner's advancement of our programs and product candidates, over which we have no control. As a result, our revenue for any particular period can be difficult to forecast. Our revenue may grow at a slower rate than in past periods or even decline on a year-over-year basis. Because of these factors, our operating results could vary materially from quarter to quarter from our forecasts. Also, due to the limited probability of success for advancement of a program or product candidate by a collaboration partner at any given stage of development and the unpredictability of when a collaboration partner may choose to continue development of a product candidate and whether any payments will be due to us, our revenue may be difficult to forecast on an absolute basis.

Additionally, we recognize revenue either as we perform our development activities, upon completion of performing our development activities or upon achieving certain clinical, regulatory, and commercialization milestones. As a result, much of our revenue is generated from agreements entered into during previous periods. Consequently, a decline in demand for our Generate Platform, a decline in new or renewed business in any one quarter or any delays in the achievement, or any failure to achieve, development, regulatory and commercial milestones by our collaboration partners with respect to product candidates generated using our Generate Platform, may not significantly reduce our revenue for that quarter but could negatively affect our revenue in future quarters. Our revenue recognition model also makes it difficult for us to rapidly increase our revenue through increased operations in any period, as revenue from collaboration partners is recognized over the course of their drug development and commercialization efforts.

Our collaboration partners have significant discretion in determining when and whether to make announcements, if any, about the status of our collaborations, including about preclinical and clinical developments and timelines for advancing collaborations, and the price of our common stock may decline as a result of announcements of unexpected or negative results or developments.

Our collaboration partners have significant discretion in determining when and whether to make announcements about the status of our partnerships, including about preclinical and clinical developments and timelines for advancing product candidates generated using our Generate Platform. We do not generally plan to disclose the development status and progress of individual product candidates of our collaboration partners, unless those collaboration partners have publicly disclosed such information or permit us to make such disclosures. Our collaboration partners may wish to report such information more or less frequently than we expect, or they may not report such information at all, in which case we would not report that information either, unless material to our financial statements. Certain of our collaboration partners may in the future make statements about their goals and expectations for collaborations with us. The actual timing of these events can vary dramatically due to a number of factors such as delays or failures in our or our current and future collaboration partners' drug discovery and development programs, the amount of time, effort, and resources committed by us and our current and future collaboration partners, and the numerous uncertainties inherent in the development of drugs. In addition, if a collaboration partner chooses to announce a collaboration with us, there is no guarantee that we will receive payments related to collaboration revenue in that quarter or even the following quarter, as such payments are only payable to us in accordance with the terms of the agreements governing such collaborations. The price of our common stock may decline as a result of the public announcement of unexpected results or developments in our collaborations, or as a result of our collaboration partners withholding such information.

Risks Related to Our Intellectual Property

Our success is largely based upon our intellectual property and proprietary technologies, and we may be unable to adequately protect and/or enforce our intellectual property.

Our success depends, in large part, on our ability to obtain and maintain patents, trademarks, trade secrets, know-how and other intellectual property rights and proprietary technology relating to our Generate Platform and our product candidates, as well as our ability to successfully enforce our rights against third-party infringers and/or defend our intellectual property against third-party challenges or misappropriation. If we (or our licensees or licensors who may have the right to prosecute or enforce certain patents within our portfolio) fail to appropriately prosecute or are unable to obtain and maintain patent protection for our product candidates (or aspects thereof), our ability to develop, license and/or commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using, selling or importing competing products. This failure or inability to properly or adequately protect the intellectual property rights relating to these product candidates could have a material adverse effect on our business, financial condition, results of operations and/or growth prospects.

The use of AI to engineer proteins is a relatively new scientific field, the continued development and potential use of which has resulted in many different patents and patent applications from organizations and individuals seeking to obtain intellectual property protection in the field. In general, patents are reserved for human inventors and significant and novel regulatory questions remain in flux about the contributory roles of AI versus the human inventors in securing intellectual property rights. We have obtained grants and issuances of certain patents relating to our Generate Platform and some of our product candidates. The issued patents and pending patent applications that we own or in-license in the United States and in key markets around the world, claim different aspects relating to our product candidates and to the engineering, development, manufacture and commercialization of other potential product candidates including, but not limited to, compositions and methods of use.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining, maintaining, enforcing and defending patents. Patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims. These risks and uncertainties include the following:

- patent applications may not result in any patent being issued;
- patents that may be issued may not include claims that cover a broad enough scope to prevent alternative solutions by competitors;
- patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide adequate barriers to entry or any competitive advantage;
- because of the extensive time required for development, testing and regulatory review of a product candidate, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization thereby reducing, or eliminating any advantage of the patent;
- our competitors, many of which have substantially greater resources than we or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have sought or obtained, patents that will limit, interfere with or eliminate our ability to make, use and sell our product candidates;
- there may be significant pressure on the U.S. government and other governmental bodies to limit the scope of patent protection or impose compulsory licensing of patent rights for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have less robust patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products using our technologies and patents; and
- we may be involved in lawsuits and/or proceedings before government agencies, such as patent offices, to defend or enforce our patents or the patents we have rights to enforce, which could be expensive, time-consuming, distracting and/or unsuccessful.

In addition to patents, we also rely on proprietary source code, trade secrets and know-how. Although we have taken steps to protect our unpatented proprietary source code, trade secrets and know-how, including maintaining data security protocols and capabilities and entering into confidentiality agreements with third-parties, and confidential information and assignment agreements with employees, consultants and advisors, there exists the potential that third-parties may still somehow obtain this information or arrive at the same or similar information independently, which could reduce or eliminate our competitive advantages. Moreover, we may become subject to allegations that we directly or indirectly (through our consultants, advisors or independent contractors that we may engage to assist us in developing our product candidates) have wrongfully or inadvertently disclosed, acquired or used trade secrets or other proprietary information of third-parties.

We may be forced to litigate to enforce or defend our intellectual property rights.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets and know-how against unauthorized use, but we may not be able to detect or prevent, alone or with our licensors, infringement, misappropriation or other violation of our intellectual property rights. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable or limited or narrowed in scope such that we may no longer be able to adequately prevent the manufacture, sale or import of competitive product. In an infringement proceeding, a court may decide that a patent we own or a patent we may license in the future is invalid or unenforceable or may refuse to stop the other party from using the invention at issue. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Further, an adverse result in any litigation or other proceedings before government agencies such as the United States Patent and Trademark Office (the “USPTO”), may place pending applications at risk of non-issuance or limitations in scope. Further, derivation proceedings, *ex parte* reexamination, inter partes review, post grant review and opposition proceedings provoked by third-parties or brought by the USPTO or any foreign patent authority may be used to challenge the inventorship, ownership, claim scope or validity of our patents. Additionally, because of the substantial amount of discovery typically required in connection with intellectual property litigation, there is a risk that some of our confidential

and proprietary information, trade secrets or know-how could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the value of the company. Such litigation or proceedings could substantially increase our operating losses. reduce the resources available for development activities or any future sales, marketing or distribution activities and distract our personnel from their normal responsibilities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

The U.S. government and/or government agencies have provided funding or other assistance in connection with the development of the intellectual property rights owned by or licensed to us and if we enter into future arrangements involving government funding, and we make inventions as a result of such funding, our intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh Dole Act of 1980 (the "Bayh Dole Act").

The U.S. government and/or government agencies have provided funding or other assistance in connection with the development of the intellectual property rights owned by or licensed to us, and if we enter into future arrangements involving government funding, and we make inventions as a result of such funding, our intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh Dole Act. To the extent any of our current and future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh Dole Act may similarly apply. If we enter into future arrangements involving government funding, any exercise by the government of certain rights could harm our competitive position, business, financial condition, results of operations and growth prospects.

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 governmental purposes. In addition, the U.S. government would have the right to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third-party if the government 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, which are referred to as march-in rights. The U.S. government will also have the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, 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 U.S. 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 U.S. or that under the circumstances domestic manufacture is not commercially feasible.

If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages or be required to stop our product development and commercialization efforts.

Our commercial success depends in part on our ability and the ability of any of our future partners to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing on the intellectual proprietary rights of third-parties. There is a substantial amount of litigation and patent office proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology, biopharmaceutical, pharmaceutical and high-tech industries, including patent infringement lawsuits, oppositions, ex parte reexaminations, post-grant review, inter partes review and interference proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third-parties, exist in the fields in which we are pursuing product candidates.

Third-parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with that purport to claim compositions, formulations, methods of manufacture or methods for treatment relating to our product candidates, their manufacture or use. Because patent applications in most countries remain confidential for a period of time after they are filed (commonly, 18 months), it is possible that there are unpublished patent applications that may later issue with claims that our product candidates may be alleged to infringe. Because patent applications can take many years to issue, there may be pending patent applications which do not currently seem relevant, but may later result in issued patents that our product candidates may be alleged to infringe. In addition, third-parties may obtain patents in the future and then allege that our technologies infringe upon these patents. Additionally, under U.S. patent law, a patent owner may seek a reissue within two years of issuance of a patent to broaden the scope of that patent's claims. As a result, patents that, at the time of issuance, do not appear relevant to our activities may later be broadened in a manner that could impact our business. We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we or our licensors have identified or will identify each and every third-party patent and pending patent application in the U.S. and abroad that is relevant to or necessary for the development, manufacture, and

commercialization of our current and future products and product candidates in any jurisdiction. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending patent application will issue with claims of relevant scope. Alternatively, we may incorrectly determine that the Hatch-Waxman Amendments (as defined below) are a defense for a safe harbor to infringement of a patent we consider relevant to the research or clinical development of our product candidates. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop, manufacture and market our products and product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Defense of infringement and other claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

If a third-party alleges that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property allegations, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention and financial resources from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees (and, in certain jurisdictions outside of the U.S., we could be ordered to pay the patent owner's attorneys' fees even without such finding);
- a court prohibiting us from developing, manufacturing, importing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights to use, which it is not required to do;
- even if a license is available from a third-party, which may not be available, we may have to pay substantial royalties, upfront fees, milestones and other amounts and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

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

Our ability to commercialize our product candidates in the United States and abroad may be adversely affected if we cannot successfully defend against infringement allegations or obtain a license on commercially reasonable terms to relevant third-party patents that cover our product candidates. Even if we have a strong defense and/or believe that third-party intellectual property allegations are without merit, there can be no assurance that a court would find in our favor on questions of infringement, validity, *enforceability* and/or priority. A court of competent jurisdiction could hold that these third-party patents are valid and enforceable and have been infringed upon, which could materially and adversely affect our ability to commercialize our product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is high, which requires us to present clear and convincing evidence as to the invalidity of any such U.S. patent claims, there is no assurance that a court of competent jurisdiction would invalidate the asserted claims of any such U.S. patent.

If we are found to infringe a third-party's intellectual property rights, and we are unsuccessful in demonstrating that any such patents are invalid or unenforceable, we could be required to pay damages and/or an ongoing royalty or obtain a license from such third-party to continue developing, manufacturing, and marketing our product candidates and our technologies. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be non-exclusive, thereby giving our competitors and other third-parties access to the same technologies licensed to it, and it could require us to pay substantial licensing fees and/or make ongoing royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. We also could be temporarily or permanently forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed on a patent or other intellectual property right.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have acquired patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others.

We may not be successful in obtaining or maintaining necessary intellectual property rights to product components and manufacturing processes for our development pipeline.

At present, we have rights to certain intellectual property, through licenses from third-parties and under patent filings that we own to develop our product candidates. Because our pipeline may involve additional product candidates that could require the use of proprietary rights held by third-parties, the growth of our business could depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidates may require specific pharmaceutical formulations to work effectively and efficiently, and these rights may be held by others. We may be unable to acquire or in-license intellectual property rights that may be necessary to permit us to implement our platform technologies or develop, manufacture or use our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Further, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the third-party may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our product candidate and enabling our competitors to compete with our product candidate.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

Our rights to develop and commercialize our product candidates are, and in the future, may be subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third-parties, or these agreements are terminated, or we otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are dependent on patent rights, know-how and proprietary technology licensed or otherwise acquired from third parties, and we may also enter into additional agreements with third-parties in the future. Our current license agreements with third parties impose, and may in the future impose additional diligence, development and commercialization timelines, milestone payments, royalties, indemnification, insurance, non-competes or other obligations on us. If we fail to comply with our obligations to our licensors, collaborators or other third parties, our counterparties may have the right to terminate or take other actions under these agreements. Termination of these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology that are necessary for our business. In particular, we depend substantially on the Flagship Agreement, pursuant to which we in-license patent rights, know-how and other rights that cover, among other things, GB-0895 and certain aspects of our proprietary AI models. As described elsewhere in this prospectus, Flagship Pioneering may terminate the Flagship Agreement for cause under specified circumstances. In addition, under the Stock Purchase Agreement with PM LLC, we are subject to certain new diligence, non-compete and reporting obligations, including with respect to the development of product candidates in various countries. If we breach these obligations, PM LLC may have the right to acquire development and commercialization rights in the applicable country, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. For more information, please see Notes 14 and 15 in our unaudited condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

Our success will depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property. Further, certain patent filings relating to our product candidates may now or in the future be subject to step-in rights of certain of our licensors. We have limited control over certain of our licensors', and may in the future have limited control of our other licensors', prosecution activities or use or licensing of any other intellectual property that may be related to our in-licensed intellectual property. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue from these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. If any of our licensors or licensees having rights to file, prosecute, maintain and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors or other third-parties from making, using or selling competing products. In addition, we may sublicense certain of our rights under various third-party licenses to our collaboration partners. Any impairment of these sublicensed rights could result in reduced revenues under our partnership, collaboration or licensing arrangement or result in termination of an agreement by one or more of our collaboration partners. In addition, intellectual property rights that we may in-license in the future may be sublicensed under intellectual property owned by third-parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or

should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with our licensors, such licensors may have the right to control enforcement of our licensed patents or defense of any allegations asserting the invalidity of such patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors or, in some cases, other necessary parties, such as any co-owners of patents or other intellectual property from which we have not yet obtained a license. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such allegations to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of allegations asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after assuming control.

Our current or future license agreements may not provide exclusive or sufficient rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates in the future. Some licenses granted to us may be subject to certain preexisting rights held by the licensors or certain third-parties. As a result, we may not be able to prevent third-parties from developing and commercializing competitive products in certain territories or fields.

In the event that our third-party licensors or other counterparties determine that, in spite of our efforts, we have breached a license agreement or have failed to meet certain obligations thereunder, it may elect to terminate the applicable agreement or, in some cases, one or more licenses under such agreement or otherwise restrict our rights under the agreement. Such termination or restriction of rights could result in us losing the ability to develop and commercialize product candidates and technology covered by the licensed intellectual property. In the event of such termination, or if the underlying patent rights under a third-party in-license or other agreement fail to provide the intended exclusivity, third-parties may be able to seek regulatory approval of, and to market, products identical to ours and we may be required to cease the development and commercialization of our product candidates. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to allegations, regardless of their merit, that we are infringing or otherwise violating a licensor's rights. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, the agreements under which we license or otherwise acquire intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant patents, know-how and proprietary technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Disputes may also arise between us and our licensors or other counterparties regarding intellectual property subject to a license agreement, including: the scope of rights granted under the agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement; our right to sublicense patent and other rights to third-parties under collaborative development relationships; our diligence obligations with respect to the use of the licensed or otherwise acquired technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaboration partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

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

In addition to patent protection, we rely heavily upon proprietary source code and know-how protection and data security protocols and capabilities, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third-parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, CDMOs, consultants, advisors and other third-parties to execute confidentiality agreements upon the commencement of employment, consulting or business relationships with us. These agreements generally provide that all confidential information concerning our business or financial affairs developed by or made known to an individual or entity during the course of that party's

relationship with us are to be kept confidential and not disclosed to third-parties, except in certain specified circumstances. In the case of employees, the agreements also provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In the case of consultants and other third-party service providers, the agreements provide us with certain rights to all inventions arising from the services provided to us by those individuals or entities. However, we cannot guarantee that we have entered into agreements with each party that may have or have had access to our proprietary technologies and processes. Additionally, the assignment of intellectual property rights may not be self-executing, or assignment agreements may be breached, and we may be forced to bring claims against third-parties, or defend allegations that they may bring against us, to determine the ownership of what we regard as our intellectual property. We may not be able to obtain adequate remedies for any breaches of such agreements. Ultimately, enforcing a claim that a party wrongfully or illegally disclosed or misappropriated trade secrets or know-how can be difficult, expensive and time consuming, and the outcome is unpredictable.

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

Certain former employees have obtained employment with companies or academic institutions that could be considered competitive with us and are operating their business in areas that are similar to ours, including in their business model, product design efforts, product development or formulation technology. This competition may be limited by contractual provisions which may or may not be enforceable by us in the Commonwealth of Massachusetts or other jurisdictions. In addition, we may not be aware of such competitive employment arrangements until after our trade secrets or know-how has been disclosed to potentially competitive companies.

If we choose to go to court to stop a third-party from using any of our trade secrets or know-how, we may incur substantial costs. In addition, courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets or know-how. Even if we are successful, these types of lawsuits may consume, in addition to substantial costs, significant amounts of our time and other resources. We may also need to share our proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may be subject to allegations that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third-parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology industry, we employ individuals, including certain of our key employees, who are or were previously employed at academic institutions or other biotechnology companies, including our competitors or potential competitors. For example, our co-founder, Dr. Gevorg Grigoryan, Ph.D., has held various positions at Dartmouth College since 2017. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to allegations that we, or our employees, consultants or independent contractors, have inadvertently or otherwise used or disclosed intellectual property, including trade secrets, know-how or other proprietary information, of any of our employees' former employers or other third-parties. Litigation may be necessary to defend against these allegations. If we fail in defending any such allegations, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such allegations, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to allegations challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to allegations that former employees, collaborators or other third-parties have an ownership interest in our patents or other intellectual property. Ownership disputes may arise, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other allegations challenging inventorship or ownership. If we fail in defending any such allegations, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse impact on our business. Even if we are

successful in defending against such allegations, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third-parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 or applications will be due to be paid to the USPTO and various non-U.S. patent agencies in several stages over the lifetime of the patents or applications. The USPTO and non-U.S. patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. 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 impact on our business.

In addition, public health pandemics, geopolitical instability, natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for our product candidates. There could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the U.S., China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some, but not all cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may also be dependent on our licensors to take the necessary actions to comply with these requirements with respect to our licensed intellectual property.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court.

If we or one of our collaboration partners were to initiate legal proceedings against a third-party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent subject matter eligibility, novelty, non-obviousness, written description and/or enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third-parties may also raise similar allegations before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include ex parte reexamination, inter partes review, post grant review, interference proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of patent rights covering a product candidate, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1).

If we do not obtain sufficient patent term for our product candidates, our business may be materially harmed.

Patents have a limited term. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from the earliest non provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and also depends upon many factors, including the type of patent, the scope of coverage, the availability of regulatory related extensions, the availability of extensions for patent office delays during the examination process, the availability of legal remedies in a particular country and the validity and enforceability of the patent, and whether a portion of the patent term has been terminally disclaimed based on other patents. These factors may emerge and change over the course of time, and accordingly, a patent's expiration date might change over time in unpredictable ways. Various extensions including patent term extension and patent term adjustment may be available, but the lives of such extensions, and the protections they afford, are limited in the United States and other countries and regions. Additional patent terms may be available through a patent term adjustment process in the United States, resulting from USPTO delays during prosecution. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from generics or biosimilars.

Depending upon the timing, duration and specifics of FDA regulatory approval of our product candidates, one or more patents issued from U.S. patent applications that we or a future licensor file may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug or biologic. A maximum of one patent may be extended per FDA-approved drug as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates.

Despite the possibility of an extension, we may not be granted an extension in the United States or another jurisdiction because of, for example, failure to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time or the scope of patent protection afforded could be less than we request.

For biologics, separate non-patent exclusivity under the BPCIA may apply. The FDA cannot make approval of a biosimilar effective until 12 years after the reference product's first licensure, but policy changes could affect the scope or duration of this exclusivity, and competitors may nonetheless pursue full BLAs. As a result, even with patents and any extensions, competition from biosimilars or other biologics could occur earlier than anticipated.

If we are unable to obtain patent term extension or restoration, or the foreign equivalent, or the term of any such extension is less than we request, our competitors or other third-parties may obtain approval of competing drugs following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors or other third-parties may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their drug earlier than might otherwise be the case. Any of the foregoing could materially harm our business, financial condition, results of operations and growth prospects.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies and innovations 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, but enforcement rights are not as strong as those in the U.S. or Europe. These products may compete with our product candidates, and our and our licensors' future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the U.S., but may issue as patents with claims of different scope or may even be refused in other jurisdictions. Furthermore, the requirements for patentability differ in certain jurisdictions and countries. Some countries do not grant claims directed to methods of treatment or have additional restrictions on the scope of method of treatment claims compared to the U.S. Accordingly, depending on the country, the scope of patent protection may vary for the same product candidate.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain protection efforts in all such markets. Additionally, the prosecution of patent applications in other jurisdictions is often a longer process and patents may be granted at a later date than in the U.S., potentially delaying our ability to assert such patents against competitors. Accordingly, our efforts to protect our intellectual property rights in such

countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the U.S. and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property rights, which could make it difficult for us to stop the infringement of any patents we obtain or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we obtain at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third-parties to legal claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third-parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third-parties with respect to any patents relevant to our business, our competitive position may be impaired.

In Europe, a new unitary patent system took effect on June 1, 2023, which may significantly impact European patents, including those granted before the introduction of the new system. Under the new system, applicants can, upon grant of a European patent, opt for that patent to become a unitary patent which will be subject to the jurisdiction of a new unitary patent court (“UPC”). During the first seven years of the UPC’s existence, patents granted before the implementation of the new system can be opted out of UPC jurisdiction, and validated as national patents in any one or more of the UPC countries. We may decide to opt out future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. Patents that are under the jurisdiction of the UPC may be challenged in a single UPC-based revocation proceeding that, if successful, could invalidate the patent in all countries who are signatories to the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Further, because the UPC is a new court system and there is no precedent for the court’s laws, there is increased uncertainty regarding the outcome of any patent litigation. We are unable to predict what impact the new patent regime may have on our ability to exclude competitors in the European market. In addition to changes in patents laws, geopolitical dynamics, such as the conflict between Russia and Ukraine, may also impact our ability to obtain and enforce patents in particular jurisdictions, such as the enforcement of patent rights in Russia. If we are unable to obtain and enforce patents as needed in particular markets, our ability to exclude competitors in those markets may be reduced.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biotechnology industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and in other major jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent rulings from the U.S. Supreme Court and the Court of Appeals for the Federal Circuit have narrowed the scope of patent protection available in specified circumstances and weakened the rights of patent owners in specified situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, 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. In addition, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of issued patents. Depending on future actions by the U.S. Congress, federal courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors’ ability to obtain new patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the federal courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the

patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

The USPTO has issued subject matter eligibility guidance instructing USPTO examiners on the ramifications of the Supreme Court rulings in Mayo Collaborative Services v. Prometheus Laboratories, Inc. and Association for Molecular Pathology v. Myriad Genetics, Inc., and applied the Myriad ruling to natural products and principles including all naturally occurring molecules. In addition, the USPTO continues to provide updates to its guidance that may make it impossible for us to obtain similar patent claims in future patent applications. Currently, our patent portfolio contains claims of various types and scope, including methods of medical treatment. The presence of varying types of claims in our patent portfolio significantly reduces, but may not eliminate, our exposure to potential validity challenges alleging a lack of subject matter eligibility. Furthermore, U.S. Court of Appeals for the Federal Circuit has held that an inventor on a U.S. patent must be a natural person and not a machine or AI. As a result, AI systems, regardless of their sophistication, cannot be named as inventors or joint inventors on a patent application as they are not natural persons. The USPTO has recently issued inventorship guidance for AI-assisted inventions. Given that we use AI in certain aspects of our Generate Platform, certain AI-assisted inventions may be deemed ineligible for patent protection if it is determined that there is not a sufficient level of human inventive contribution.

For our U.S. patent applications, which contain claims entitled to priority date after March 16, 2013, there is a greater level of uncertainty due to the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), which was signed into law on September 16, 2011. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These included provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. The USPTO has promulgated regulations and developed procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act did not come into effect until March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

An important change introduced by the Leahy-Smith Act is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This requires us to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either: (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among some of the other changes introduced by the Leahy-Smith Act are changes that limit where a patentee may file a patent infringement suit and new procedures providing opportunities for third-parties to challenge any issued patent in the USPTO. These new post grant challenges include post grant review and inter partes review proceedings before the Patent Trial and Appeal Board at the USPTO. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third-party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third-party may attempt to use the USPTO procedures to invalidate patent claims that would not have been invalidated if first challenged by the third-party as a defendant in a district court action. However, recent changes at the USPTO have resulted in many fewer inter partes review proceedings being instituted, and the USPTO has proposed modifications to the rules of practice for implementing inter partes review proceedings. The proposed modifications, if adopted, could impact the ability of third-parties, including us, to challenge the validity of granted U.S. patents before the USPTO.

Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of patent applications and the maintenance, enforcement or defense of issued patents. For example, the United States and foreign government actions related to the conflict between Russia and Ukraine resulted in Russia issuing Decree No. 299 that effectively nullifies the enforcement of Russian patents owned by entities and individuals in “unfriendly” countries, including the U.S.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated or successfully challenged. If our trademarks and trade names are not adequately protected, or if we are unable to obtain desired trademarks or trade names, then we may not be able to build brand name recognition in our markets of interest and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish our product candidates, if approved for marketing, from third-party products. Once we select new trademarks and apply to register them, our trademark applications may not be

approved. During trademark registration proceedings in the U.S. and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections.

We have also not yet registered trademarks for any of our product candidates in any jurisdiction. Any trademark applications we file may be rejected and registered trademarks may not be obtained, maintained or enforced. If we do not successfully register our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our trademark rights against third-parties, which could adversely affect our business and our ability to effectively compete in the marketplace.

In addition, any proprietary name we propose to use with any of our product candidate in the U.S. will need to be approved by the FDA, regardless of whether we have registered, or applied to register, the proposed proprietary name as a trademark. The FDA conducts a review of proposed proprietary names, including an evaluation of potential for confusion with other products' proprietary names, as part of the BLA review process. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary name that would qualify under applicable trademark laws, not infringe the existing rights of third-parties and be acceptable to the FDA.

In addition, our unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic, or determined to be infringing on, misappropriating or violating other marks. In the USPTO and in comparable agencies in many foreign jurisdictions, third-parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademark registrations may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion.

Our competitors may also infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. We may not be able to protect our rights to our trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. Any of the foregoing events may have a material adverse effect on our business.

Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement allegation asserted by the owner of a senior trademark. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain names or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit it to maintain our competitive advantage. For example:

- our product candidates, if approved, may eventually become commercially available in generic or biosimilar product forms;
- others may be able to make similar molecules to our product candidates that are not covered by the claims of the patents that we license or own now or in the future;
- we, or current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions, potentially resulting in the invalidation of such patents or refusal of such applications;
- we, or current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or own now or in the future.
- we, or current or future licensors or collaborators, may fail to meet our obligations to the U.S. government regarding any patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing on our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own or license in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our patents;

- it is possible that there are unpublished patent applications that may later issue with claims covering our product candidates or technology similar to ours;
- it is possible that our patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable or result in a change in ownership;
- issued patents to which we hold rights may be held invalid, unenforceable or narrowed in scope, including as a result of legal challenges;
- the claims of our issued patents or patent applications, if and when issued, may not cover our product candidates or narrowly cover them in such a way that competitors may be able to design around to avoid infringement allegations;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of current or future licensors or collaborators to the same extent as the laws of the United States;
- the inventors of our patents or patent applications may become involved with competitors, develop products or processes that are similar to or alternative to those claimed in our patent filings or become hostile to our patents or patent applications on which they are named as inventors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we have engaged in scientific collaborations in the past and we intend to continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- the product candidates we develop may be covered by third-party patents or other intellectual property rights;
- the patents of others may prohibit or otherwise harm our ability to conduct our business; or
- we may choose not to file a patent in order to maintain certain know-how, and a third-party may subsequently commercialize the technology and/or file a patent covering such intellectual property.
- Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to the Commercialization of Our Pipeline

We have no sales, distribution or marketing experience, and may invest significant financial and management resources to establish these capabilities. If we are unable to establish such capabilities or enter into agreements with third-parties to market and sell our future products, if approved, we may be unable to generate any revenues.

Given our stage of development as a company, we have no sales, distribution or marketing experience. To successfully commercialize any products that may result from our programs, we will need to develop sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of these product candidates. Any failure or delay in the development of our or third-parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates.

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

- inadequate funding;
- our inability to recruit and retain an adequate number of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade an adequate number of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We may enter into partnership, collaboration and licensing arrangements with third-parties to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If these third-parties do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product revenue to sustain

our business. We may be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third-party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

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

The biopharmaceutical market is intensely competitive. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we may be unable to successfully commercialize any drugs that we develop.

The biopharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations, known and unknown, are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- greater financial, technical and human resources than we have at every stage of the engineering, development, manufacture and commercialization of products;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals and in manufacturing, marketing and selling products;
- product candidates that are based on previously tested or accepted technologies;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Accordingly, our competitors may be more successful than us in obtaining patent protection, regulatory exclusivities or FDA approval and commercialize products or achieve widespread market acceptance more rapidly than we do, which may impact future approvals or sales of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of our product candidates, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities and patent position. Our profitability and financial position will suffer if our product candidates receives regulatory approval but cannot compete effectively in the marketplace.

In addition, our competitors may develop partnership, collaboration and licensing arrangements with or receive funding from larger pharmaceutical or biotechnology companies, providing them with an advantage over us. Our competitors may also succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than our product candidates, which could render our product candidates obsolete and noncompetitive. Our competitors may therefore be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our products, if approved.

We expect to face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop products. We also expect to face competition from new drugs that enter the market. There are a number of drugs currently under development, which may become commercially available in the future, for the treatment of the conditions for which we are trying, or may in the future try, to develop products. These drugs may be more effective, safer, less expensive or marketed and sold more effectively, than any products we develop. In most cases, we do not currently plan to run head-to-head clinical trials evaluating our product candidates against the current standards of care, which may make it more challenging for our product candidates to compete against the current standards of care due to the lack of head-to-head clinical trial data.

If we successfully develop any product candidates, and obtain approval for them, we expect to face competition based on many different factors, including: the safety and effectiveness of our products relative to alternative therapies, if any; the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration; the timing and scope of regulatory approvals for these product candidates; the availability and cost of manufacturing, marketing and sales capabilities; the price of any approved product; reimbursement coverage; and patent position.

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 and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our product candidates.

The commercial success of any current or future product candidate, if approved, will depend upon the degree of market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals, the commercial success of our products will depend in part on the medical community, patients and third-party or governmental payors, and our products in particular, as medically useful, cost-effective and safe. Furthermore, ethical, social and legal concerns about the application of AI to research and development of products could result in additional regulations restricting access to or otherwise limit demand for our products. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including: the potential efficacy and potential advantages over alternative treatments; the ability to offer our products, if approved, at competitive prices; the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling; the prevalence and severity of any side effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered; relative convenience and ease of administration; any restrictions on the use of our products, if approved, together with other medications; the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; the strength of marketing and distribution support and timing of market introduction of competitive products; publicity concerning our products or competing products and treatments; and sufficient third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors due to the complexity and uniqueness of our product candidates.

Even if we are successful in getting marketing approval for any product, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs and entry into managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products once approved, whether due to healthcare reform legislation or otherwise, market acceptance and commercial success would be reduced.

In addition, if any of our products are approved for marketing, we or a collaboration partner will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports for such product, and will need to continue to comply (or ensure that our third-party providers comply) with current cGMP and GCPs for any clinical trials that we or a collaboration partner conduct post-approval. In addition, there is always the risk that we or a collaboration partner or regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any such failure to comply or other issues with our product candidates identified post-approval could have a material adverse impact on our business, financial condition and results of operations.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets for which we may rely on collaboration with third-parties. Recent and ongoing changes in the United States trade policy with foreign countries, including the continued uncertainty surrounding U.S. tariffs and potential retaliatory measures by foreign governments may disrupt the global supply chain for biopharmaceutical products. For example, in September 2025, President Trump announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity. It is not yet clear whether these tariffs would apply to the importation of APIs and possibly bulk drug products that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. Any direct tariffs, if imposed on pharmaceutical products, may result in increased costs for raw materials and contract manufacturing services, reduced ability to source critical contract manufacturing organizations, and a delay in our development timelines.

We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable foreign regulatory authority and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately

commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

We are subject to export and import controls, economic sanctions and anti-corruption laws and regulations of the United States and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which can harm our business.

Because we plan to market our products, if approved, outside of the United States, our business is subject to risks associated with doing business outside of the United States including, an increase in our expenses, diversion of our management's attention from the acquisition or development of product candidates or forgoing profitable licensing opportunities in these geographies. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: efforts to develop an international sales, marketing and distribution organization; changes in a specific country's or region's political and cultural climate or economic condition; unexpected changes in foreign laws and regulatory requirements; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in foreign countries; trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties or suspension or revocation of export privileges; the effects of applicable foreign tax structures and potentially adverse tax consequences; and significant adverse changes in foreign currency exchange rates.

In addition to FDA and related regulatory requirements in the United States and abroad, we are subject to extensive additional federal, state and foreign anti-bribery regulations, which include the U.S. Foreign Corrupt Practices Act, U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the UK Bribery Act 2010 and similar laws in other countries outside of the United States. We are developing and implementing a corporate compliance program based on what we believe are current best practices in the biotechnology industry for companies similar to ours, but we cannot guarantee that we, our employees, our consultants or our third-party contractors are or will be in compliance with all federal, state and foreign regulations regarding bribery and corruption. Moreover, our collaboration partners and third-party contractors located outside the United States may have inadequate compliance programs or may fail to respect the laws and guidance of the territories in which they operate. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition and results of operations.

The insurance coverage and reimbursement status of newly approved products, in a new category of medicines, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments such as the products that we hope to develop and sell. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment in any of our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational. For example, GB-4362, for which an IND was cleared by the FDA in December 2025, is currently being considered as a potential supportive care treatment to ameliorate important and deleterious side effects of certain cancer treatments, and third-party payors have been known to closely scrutinize the value proposition offered by supportive care treatments.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. The Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"), determines whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for products.

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. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for our product candidates that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many biopharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases

when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Outside the United States, certain countries, including a number of member states of the European Union (the "Member States"), set prices and reimbursement for pharmaceutical products, or medicinal products, as they are commonly referred to in the European Union, with limited participation from the marketing authorization holders. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaboration partners. If the regulatory authorities in these foreign jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaboration partners, our revenues from sales by us or our collaboration partners and the potential profitability of our products in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world but have been most drastic in the European Union.

Additionally, the requirements governing product pricing vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed, while in others, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for our product candidates. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates.

We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

The containment of healthcare costs has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products.

For example, the Inflation Reduction Act of 2022 (the "IRA") includes several provisions that will impact our business to varying degrees, including provisions that allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, among others.

Further, the IRA also imposed rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenue generated from the sale of any approved products.

The One Big Beautiful Bill Act (the "OBBBA") also included significant reforms to Medicaid, including an estimated $1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our business is currently unknown, any decrease in the number of insured patients or reimbursement levels for our products could adversely affect our revenue and commercial prospects.

In May 2025, the U.S. President signed Executive Order 14297, titled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," directing the Department of Health and Human Services to establish "most-favored-nation" ("MFN") drug price targets benchmarked to the lowest price paid for a branded drug in any Organization for Economic Co-operation and Development member country with per-capita gross domestic product at least 60% of U.S. per-capita gross domestic product. Since the issuance of Executive Order 14297, the U.S. government has entered into voluntary agreements with a growing number of pharmaceutical manufacturers (16 as of early 2026) under which participating manufacturers have agreed, among other things, to make MFN prices available to state Medicaid programs, launch certain new products at or near MFN prices, and sell directly to consumers through the TrumpRx.gov direct-to-consumer platform that launched in January 2026, generally in exchange for a three-year deferral of Section 232 pharmaceutical tariffs imposed on drug imports. In addition, in late 2025, CMS proposed two Medicare rebate models (GLOBE for Medicare Part B drugs and GUARD for Medicare Part D drugs) that would incorporate international price benchmarks into rebate calculation methodologies on a trial basis, and announced the GENEROUS model, under which participating manufacturers would offer MFN-aligned supplemental rebates to state Medicaid programs. The scope, duration, and enforceability of these MFN initiatives remain uncertain, as does the extent to which any future administration may expand, modify, or rescind them or seek legislative codification. If we receive marketing approval for any of our product candidates, we may face pressure through voluntary manufacturer agreements, administrative rulemaking, Section 232 tariff leverage, direct-to-consumer distribution platforms, or future legislative codification to offer our products at prices materially below those we might otherwise realize, which could adversely affect our revenues and the commercial prospects of our products.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

In December 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and became applicable in January 2025, is intended to boost cooperation among Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit Member States to use common HTA tools, methodologies and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual Member States will continue to be responsible for assessing nonclinical (e.g., economic, social, ethical) aspects of health technologies and making decisions on pricing and reimbursement.

These laws, and future supranational, national state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

If the market opportunities for our product candidates are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.

The estimates of market opportunity and forecasts of market growth included in documents that we file with the SEC may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Although we are initially focused on developing and commercializing GB-0895 for the treatment of severe asthma, we also plan to evaluate developing GB-0895 for the treatment of COPD, such evaluation to take into account expected clinical timelines, regulatory feedback, costs and the clinical data from our Phase 1b trial. In addition, an important area of focus of our research and product development activities is the development of treatments for severe rare genetic diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates and independent market research, industry and general publications obtained from third-parties. Market opportunity estimates and growth forecasts included in this Quarterly Report and the other documents that we file with the SEC are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. Additionally, the potentially addressable patient population may not ultimately be amenable to treatment with our product candidate if we cannot achieve our intended dosing interval. Our market opportunity may also be limited by current and future

products of our competitors that are already available in the market or may enter the market for such patients. If any of our estimates prove to be inaccurate, the market opportunity for our product candidates could be significantly diminished and have an adverse material impact on our business.

The market opportunities of some of our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and for which the market opportunities may be small.

In some therapeutic areas, like oncology, the FDA often approves new therapies initially only for use by patients with relapsed or refractory advanced disease. For example, we are developing GB-5267 in collaboration with Roswell Park and plan to conduct a Phase 1 clinical trial in patients with relapsed or refractory platinum-resistant ovarian cancer in 2026. In the event GB-5267 proves to be sufficiently beneficial we would expect that approval could be sought in earlier lines of treatment and potentially as a first line therapy but there is no guarantee that GB-5267 or any other product candidates targeting relapsed or refractory diseases, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

In addition, our projections of both the number of people who have platinum-resistant ovarian cancer or other cancers we may be targeting, as well as the subset of people with these cancers in a position to receive second- or third-line therapy, and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of trial participants may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our products, if approved, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Off-label use or misuse of our product candidates may harm our reputation in the marketplace or result in injuries that lead to costly product liability suits.

If our product candidates are approved by the FDA, we will only promote or market them in a manner consistent with their approved labeling. We will train our marketing and sales force to comply with laws and regulations restricting the promotion of our product candidates for uses outside of the indications for use approved by the Regulatory Authorities, known as “off-label uses.” Physicians are permitted to prescribe medications for off-label conditions and indications not listed on these approved labels. Furthermore, the use of our product candidates for indications other than those approved by the FDA may not effectively treat such conditions. The FDA’s Office of Prescription Drug Promotion (“OPDP”) actively scrutinizes promotional communications, including digital and social media; any materials that are false, misleading or promote unapproved uses can lead to enforcement actions and could necessitate corrective communications. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation. Similar requirements and considerations apply abroad.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, and false claims laws. If we are unable to comply, or have not fully complied with such laws, we could face substantial penalties.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations that will impact, among other things, our proposed sales, marketing, and educational programs. The laws that will affect our operations include, but are not limited to the following:

- The federal Health Care Program Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.
- The federal civil and criminal false claims laws and civil monetary penalty laws prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- The FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices.
- Federal transparency laws, including the federal Physician Payment Sunshine Act, which require disclosure of payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.
- Federal government price reporting laws, which require drug makers to calculate and report complex pricing metrics in an accurate and timely manner to government programs.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- State law equivalents of each of the above federal laws and state 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 are also applicable to us and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities, including certain consulting agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options could be subject to challenge under one or more such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, mandatory or discretionary exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

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

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

We face an inherent risk of product liability exposure related to the testing of any of our current or future product candidates in clinical trials, and we may face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against allegations that our product candidates caused injuries, or we failed to warn of potential injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, allegations of liability may result in decreased demand for any product candidate that we may develop; loss of revenue; substantial monetary awards to patients, healthy volunteers or their children; significant time and costs to defend the related litigation; withdrawal of clinical trial participants; the inability to commercialize any product candidate(s) that we may develop; and injury to our reputation and significant negative media attention.

We carry product liability insurance which we believe to be sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Risks Related to Our Business Operations and Employee Matters

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

Our ability to compete in the highly competitive biotechnology industry depends upon our ability to attract and retain highly qualified managerial, scientific, technical and medical personnel. We are highly dependent upon members of our management, as well as technology and scientific teams, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the development of our Generate Platform and our pipeline. Each of the members of our management team, and all of our employees, including key technical personnel, scientists and clinicians, are employed "at will," meaning we or each officer or employee may terminate the employment relationship at any time. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We currently do not have "key person" insurance on any of our employees. Many of our key employees, including members of our leadership team, have been with us for an several years, and have a significant amount of fully vested stock options or other long-term equity incentives which may become valuable and will be publicly tradable if we become a public company. We may not be able to retain these employees due to the competitive environment in the biotechnology industry, particularly in the greater Boston, Massachusetts region.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory approval 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. The loss of the services of one or more of our current employees or advisors might impede the achievement of our research, development, regulatory approval and commercialization objectives. In addition, we have flexibly added capability and capacity through the use of contractors. We may not be able to retain the services of such personnel, which might result in delays in the operation of our business.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel, including in AI, research, clinical operations, regulatory affairs, therapeutic area management and manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on favorable terms given the competition among numerous biotechnology companies and academic institutions for individuals with similar skill sets. In addition, adverse publicity, failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse impact on our business, financial condition, results of operations and prospects.

Our information technology systems or our infrastructure may fail or experience security breaches and incidents that could adversely impact our business and operations and subject us to liability.

Our information technology systems and data are vulnerable to compromise or damage from cybersecurity attacks or accidents. We have experienced significant growth in the complexity of our data and the software tools that our hardware infrastructure supports. We rely significantly upon information technology systems and infrastructure owned and maintained by us or by third-party providers to generate, collect, store and transmit confidential and proprietary information and data (including but not limited to intellectual property, proprietary business information and personal information) and to operate our business. We also outsource elements of our operations to, and obtain products and services from, third-parties and engage in collaborations for drug design with third-parties, each of which has or could have access to our confidential or proprietary information. Our employees on occasion travel to countries which are at elevated risk of cyber-intrusion, data theft and expropriation.

We deploy and operate an array of technical and procedural controls to reduce the risks to our information technology ("IT") systems, infrastructure and data and to work to maintain the availability, confidentiality and integrity of our data, and we expect to continue to incur significant costs on such detection and prevention efforts. While we continue to make investments to improve the protection of data and information technology, including in the hiring of qualified IT personnel, periodic cyber security awareness trainings, improvements to IT infrastructure and controls, and conduct regular testing of our systems, there can be no assurance that our efforts will prevent service interruptions or security breaches. Despite these measures, our information technology and other internal infrastructure systems face the risk of failures, interruptions, security breaches and incidents or other harm from various causes or sources, and third-parties with whom we share confidential or proprietary information face similar risks and may experience similar events that materially impact us. These causes or sources include but are not limited to the following:

- service interruptions;
- system malfunctions;
- computer viruses and other malicious code;
- natural disasters and force majeure events;

- global political instability;
- warfare;
- cyber-intrusions by hostile nation-state actors;
- telecommunication and electrical failures;
- inadvertent or intentional actions by our employees or third-party providers; and
- cyber-attacks by malicious third-parties, including the deployment of ransomware and malware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information.

With respect to cyber-attacks, the techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups and individuals with a range of motives (including industrial espionage) and expertise, such as organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. These risks may be heightened in connection with geopolitical events such as the conflict between Russia and Ukraine. The costs to investigate and mitigate actual and suspected cybersecurity breaches and incidents could be significant. We may not be able to anticipate all types of security threats and implement preventive measures effective against all such threats. In addition, an increased amount of work is occurring remotely, including through the use of mobile devices. This could increase our cybersecurity risk, create data accessibility concerns and make us more susceptible to communication disruptions.

We have experienced, and we may continue to experience, cyber-attacks, security breaches and incidents and other system failures, although to our knowledge we have not experienced any material interruption or incident. The loss, corruption, unavailability of or damage to our data would interfere with and undermine the insights we draw from our Generate Platform and could impair the integrity of our clinical trial data, leading to regulatory delays or the inability to get our product candidates approved. If we do not accurately predict and identify our infrastructure requirements and failures and timely enhance our infrastructure, or if our remediation efforts are not successful, it could result in a material disruption of our business operations and development programs, including the loss or unauthorized disclosure of our know-how, individuals' personal information or other proprietary or sensitive data. A security breach or incident that leads to unauthorized acquisition, disclosure or other processing of our intellectual property or other proprietary information could also affect our intellectual property rights and enable competitors to compete with us more effectively.

Likewise, as we rely on third-parties such as CROs, contractors and consultants, including for the manufacture of our product candidates and for the conduct of our clinical trials, similar events relating to their systems and operations could also have a material adverse effect on our business and lead to regulatory agency actions. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in or denials of our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any security compromise affecting us, our collaborators or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed, result in substantial costs and distract management. For more information, see "—We, our collaboration partners, and our service providers are subject to a variety of stringent and evolving privacy and data security laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations."

Failures, disruptions, security breaches and incidents, cyber-attacks and other harmful events impacting data processed or maintained in our business, or information technology systems or infrastructure used in our business, including those resulting in a loss of or damage to our information technology systems or infrastructure, or the loss of or inappropriate acquisition, disclosure or other processing of confidential, proprietary or personal information, or the perception any of these has occurred, could expose us to a risk of loss, enforcement measures, regulatory agency investigations, proceedings and other actions, penalties, fines, indemnification allegations, litigation, potential civil or criminal liability, collaborators' loss of confidence, damage to our reputation and other consequences, which could materially adversely affect our business and results of operations. While we maintain insurance coverage for certain expenses and liabilities related to failures or breaches of our information technology systems, it may not be adequate to cover all losses associated with such events. In addition, such insurance may not be available to us in the future on satisfactory terms or at all. Furthermore, if the information technology systems of third-parties with whom we do business become subject to disruptions or security breaches or incidents, we may have insufficient recourse against them.

Interruptions in the availability of server systems or communications with internet or cloud-based services, or failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems, could harm our business.

We rely on third-party data centers and telecommunications solutions, including cloud infrastructure services such as Amazon Web Services, to host substantial portions of our Generate Platform and to support our business operations. We

have limited control over these cloud-based service or other third-party providers, although we attempt to reduce risk by minimizing reliance on any single third-party or its operations. We have experienced, and expect we may in the future again experience system interruptions, outages or delays due to a variety of factors, including infrastructure changes, human or software errors, website hosting disruptions and capacity constraints. A prolonged service disruption affecting our cloud-based solutions could damage our reputation or otherwise materially harm our business.

Further, if the security measures of our third-party data center or cloud infrastructure providers are breached by cyber-attacks or other means and unauthorized access to our information technology systems or data occurs, it could result in interruptions to our operations and the loss of proprietary or confidential information, which could damage our reputation, cause us to incur substantial costs, divert our resources from other tasks and subject us to significant legal and financial exposure and liabilities, any one of which could materially adversely affect our business, results of operations, and prospects. Such third-party providers may also be subject to natural disasters, global political instability, warfare, power losses, telecommunications failures or other disruptive events that could negatively affect our business and require us to incur significant costs to secure alternate cloud-based solutions. In addition, any changes in our third-party providers' service levels or features that we utilize or the termination of our agreements could also adversely affect our business.

Our employees, principal investigators and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and consultants. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the Regulatory Authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the Regulatory Authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate and plan to operate in a highly regulated industry and we could now or in the future be subject to litigation, government investigation and enforcement actions on a variety of matters in the U.S. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other allegations and legal proceedings which may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business and results of operations. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources and cause reputational harm.

Employee litigation and unfavorable publicity could negatively affect our future business.

Our employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile workplace, discrimination, wage and hour disputes, sexual harassment or other employment issues. In recent years there has been an increase in the number of discrimination and harassment allegations generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these allegations have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment-related lawsuits have had to terminate management or other key personnel and have suffered reputational harm that has negatively impacted their business. If we were to face any employment-related allegations, our business could be negatively affected.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage in the future, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. If we obtain marketing approval for any product candidates that we or our collaborators may develop, we intend to acquire insurance coverage to include the sale of commercial products, but we may be unable to obtain such insurance on commercially reasonable terms or in adequate amounts. The coverage or coverage limits currently maintained under our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may identify. Additionally, operating as a public company has made it more expensive for us to obtain directors and officers liability insurance. If we do not maintain adequate levels of directors' and officers' liability insurance, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors and in our leadership team.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We and our current and future CDMOs 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. Our operations will involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third-parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us 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 allegations that may be asserted against us in connection with our storage or disposal of biological or hazardous 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 our current and any future CDMOs, 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. In addition, our supply chain may be adversely impacted if any of our CDMOs become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health and safety laws and regulations.

We or the third-parties upon whom we depend may be adversely affected by natural disasters or other business interruptions such as cybersecurity attacks and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations, and have a material adverse impact on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, cybersecurity attack or other force majeure event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as the manufacturing facilities of our CDMOs, limited our ability to access or use our Generate Platform 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 currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. Cybersecurity liability insurance is difficult to obtain and may not cover any damages we would sustain based on any breach of our computer security protocols or other cybersecurity attack. 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 impact on our business.

Risks Related to Ownership of Our Common Stock

The price of our common stock may be volatile and fluctuate substantially, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our stock price is likely to be volatile. The stock market in general, and the market for biotechnology companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. The market price for our common stock may be influenced by many factors, including: the commencement, enrollment, completion or results of preclinical and clinical trials of our product candidates or those of our competitors; the success of competitive products or technologies; commencement or termination of partnership, collaboration and licensing arrangements; regulatory or legal developments in the United States and other countries; developments or disputes concerning patent applications, issued patents or other proprietary rights; significant lawsuits, including patent or stockholder litigation; the recruitment or departure of key personnel; the level of expenses related to any of our product candidates or clinical development programs; the results of our efforts to discover, develop, acquire or in-license additional product candidates; actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; variations in our financial results or those of companies that are perceived to be similar to us; changes in the structure of healthcare payment systems; market conditions in the biotechnology and high-tech sectors, including high interest rates and borrowing costs; general economic, industry and market conditions; and the numerous product candidates in our pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts.

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

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such allegations and divert management's attention and resources, which could seriously harm our business, financial condition, results of operations and prospects.

We may not be able to satisfy listing requirements of the Nasdaq Global Select Market ("Nasdaq") or maintain a listing of our common stock on Nasdaq.

Since our common stock is listed on Nasdaq, we must meet certain financial and liquidity criteria to maintain such listing. If we violate Nasdaq's listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. The delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of our stockholders' investment.

Our quarterly and annual operating results may fluctuate in the future. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability, as well as negatively impact our ability to exist as a standalone company.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to our product candidates, which may change from time to time;
- the timing and status of enrollment for clinical trials;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with CDMOs;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for our product candidates from regulatory authorities in the United States and internationally;
- exchange rate and interest rate fluctuations;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; and

- the level of demand for our product candidates, if approved, which may vary significantly over time.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We believe the nature of our pipeline is not suitable to providing forward-looking guidance on the expected timing of individual product candidate milestones, particularly data readout timing. While as a general matter we intend to periodically report on the status of our development programs, including articulating anticipated next steps in the form of development plans or potential data readouts, we do not currently plan to provide forward-looking guidance on the timing of those next steps. In addition, we do not control the timing of disclosure of any such milestones related to certain of our product candidates that are managed by our collaboration partners, including Amgen and Novartis. Any disclosure by our collaboration partners of data that is perceived as negative, whether or not such data is related to other data that we or others release, may have a material adverse impact on our stock price or overall valuation. Not providing forward-looking guidance on the expected timing of product candidate milestones may lead to speculation by investors, shareholders, analysts and other market participants and in the media as to the progress of our individual product candidates, or our product candidates as a whole, which may have a material adverse impact on our stock price or valuation.

Sales of a substantial number of shares of our common stock by our stockholders in the public market could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of March 31, 2026, we have 128,192,484 shares of common stock outstanding. Of these shares, the 25,000,000 shares sold in our IPO may be resold in the public market immediately. The resale of 103,142,484 shares of our outstanding common stock is currently restricted under securities laws or as a result of lock-up or other agreements, but will be able to be sold after the expiration of the lock-up in August 2026 and termination of restrictions under securities laws. Moreover, holders of an aggregate 94,349,702 shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered all shares of common stock that we may issue under our equity compensation plans or that are issuable upon exercise of outstanding options. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and lock-up agreements. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through public or private equity or debt financings, government or other third-party grants, asset sales, royalty financings, partnership, collaboration and licensing arrangements, or a combination of these approaches. To the extent that we raise additional capital through the sale of stock or convertible or exchangeable debt securities, warrants or other similar equity securities, our stockholders' ownership interest could be diluted and the terms may include liquidation or other preferences that adversely affect our stockholders' rights as common stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations and alliances and licensing arrangements with third-parties or through asset sales, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. If no, or few, analysts commence coverage of us, the trading price of our stock may decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

Our executive officers, directors, five percent stockholders and their affiliates beneficially own a significant percentage of our common stock. As a result, these stockholders, acting together, may be able to exert significant influence over matters

such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction.

Some of these persons or entities may have interests different than other stockholders. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. The significant concentration of ownership may adversely affect the trading price of our common stock due to investors' perceptions that may create conflicts of interest.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Provisions in our fourth amended and restated certificate of incorporation (the "amended and restated certificate of incorporation") and amended and restated bylaws (the "amended and restated bylaws") may significantly reduce the value of our shares to a potential acquiror or make it difficult for a third-party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock and may fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. The issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors are elected each year;
- stockholders are not entitled to remove directors other than by a two-thirds vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in our stockholders' best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

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

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

We do not currently intend to declare or pay 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. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

Our amended and restated bylaws designate the Court of Chancery of the State of Delaware or the United States District Court for the District of Massachusetts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery of the State of Delaware having personal jurisdiction over the indispensable parties named as defendants therein (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Furthermore, Section 22 of the Securities Act creates

concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the U.S. may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General Risk Factors

We 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. We will be subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the federal securities laws, including the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including requirements to file annual, quarterly and event driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an EGC. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will 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. We may not be able to produce reliable financial statements or file these financial statements as part of a periodic report in a timely manner with the SEC or comply with the Nasdaq listing requirements. In addition, we could make errors in our financial statements that could require us to restate our financial statements.

We are an EGC, and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an EGC, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We will remain an EGC until the earlier of: (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the closing of our IPO; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which means the first day of the year following the first year in which the market value of our common stock that is held by non-affiliates exceeds $700 million. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include: not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"); not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements; reduced disclosure obligations regarding executive compensation; and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this Quarterly Report. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive, as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an EGC may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an EGC to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an EGC we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not EGCs.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with our IPO, we began the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404, which will require annual management assessment of the effectiveness of our internal control over financial reporting starting with our second filing of an Annual Report on Form 10-K.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy or consequent inability to produce accurate financial statements on a timely basis could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis cause investors to lose confidence in the accuracy and completeness of our financial reports and could cause the market price of our common stock to decline significantly.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the closing of our IPO, we became subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our future ability to utilize our NOL carryforwards and certain other tax attributes may be limited.

Since our inception, we have incurred losses and we may never achieve profitability. As of December 31, 2025, we had U.S. federal NOL carryforwards of $331.8 million (which are not subject to expiration) and state NOL carryforwards of $287.6 million (which begin to expire in various amounts in 2045). We also had U.S. federal research and development tax credit carryforwards of $24.9 million available to offset future U.S. federal income taxes, which expire at various times through 2040. As of December 31, 2025, we had state tax credit carryforwards of $13.4 million which expire at various times through 2040. To the extent that we continue to generate taxable losses, under current law, our unused U.S. federal NOLs may be carried forward to offset a portion of future taxable income, if any. Additionally, we continue to generate business tax credits, including research and development tax credits, which generally may be carried forward to offset a portion of future taxable income, if any, subject to expiration of such credit carryforwards. Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as one or more shareholders or groups of shareholders who own at least five percent of the corporation's equity increasing their equity ownership in the aggregate by more than 50 percentage points (by value) over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. Similar rules may apply under state tax laws. Our prior equity offerings and other changes in our stock ownership have resulted in such ownership changes in the past and on December 31, 2025, we have recorded a $207.8 million valuation allowance against deferred tax assets to reflect tax assets which may not be fully realized as a result of such ownership changes. In addition, we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOLs or other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. There is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs or business tax credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs or tax credits, even if we attain profitability.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our business and our financial condition. In recent years, many such changes have been made and changes are likely to continue to occur in the future. We cannot predict whether, when, in what form or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided or whether they could increase our tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

We, our collaboration partners, and our service providers are subject to a variety of stringent and evolving privacy and data security laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations.

In the ordinary course of our business, we and the third-parties upon which we rely collect, receive, store or otherwise process personal data, including information we may collect about participants in our clinical trials. Our data processing activities subject us to numerous, evolving privacy and data security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to privacy and data security.

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving in a manner that is increasingly stringent and, globally, this legal and regulatory framework is likely to remain uncertain for the foreseeable future. We must devote significant resources to understanding and complying with the changing landscape in this area. Each law is also subject to various interpretations by courts and Regulatory Authorities, creating additional uncertainty, and we may fail to comply with the evolving data protection laws, which may expose us to risk of enforcement actions taken by authorities, private rights of action in some jurisdictions and potential significant penalties if we are found to be non-compliant. Some of these laws and regulations also carry the possibility of criminal sanctions.

In the United States, numerous federal, state and local laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, federal consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), state consumer protection and privacy laws and other similar laws (e.g., wiretapping and communications interception laws) govern the processing of health-related and other personal data. At the state level, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While existing state comprehensive privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts and increase legal risk and compliance costs for us and the third-parties upon whom we rely.

Additionally, we may be subject to new laws governing the privacy of consumer health data. These various privacy and data security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. Regulators and legislators in the U.S. are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern as implemented by the Department of Justice's final rule issued in December 2024, effective April 8, 2025, prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data and biospecimens, to certain countries of concern, including China. The final rule also restricts certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. The final rule does not exempt key-coded or otherwise anonymized, pseudonymized, de-identified or encrypted data. Actual or alleged violations of the final rule may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

Outside the United States, an increasing number of laws, regulations and industry standards may govern privacy, data security and the transfer of personal data between jurisdictions. For example, the European Union's General Data Protection Regulation ("EU GDPR") and the United Kingdom's General Data Protection Regulation ("UK GDPR" and, together with the EU GDPR, "GDPR") impose strict requirements for processing personal data including relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required requirements relating to obtaining consent of individuals, disclosures about how personal data is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities and documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third-party processors. Under GDPR, companies may face temporary or definitive bans on data processing and other corrective activities, fines of up to €20 million (£17.5 million GBP) or 4% of annual global revenues, whichever is greater, and private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Non-compliance could also result in a material adverse effect on our business, financial position and results of operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the UK have significantly restricted the transfer of personal data to the United States and other countries. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum and the EU-U.S. Data Privacy Framework ("Framework") and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States (or other countries), or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third-parties and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants and activities activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Although the UK is regarded as a third country under the EU GDPR, the European Commission has adopted an adequacy decision in favor of the UK, a decision recognizing the UK as providing adequate protection under the EU GDPR and enabling data transfers from Member States to the UK without additional safeguards. The UK adequacy decision was renewed in December 2025 and will automatically expire in December 2031. The EU GDPR and the UK GDPR currently impose substantially similar obligations. However, the European Commission retains the authority to monitor developments in UK law, including implementation of the Data (Use and Access) Act 2025, and may amend, suspend or repeal the adequacy decisions if it determines that the UK no longer ensures an essentially equivalent level of protection. Any such action, or a successful legal challenge to the adequacy decisions could lead to additional compliance costs and could increase our overall risk.

Additionally in the EEA, the NIS 2 Directive ("NIS 2") is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organizations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organizations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organizations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant Member State. Member States had until October 17, 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EEA is currently fragmented and uncertain. To the extent we are subject to NIS 2, we will require additional investment of our resources in compliance programs. Under NIS 2 companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

In addition to privacy and data security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to privacy and data security, and our efforts to comply with such obligations may not be successful. We publish privacy policies and other statements, such as compliance with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to privacy and data security are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems and practices and to those of any third-parties that process personal data on our behalf.

We may at times fail in our efforts to comply with our privacy and data security obligations. Moreover, despite our efforts, our personnel or third-parties on whom we rely, including CROs supporting our clinical trials, clinical trial sites with whom we have contracted and other third-parties supporting our clinical trials, may fail to comply with such obligations, which could negatively impact our business operations. If we or the third-parties on which we rely fail, or are perceived to have failed, to address or comply with applicable privacy and data security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-action claims), and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for significant statutory damages, depending on the volume of data and the number of violations. Any of these

events could have a material adverse effect on our reputation, business, financial condition, results of operations and growth prospects, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets. The global economy and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, rising inflation, uncertainty from changes in tariff policies, fluctuating interest rates, declines in economic growth, global supply chain disruptions and uncertainty about economic stability. The global economy and financial markets may also be adversely affected by the current or anticipated impact of military conflict, terrorism or other geopolitical events, including the conflicts between Russia and Ukraine, the U.S. and Iran, and in the Middle East, as well as the increasingly strained relationship between the U.S. and China. Sanctions imposed by the U.S. and other countries in response to such conflicts may adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability.

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for any product candidates or products we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

(a) Set forth below is information regarding securities we have issued within the past three years that were not registered under the Securities Act.

Issuances of Capital Stock

Between May 9, 2023 and January 21, 2025, we issued and sold an aggregate of 33,704,613 shares of our Series C convertible preferred stock for a purchase price of $11.85 per share, for an aggregate purchase price of approximately $399.4 million.

The offers, sales and issuances of the securities described above were deemed to be exempt under Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D under the Securities Act as a transaction by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about us. No underwriters were involved in these transactions.

Grants and Exercises of Stock Options

Since January 1, 2023, we have granted to certain of our directors, employees and consultants options to purchase 18,563,330 shares of our common stock at a $10.09 per share weighted average exercise price under the 2019 Plan. Since January 1, 2023, 1,761,469 shares of common stock have been issued upon the exercise of stock options pursuant to the 2019 Plan.

The offers, sales and issuances of the securities described above were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

(b) On February 26, 2026, the SEC declared effective the Company's registration statement on Form S-1 (File No. 333-293204), as amended, filed in connection with the Company's IPO (the “Registration Statement”). Pursuant to the Registration Statement, we issued and sold 25,000,000 shares of our common stock at a price to the public of $16.00 per share. Goldman Sachs & Co. LLC and Morgan Stanley & Co. LLC acted as representatives of the underwriters for the IPO. We raised aggregate net proceeds of $369.3 million, after deducting underwriter discounts, commissions and other IPO expenses.

In connection with our IPO, no payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

We are holding a significant portion of the balance of the net proceeds in a variety of capital preservation investments, including money market funds and U.S. government securities. There has been no material change in the planned use of the net proceeds from our IPO, as described in our final prospectus filed with the SEC on February 27, 2026 pursuant to Rule 424(b) under the Securities Act.

(c) None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(a) None.

(b) None.

(c) During the fiscal quarter ended March 31, 2026, the following director and executive officer adopted a trading arrangement intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act:

- On March 13, 2026, Francis Arnold, a member of our board of directors, adopted a written trading plan (the “Arnold Plan”) for the sale of up to 232,472 shares of our common stock. The Arnold Plan is intended to satisfy the conditions of Rule 10b5-1(c) and was adopted during an open trading window and at a time when Ms. Arnold was not aware of material nonpublic information. The Arnold Plan provides for sales to commence on or after September 30, 2026 and to terminate on March 31, 2027, subject to earlier completion or termination in accordance with its terms.

- On March 13, 2026, Sean Martin, Chief Legal Officer and General Counsel, adopted a written trading plan (the “Martin Plan” and together with the Arnold Plan, the "Plans") for the sale of up to 116,800 shares of the Company’s common stock. The Martin Plan is intended to satisfy the conditions of Rule 10b5-1(c) and was adopted during an open trading window and at a time when Mr. Martin was not aware of material nonpublic information. The Martin Plan provides for sales to commence on or after November 2, 2026 and to terminate on March 5, 2027, subject to earlier completion or termination in accordance with its terms.

Except as described above, none of our other directors or executive officers adopted or terminated a 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement (as defined in Item 408(c) of Regulation S-K) during the fiscal quarter covered by this report.

Item 6. Exhibits.

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Generate Biomedicines, Inc. (Incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-43165) filed on March 2, 2026).
3.2	Amended and Restated Bylaws of Generate Biomedicines, Inc. (Incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-43165) filed on March 2, 2026).
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-293204) filed on February 13, 2026).
4.3	Amended and Restated Investors' Rights Agreement, by and between the Registrant and certain of its stockholders, dated as of May 9, 2023 (Incorporated by reference to Exhibit 4.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-293204) filed on February 13, 2026).
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.
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.
32.1+	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

\+ The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates them by reference.

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.

Generate Biomedicines, Inc.

Date: May 7, 2026

By: /s/ Michael Nally
Michael Nally, M.B.A.
Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 7, 2026

By: /s/ Jason Silvers
Jason Silvers, M.D., J.D.
President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

CERTIFICATIONS

I, Michael Nally, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended March 31, 2026 of Generate Biomedicines, 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

5. The registrant's other certifying officer 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: May 7, 2026 By: **/s/ Michael Nally**

Michael Nally
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

CERTIFICATIONS

I, Jason Silvers, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended March 31, 2026 of Generate Biomedicines, 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

5. The registrant's other certifying officer 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: May 7, 2026 By: **/s/ Jason Silvers**

Jason Silvers
President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Generate Biomedicines, Inc. (the "Company") for the period ended March 31, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, 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: May 7, 2026 By: **/s/ Michael Nally**
Michael Nally
Chief Executive Officer
(Principal Executive Officer)

Date: May 7, 2026 By: **/s/ Jason Silvers**
Jason Silvers
President and Chief Financial Officer
(Principal Financial Officer)