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, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38853

NGM BIOPHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**26-1679911**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

333 Oyster Point Boulevard
South San Francisco, CA 94080
(Address of principal executive offices including zip code)

(650) 243-5555
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on which Registered
Common Stock, par value $0.001 per share	NGM	The Nasdaq Stock Market LLC

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 ☒

As of May 1, 2023, the registrant had 82,358,909 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)
(Unaudited)

	March 31, 2023	December 31, 2022*
Assets		
Current assets:		
Cash and cash equivalents	$ 67,549	$ 73,456
Short-term marketable securities	163,455	198,036
Related party receivable from collaboration	1,257	7,580
Prepaid expenses and other current assets	8,769	9,787
Restricted cash	1,499	—
Total current assets	242,529	288,859
Property and equipment, net	7,966	8,496
Operating lease right-of-use asset	1,586	2,096
Restricted cash	2,455	3,954
Other non-current assets	4,301	3,997
Total assets	$ 258,837	$ 307,402
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 13,293	$ 8,453
Accrued liabilities	20,161	33,638
Operating lease liability, current	4,073	5,385
Contract liabilities	376	366
Total current liabilities	37,903	47,842
Total liabilities	37,903	47,842
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000 shares authorized; no shares issued or outstanding as of March 31, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.001 par value; 400,000 shares authorized; 82,056 and 81,885 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	82	82
Additional paid-in capital	850,229	841,413
Accumulated other comprehensive loss	(97)	(302)
Accumulated deficit	(629,280)	(581,633)
Total stockholders' equity	220,934	259,560
Total liabilities and stockholders' equity	$ 258,837	$ 307,402

See accompanying notes to these unaudited condensed consolidated financial statements.

*The condensed consolidated balance sheet as of December 31, 2022 has been derived from the audited financial statements as of that date.

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Related party revenue	$ 2,247	$ 20,948
Operating expenses:		
Research and development	40,857	42,806
General and administrative	11,584	10,723
Total operating expenses	52,441	53,529
Loss from operations	(50,194)	(32,581)
Interest income, net	2,584	176
Other expense, net	(37)	(45)
Net loss	$ (47,647)	$ (32,450)
Net loss per share, basic and diluted	$ (0.58)	$ (0.42)
Weighted average shares used to compute net loss per share, basic and diluted	82,008	78,023

See accompanying notes to these unaudited condensed consolidated financial statements.

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Net loss	$ (47,647)	$ (32,450)
Other comprehensive gain (loss), net of tax:		
Net unrealized gain (loss) on available-for-sale marketable securities	205	(548)
Total comprehensive loss	$ (47,442)	$ (32,998)

See accompanying notes to these unaudited condensed consolidated financial statements.

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2022	81,885	$ 82	$ 841,413	$ (302)	$ (581,633)	$ 259,560
Issuance of common stock upon exercise of stock options	171	—	279	—	—	279
Stock-based compensation expense	—	—	8,537	—	—	8,537
Comprehensive gain	—	—	—	205	—	205
Net loss	—	—	—	—	(47,647)	(47,647)
Balance at March 31, 2023	82,056	$ 82	$ 850,229	$ (97)	$ (629,280)	$ 220,934

	Common Stock		Additional Paid-In Capital	Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	77,962	$ 78	$ 754,664	$ (129)	$ (418,966)	$ 335,647
Issuance of common stock upon exercise of stock options	125	—	668	—	—	668
Stock-based compensation expense	—	—	7,820	—	—	7,820
Comprehensive loss	—	—	—	(548)	—	(548)
Net loss	—	—	—	—	(32,450)	(32,450)
Balance at March 31, 2022	78,087	$ 78	$ 763,152	$ (677)	$ (451,416)	$ 311,137

See accompanying notes to these unaudited condensed consolidated financial statements.

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating activities		
Net loss	$ (47,647)	$ (32,450)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,537	7,820
Depreciation	609	1,427
(Accretion of discount) amortization of premium on marketable securities	(1,525)	518
Non-cash lease expense	510	475
Other non-cash expenses	538	460
Changes in operating assets and liabilities:		
Related party receivable from collaboration	6,323	4,842
Prepaid expenses and other assets	714	241
Accounts payable	4,840	(431)
Accrued and other liabilities	(13,424)	(4,747)
Operating lease liability	(1,312)	(1,236)
Contract liabilities	10	(12,657)
Net cash used in operating activities	(41,827)	(35,738)
Investing activities		
Purchase of marketable securities	(14,464)	(86,904)
Proceeds from maturities of marketable securities	50,775	80,336
Purchases of property and equipment	(670)	(285)
Net cash provided by (used in) investing activities	35,641	(6,853)
Financing activities		
Proceeds from exercise of stock options	279	668
Net cash provided by financing activities	279	668
Net decrease in cash and cash equivalents	(5,907)	(41,923)
Cash, cash equivalents and restricted cash, at beginning of period	77,410	153,294
Cash, cash equivalents and restricted cash, at end of period	$ 71,503	$ 111,371
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment purchases not yet paid	$ 15	$ 436

See accompanying notes to these unaudited condensed consolidated financial statements.

NGM BIOPHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Organization and Description of Business

NGM Biopharmaceuticals, Inc. and its wholly-owned subsidiary, NGM Biopharmaceuticals Australia Pty Ltd., or NGM Australia, collectively referred to as the Company, is a biopharmaceutical company focused on discovering and developing novel, potentially life-changing medicines based on scientific understanding of key biological pathways underlying grievous diseases with critical unmet or underserved patient need. The Company's portfolio of product candidates range from early discovery to Phase 2b development and includes four programs in active ongoing clinical development. The Company has additional programs that are in various stages of development ranging from functional validation to preclinical development.

The Company was incorporated in Delaware in December 2007 and commenced operations in 2008. The Company's headquarters are located at 333 Oyster Point Blvd., South San Francisco, California 94080.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, and Regulation S-X for interim consolidated financial information. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes for the year ended December 31, 2022 included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022 filed with the U.S Securities and Exchange Commission, or SEC, on February 28, 2023. These unaudited condensed consolidated financial statements reflect all adjustments that management believes are necessary for a fair presentation of the periods presented. All such adjustments are of a normal recurring nature and are not necessarily indicative of results expected for the full fiscal year ending December 31, 2023, or for any subsequent interim period.

These unaudited condensed consolidated financial statements include the consolidated accounts of NGM Biopharmaceuticals, Inc. and its wholly-owned foreign subsidiary, NGM Australia. All intercompany balances and transactions have been eliminated upon consolidation.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP requires management to make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses. Specific accounts that require management estimates include, but are not limited to, stock-based compensation expense, contract manufacturing accruals, clinical trial accruals and revenue recognition in accordance with Accounting Standards Update, or ASU, 2014-09, Revenue from Contracts with Customers (Topic 606), or ASC 606. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates, and to the extent that there are differences between management's estimates and actual results, the Company's future financial statement presentation, financial condition, results of operations and cash flows may be affected.

Sources and Uses of Liquidity

Since inception, the Company has incurred net losses and negative cash flow from operations. During the three months ended March 31, 2023 and 2022, net losses were $47.6 million and $32.5 million, respectively. As of March 31, 2023, the Company had an accumulated deficit of $629.3 million. The Company expects its accumulated deficit will continue to increase over time and does not expect to experience positive cash flows from operations in the near future.

As of March 31, 2023, the Company had $231.0 million of cash, cash equivalents and short-term marketable securities.

In June 2020, the Company entered into an Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC. As of March 31, 2023, $76.2 million of the Company's common stock remained available to be sold under the Sales Agreement, subject to conditions specified in the Sales Agreement.

The Company believes its existing cash, cash equivalents and short-term marketable securities will be sufficient to fund its operations for a period of at least one year from the issuance of these condensed consolidated financial statements.

To fully implement the Company's business plan and fund its operations, the Company needs to raise significant additional capital through public or private equity or debt offerings (which may include potential net proceeds from future sales, if any, under the Sales Agreement), collaboration, out licensing, partnership or other business development arrangements, or a combination of the foregoing. None may be possible and, as a result, the Company may need to significantly delay, scale back or discontinue development of or abandon some or all of its product candidates, or scale back or discontinue the Company's discovery research efforts, any of which could have a material adverse effect on the Company's business, operating results and prospects, or the Company may be required to cease operations altogether.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, the related party receivable from collaboration and other current assets and liabilities approximate their respective fair values due to their short-term nature.

Cash and Cash Equivalents

Cash and cash equivalents are stated at fair value. Cash equivalents are securities with an original maturity of three months or less at the time of purchase. The Company limits its credit risk associated with cash and cash equivalents by investing in highly rated money market funds and placing its cash with banks it believes are highly creditworthy in amounts that may at times exceed federally insured limits. As of March 31, 2023 and December 31, 2022, cash and cash equivalents consisted of bank deposits and investments in money market funds.

Marketable Securities

The appropriate classification of the Company's marketable securities is determined at the time of purchase and such designations are re-evaluated at each balance sheet date. All of the Company's securities are considered as available-for-sale and carried at estimated fair values and reported in cash equivalents and short-term marketable securities. Unrealized gains and losses on available-for-sale securities are excluded from net loss and reported in accumulated other comprehensive loss as a separate component of stockholders' equity. Interest income, net, includes interest, amortization of purchase premiums and accretion of purchase discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method.

The Company's investments are regularly reviewed for other-than-temporary declines in fair value. This review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in fair value of an investment is below its carrying value and this decline is other-than-temporary, the Company reduces the carrying value of the security it holds and records a loss for the amount of such decline. As of March 31, 2023, the Company did not record any impairment related to other-than-temporary declines in the fair value of securities.

Restricted Cash

The Company's restricted cash balances represent collateral required under the Company's facility lease agreements. Collateral that will not be returned to the Company within twelve months from the date of these condensed consolidated financial statements is classified as a non-current asset.

Concentration of Credit and Other Risks

Cash, cash equivalents and marketable securities from the Company's available-for-sale and marketable securities portfolio potentially subject the Company to concentrations of credit risk. The Company is invested in

money market funds and marketable securities through custodial relationships with major United States, or U.S., banks. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government.

In reference to the recent closure of Silicon Valley Bank, or SVB, which is now a division of First Citizens Bank, as of March 31, 2023, the Company had approximately $6.0 million in deposits and other accounts with SVB, consisting of $4.0 million in letters of credit related to the Company's facilities leases that were classified as restricted cash on the Company's balance sheet and approximately $1.9 million held in a sweep account used to purchase shares in money-market funds through SVB. The Company incurred no losses as a result of the closure of SVB.

Related party receivables from collaboration and partnering arrangements are typically unsecured. Accordingly, the Company may be exposed to credit risk generally associated with its current amended and restated research collaboration, product development and license agreement, or the Amended Collaboration Agreement, with Merck Sharp & Dohme LLC, or Merck, and any future collaboration or partnering arrangements with other potential future partners. To date, the Company has not experienced any losses related to these receivables.

Amounts recognized as revenue prior to the Company having an unconditional right (other than a right that is conditioned only on the passage of time) to receipt are recorded as contract assets in the Company's condensed consolidated balance sheets. Although the Company expects to have an unconditional right to receive such amounts, the Company may be exposed to the risk of not receiving the recorded amounts under its current collaboration agreement with Merck and any future collaboration or partnering arrangements with other potential future partners. To date, the Company has not experienced any losses related to contract assets.

Merck accounted for 100% of the Company’s revenue for the three months ended March 31, 2023 and 2022.

Property and Equipment, Net

Property and equipment are recorded at cost and consists of computer equipment, laboratory equipment and office furniture and leasehold improvements. Maintenance and repairs, and training on the use of equipment, are expensed as incurred. Costs that improve assets or extend their economic lives are capitalized. Depreciation is recognized using the straight-line method based on an estimated useful life of the asset, which is as follows:

Computer equipment	3 years
Laboratory equipment and office furniture	3 years
Leasehold improvement	Shorter of life of asset or lease term

Leases

Effective January 1, 2021, the Company adopted ASU 2016-02, Leases (Topic 842), referred to as ASC 842. Under ASC 842, the Company determines if an arrangement is a lease at inception. Lease assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Lease liabilities are measured at the lease commencement date as the present value of future minimum lease payments over the term of the lease. Lease assets are measured as the lease liability plus initial direct costs and prepaid lease payments less lease incentives. In measuring the present value of the future minimum lease payments, the Company generally uses its incremental borrowing rate. The lease term is the noncancelable period of the lease and includes options to extend or terminate the lease when it is reasonably certain that an option will be exercised. Leases with terms of 12 months or less are not recorded on the Company's balance sheet. Lease expense is recognized on a straight-line basis over the lease terms, or in some cases, the useful life of the underlying asset. The Company accounts for the lease and non-lease components as a single lease component. The Company’s lease agreement for its corporate office space and facilities is classified as an operating lease.

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized as the amount by which the

carrying amount of the asset exceeds the estimated fair value of the asset. As of March 31, 2023 and December 31, 2022, no revision to the remaining useful lives or write-down of long-lived assets was required.

Income Taxes

Income taxes are accounted for under the liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and the operating loss and tax credit carryforwards. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Deferred tax assets and liabilities are measured at the balance sheet date using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period such tax rate changes are enacted. The net deferred tax assets have been fully offset by a valuation allowance.

Revenue Recognition

Under ASC 606, the Company estimates each arrangement's total transaction price, which includes unconstrained variable consideration, and the recognition of that transaction price based on a cost-based input method that requires estimates to determine, at each reporting period, the percentage of completion based on the estimated total effort required to complete the project and the total transaction price. The unconstrained variable consideration amount included in the transaction price represents an amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur.

The Company applies the following five-step revenue recognition model outlined in ASC 606 to adhere to this core principle: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the Company satisfies a performance obligation.

All of the Company's revenue to date has been generated from its collaboration agreements, primarily its collaboration agreement with Merck. The terms of these agreements generally require the Company to provide (i) license options for its compounds, (ii) research and development, or R&D, services and (iii) non-mandatory services in connection with participation in research or steering committees. Payments received under these arrangements may include non-refundable upfront license fees, partial or complete reimbursement of R&D costs, contingent consideration payments based on the achievement of defined collaboration objectives and royalties on sales of commercialized products. In some agreements, the collaboration partner is solely responsible for meeting defined objectives that trigger contingent or royalty payments. Often the partner only pursues such objectives subsequent to exercising an optional license on compounds identified as a result of the R&D services performed under the collaboration agreement.

The Company assesses whether the promises in its arrangements, including any options provided to the partner, are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to a compound is distinct from R&D services or participation in research or steering committees, as well as whether options create material rights in the contract. In situations when a contract includes distinct R&D services that are substantially the same and have the same pattern of transfer to the customer over time, they are recognized as a series of distinct services.

The transaction price in each arrangement is generally comprised of a non-refundable upfront fee and unconstrained variable consideration related to the performance of R&D services. The unconstrained variable consideration amount included in the transaction price represents an amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. The Company typically submits a budget for the R&D services to the partner in advance of performing the services. The transaction price is allocated to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation. Judgment is required to determine the SSP. In instances where the SSP is not directly observable, such as when a license or service is not sold separately, SSP is determined using information that may include market conditions and other observable inputs. The Company utilizes judgment to assess the nature of its performance obligations to determine whether they are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress toward completion. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company's collaboration agreements may include contingent payments related to specified development and regulatory milestones or contingent payments for royalties based on sales of a commercialized product. Milestones can be achieved for such activities in connection with progress in clinical trials, regulatory filings

in various geographical markets and marketing approvals from health authorities. Sales-based royalties are generally related to the volume of annual sales of a commercialized product. At the inception of each agreement that includes such payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or its partner's control, such as those related to regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation based on a relative SSP basis. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of each such milestone and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Pursuant to the guidance in ASC 606, sales-based royalties are not included in the transaction price. Instead, royalties are recognized at the later of when the performance obligation is satisfied or partially satisfied, or when the sale that gives rise to the royalty occurs.

Contract modifications, defined as changes in the scope or price (or both) of a contract that are approved by the parties to the contract, such as a contract amendment, exist when the parties to a contract approve a modification that either creates new, or changes existing, enforceable rights and obligations of the parties to the contract. Depending on facts and circumstances, the Company accounts for a contract modification as one of the following: (i) a separate contract; (ii) a termination of the existing contract and a creation of a new contract; or (iii) a combination of the preceding treatments. A contract modification is accounted for as a separate contract if the scope of the contract increases because of the addition of promised services that are distinct and if the price of the contract increases by an amount of consideration that reflects the Company's standalone selling prices of the additional promised services. When a contract modification is not considered a separate contract and the remaining services are distinct from the services transferred on or before the date of the contract modification, the Company accounts for the contract modification as a termination of the existing contract and a creation of a new contract. When a contract modification is not considered a separate contract and the remaining services are not distinct, the Company accounts for the contract modification as an add-on to the existing contract and as an adjustment to revenue on a cumulative catch-up basis.

Research and Development

R&D costs are expensed as incurred. R&D expenses primarily include salaries and benefits for medical, clinical, quality, preclinical, manufacturing and research personnel, costs related to research activities, preclinical studies, clinical trials, drug manufacturing expenses and allocated overhead and facility occupancy costs. The Company accounts for non-refundable advance payments for goods or services that will be used in future R&D activities as expenses when the goods have been received or when the service has been performed rather than when the payment is made.

Clinical trial costs are a component of R&D expenses. The Company accrues estimated costs for its clinical trial activities performed by third parties, including clinical research organizations, or CROs, and other service providers based upon estimates of the proportion of work completed over the life of the individual clinical trial and patient enrollment rates in accordance with associated agreements. The Company's estimates are determined through detailed discussions with internal personnel and its service providers as to the progress of each clinical trial and by reviewing contracts, vendor agreements and purchase orders for previously agreed-upon rates and fees to be paid for such services.

Stock-Based Compensation

The Company's stock-based compensation programs include stock option and restricted stock unit, or RSU, grants, as well as shares issued under its 2019 Employee Stock Purchase Plan, or ESPP. Grants are awarded to employees, directors and non-employees. The Company measures stock-based compensation expense for all stock-based awards at the grant date based on the fair value measurement of the award. The expense is recorded on a straight-line basis over the requisite service period, which is generally the vesting period, for the entire award. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures materially differ from estimates. The Company calculates the fair value measurement of stock options using the Black-Scholes option-pricing model.

Comprehensive Loss

Comprehensive loss is composed of net loss and certain changes in stockholders' equity that are excluded from net loss, primarily unrealized gains or losses, net of taxes, on the Company's marketable securities.

Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding during the period, less shares subject to repurchase and excludes any dilutive effects of stock-based options and awards. Diluted net income per share is computed by giving effect to all potentially dilutive shares, including common stock issuable upon exercise of stock options and the assumed vesting of outstanding RSUs. However, where there is a diluted net loss per share, no adjustment is made for potentially issuable shares since their effect would be anti-dilutive. In this case, diluted net loss per share is equal to basic net loss per share.

Net loss per share was computed as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2023	**2022**
Numerator:		
Net loss	$ (47,647)	$ (32,450)
Denominator:		
Weighted average number of shares used in calculating net loss per share—basic and diluted	82,008	78,023
Net loss per share—basic and diluted	$ (0.58)	$ (0.42)

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Options to purchase common stock	17,986	13,240
Shares committed under the ESPP	1,114	390
RSUs	989	—
Total	20,089	13,630

Segment and Geographical Information

The Company operates in one business segment. Substantially all of the Company's long-lived assets, primarily comprised of property and equipment, are based in the United States. For the three months ended March 31, 2023 and 2022, the Company's revenues were entirely within the United States based upon the location of the Company and Merck.

Recent Accounting Pronouncements

New accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's results of operations and financial position upon adoption.

3. Fair Value Measurements

Cash equivalents and marketable securities are classified as available-for-sale securities and consisted of the following (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
As of March 31, 2023				
U.S. treasury securities	$ 68,794	$ 3	$ (61)	$ 68,736
Money market funds	64,816	—	—	64,816
Commercial paper	40,002	—	—	40,002
Corporate and agency bonds	34,258	—	(52)	34,206
U.S. government agency securities	20,498	13	—	20,511
Totals	$ 228,368	$ 16	$ (113)	$ 228,271
Classified as:				
Cash and cash equivalents				$ 64,816
Short-term marketable securities (amortized cost of $163,552)				163,455
Total				$ 228,271

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
As of December 31, 2022				
U.S. treasury securities	$ 89,039	$ 7	$ (160)	$ 88,886
Money market funds	62,844	—	—	62,844
Corporate and agency bonds	46,300	—	(200)	46,100
Commercial paper	42,746	—	—	42,746
U.S. government agency securities	20,253	51	—	$ 20,304
Totals	$ 261,182	$ 58	$ (360)	$ 260,880
Classified as:				
Cash and cash equivalents				$ 62,844
Short-term marketable securities (amortized cost of $198,338)				198,036
Total				$ 260,880

The cash and cash equivalents amount in the table above excludes cash on deposit with banks of $2.7 million and $10.6 million as of March 31, 2023 and December 31, 2022, respectively.

To date, the Company has not recorded any impairment charges against the market value of its marketable securities. In determining whether a decline is other than temporary, the Company considers various factors including the length of time and extent to which the market value has been less than cost, the financial condition and near-term prospects of the issuer and the Company's intent and ability to retain its investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

As of March 31, 2023 and December 31, 2022, all of the Company's marketable securities had remaining contractual maturities of less than one year. As of March 31, 2023, the Company had 15 marketable securities in an unrealized loss position compared to 19 marketable securities in an unrealized loss position as of December 31, 2022. Marketable securities that had been in unrealized loss positions as of March 31, 2023 and December 31, 2022 were in an unrealized loss position for less than twelve months. The Company does not need to nor does it intend to sell marketable securities that are in an unrealized loss position and it is highly unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table summarizes, by major security type, the Company's available-for-sale securities that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	Fair Value Measurements			
As of March 31, 2023	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
U.S. treasury securities	$ 68,736	$ —	$ —	$ 68,736
Money market funds	64,816	—	—	64,816
Commercial paper	—	40,002	—	40,002
Corporate and agency bonds	—	34,206	—	34,206
U.S. government agency securities	—	20,511	—	20,511
Totals	$ 133,552	$ 94,719	$ —	$ 228,271

	Fair Value Measurements			
As of December 31, 2022	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
U.S. treasury securities	$ 88,886	$ —	$ —	$ 88,886
Money market funds	62,844	—	—	62,844
Corporate and agency bonds	—	46,100	—	46,100
Commercial paper	—	42,746	—	42,746
U.S. government agency securities	—	20,304	—	20,304
Totals	$ 151,730	$ 109,150	$ —	$ 260,880

The Company estimates the fair values of investments in commercial paper, corporate and agency bond securities and U.S. government agency securities using Level 2 inputs by taking into consideration valuations obtained from third-party pricing services.

There were no transfers of assets or liabilities between the fair value measurement levels during the three months ended March 31, 2023 and year ended December 31, 2022.

4. Balance Sheet Components

Cash, Cash Equivalents and Restricted Cash

A reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets to the amount reported within the condensed consolidated statements of cash flows is as follows (in thousands):

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 67,549	$ 73,456
Restricted cash	3,954	3,954
Total cash, cash equivalents and restricted cash	$ 71,503	$ 77,410

Property and Equipment

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

	March 31, 2023	December 31, 2022
Leasehold improvements	$ 25,867	$ 25,866
Laboratory equipment and office furniture	23,879	23,807
Computer equipment	1,433	1,433
Construction-in-progress	290	284
Total property and equipment, gross	51,469	51,390
Less: accumulated depreciation and amortization	(43,503)	(42,894)
Total property and equipment, net	$ 7,966	$ 8,496

Depreciation expense was $0.6 million and $1.4 million for the three months ended March 31, 2023 and 2022, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Clinical trials and research and development costs	$ 8,836	$ 14,597
Personnel-related costs	4,897	9,181
Manufacturing costs	1,440	6,026
Accrued expenses	4,988	3,834
Total accrued liabilities	$ 20,161	$ 33,638

5. Research Collaboration and License Agreements

Merck

In 2015, the Company entered into a research collaboration, product development and license agreement with Merck, which, together with amendments made prior to June 30, 2021, is referred to as the Original Collaboration Agreement, covering the discovery, development and commercialization of novel therapies across a range of therapeutic areas, including a broad, multi-year drug discovery and early development program that was financially supported by Merck, and scientifically directed by the Company with input from Merck. The original research phase of the collaboration was for five years and was extended by Merck for an additional two years through March 2022. As part of that extension, Merck agreed to continue to fund up to $75.0 million of the Company's R&D efforts each year consistent with the initial five-year research term and, in lieu of a $20.0 million extension fee payable to the Company, Merck agreed to make additional payments totaling up to $20.0 million in support of the Company's R&D activities during 2021 through the first quarter of 2022.

On June 30, 2021, the Company entered into an amended and restated research collaboration, product development and license agreement with Merck, or the Amended Collaboration Agreement, replacing the Original Collaboration Agreement and extending the research phase of the collaboration generally through March 31, 2024, with possible extensions for each of the various programs to allow the Company or Merck to complete ongoing development, but with a narrower scope than in the Original Collaboration Agreement. Under the Amended Collaboration Agreement, the collaboration was focused primarily on the identification, research and development of collaboration compounds directed to targets of interest to Merck in the fields of ophthalmology and cardiovascular or metabolic, or CVM, disease, including heart failure. The collaboration scope also included certain laboratory testing and other activities on compounds that are directed to one of up to two undisclosed targets outside of the fields of ophthalmology and CVM disease, or the Lab Programs.

Currently, the only ongoing research activities to be funded under the Amended Collaboration Agreement are certain CVM-related activities. The research phase for the CVM-related continuing programs will continue until March 31, 2024, unless the parties mutually agree to extend the research phase to March 31, 2026, in which case Merck would provide up to a total of $20.0 million in research funding during those additional two years. Remaining

activities under the Lab Programs were substantially completed in the first quarter of 2023. The ophthalmology compounds in the collaboration under the Amended Collaboration Agreement initially included NGM621 (and its related compounds) and compounds directed against two other undisclosed ophthalmology targets (and their related compounds). Merck had a one-time option to license NGM621, its related compounds and the ophthalmology bundle upon completion of the Phase 2 CATALINA trial. In December 2022, Merck notified the Company that it would not exercise its option to license NGM621 and its related compounds, nor would Merck exercise the related ophthalmology bundle option; accordingly, these options expired unexercised in January 2023 and the programs are now wholly-owned by the Company. Further, Merck did not elect for the Company to continue to conduct R&D on any compounds from the Company's other ophthalmology programs that were subject to the collaboration, which are preclinical and directed to undisclosed targets. Such an election would have resulted in an extended or tail period in which Merck would continue to fund the Company's R&D of such ophthalmology compounds. Because Merck did not exercise its ophthalmology license options or make such a tail period election, the programs are now wholly-owned by the Company and the Company does not have any funding from Merck to pursue such ophthalmology programs.

Pursuant to the Amended Collaboration Agreement, the Company gained the right, in its sole discretion, to independently research, develop and commercialize the collaboration compounds known as NGM120, NGM707, NGM831 and NGM438, their related compounds and all other preclinical and research assets that the Company researched or developed under the Original Collaboration Agreement but that were not included within the R&D scope of the continuing collaboration, which are referred to as the released NGM compounds. Merck retained the right to receive royalties at low single-digit rates on the sales of any released NGM compounds that receive regulatory approval and, if the Company decides during a certain time period to engage in a formal partnering process for a released NGM compound or negotiations regarding a license or asset sale of a released NGM compound, the Company is obligated to notify Merck, provide Merck with certain information and engage in good faith, non-exclusive negotiations with respect to such released NGM compound with Merck at Merck’s request.

Under the Amended Collaboration Agreement, Merck continued to have a Merck license option, as it did under the Original Agreement, to each continuing collaboration compound that is identified, researched and developed under the Amended Collaboration Agreement and reaches the specified option exercise point for such continuing collaboration compound as described below, and to its related compounds (each such continuing collaboration compound and its related compounds are referred to generally as a continuing program). In addition, under the terms of the Amended Collaboration Agreement, new CVM-related programs may be added to the continuing collaboration if recommended by the Company and selected by Merck, and Merck would have a Merck license option to such CVM-related continuing program. We do not expect any new CVM-related programs to be added to the collaboration.

The Merck license option exercise point for a continuing collaboration compound from the CVM-related continuing programs or the Lab Programs will be the designation by Merck of such continuing collaboration compound as a research program development candidate that Merck intends to progress into preclinical development.

Under the Amended Collaboration Agreement, if Merck exercises the Merck license option for a continuing collaboration compound from a CVM-related continuing program or the Lab Programs, Merck will pay the Company a $6.0 million option exercise fee at the time of selection to progress such licensed continuing collaboration compound or any of its related compounds into preclinical development and an additional $10.0 million milestone payment if such continuing collaboration compounds or one of its related compounds subsequently completes a human proof-of-concept trial. Merck will be responsible, at its own cost, for any further development and commercialization activities for continuing collaboration compounds within any such licensed continuing program.

In March 2022, the Company and Merck entered into a letter agreement, or the Letter Agreement, regarding NGM621 manufacturing activities that the Company undertook with the intention of avoiding a significant delay between the completion of the CATALINA trial and the start of any Phase 3 clinical trial for NGM621.

The Company concluded that the Amended Collaboration Agreement is a separate arrangement containing a three-year performance obligation to provide distinct R&D services in accordance with ASC 606. The total transaction price under the Amended Collaboration Agreement is $119.6 million which includes $86.0 million in research funding for the four calendar quarters that ended on March 31, 2022, $15.7 million in research funding for the ophthalmology and CVM-related continuing programs and the Lab Programs during the remaining two years of the research phase after March 2022, $13.1 million in estimated NGM621 reimbursable expenses and costs during the remaining two years of the research phase after March 2022 and $4.75 million for reimbursable amounts paid in 2022 to a third-party manufacturer in accordance with the terms of the Letter Agreement. The Company will continue to re-evaluate the transaction price as uncertain events are resolved or other changes in circumstances

occur. The Company continues performing its R&D services in the area of both the continuing collaboration compounds and the released NGM compounds and has one performance obligation across all continuing programs. The Company will continue to use the cost-based input method to calculate the amount of revenue to recognize as services are being rendered from April 1, 2021 through March 31, 2024. For the period that started on April 1, 2023 and ends on March 31, 2024, the Company expects Merck will provide funding of only approximately $4.0 million in the aggregate for the ongoing CVM-related activities and for certain costs and reimbursements related to the NGM621 program and this amount is included in the transaction price.

The Company considered whether the Merck license option created material rights in the contract and concluded that the fee attached to the exercise of such option approximated the SSP of the promised goods or services included in the option. Therefore, the Company concluded that such option did not give rise to a material right, was not a performance obligation in the Amended Collaboration Agreement and, if and when exercised, would be accounted for as separate arrangements under ASC 606.

Merck owned approximately 16% of the Company's outstanding shares as of March 31, 2023.

Summary of Related Party Revenue

The Company recognized revenue from its collaboration and license agreements as follows (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Related party revenue	$ 2,247	$ 20,948

For the three months ended March 31, 2023, the Company recognized collaboration and license revenue of $2.2 million primarily related to reimbursable R&D activities associated with the performance obligation under the Amended Collaboration Agreement under which Merck is providing significantly less annual R&D funding than it had provided through March 31, 2022. Revenue recognized related to the reimbursable R&D activities was recognized using the cost-based input model related to R&D activities.

Related Party Contract Assets and Liabilities

Amounts recognized as revenue prior to the Company having an unconditional right (or a right that is conditioned only on the passage of time) to receipt are recorded as contract assets in the Company's condensed consolidated balance sheets. If the Company expects to have an unconditional right to receive the consideration in the next twelve months, the contract asset will be classified in current assets. As of March 31, 2023 and December 31, 2022, the Company did not have a related party contract asset.

Amounts received prior to satisfying the revenue recognition criteria are recorded as contract liabilities in the Company’s condensed consolidated balance sheets. If the related performance obligation is expected to be satisfied within the next twelve months, the contract liability will be classified in current liabilities. The Company recorded contract liabilities of $0.4 million as of March 31, 2023 and as of December 31, 2022.

6. Commitments and Contingencies

Operating Leases and Lease Guarantee

In December 2015, the Company entered into an operating lease agreement, or the 333 Oyster Point lease agreement, for its corporate office space and facilities at 333 Oyster Point Blvd., South San Francisco, California, or the 333 Oyster Point facility, for approximately 122,000 square feet that expires in December 2023. The 333 Oyster Point lease agreement provided a tenant improvement allowance of $15.2 million that the Company used in 2016 towards $22.3 million in total leasehold improvements that are amortized over the lease term of seven years. As of March 31, 2023, restricted cash in current assets on the Company's condensed consolidated balance sheets included a letter of credit in the amount of $1.5 million required under the 333 Oyster Point lease agreement.

As of March 31, 2023, the weighted-average remaining lease term for the 333 Oyster Point lease agreement was 9 months and the weighted-average discount rate used to determine the Company's operating lease liability was 2.85%. Cash paid for amounts included in the measurement of the lease liabilities was $1.3 million in both the three month periods ended March 31, 2023 and 2022.

During the three months ended March 31, 2023 and March 31, 2022, the components of lease costs, which were included in general and administrative expenses on the Company's condensed consolidated statements of operations, were as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Operating lease costs	$ 541	$ 541
Variable lease costs (1)	339	324
Total lease cost	$ 880	$ 865

(1) Variable lease costs include certain additional charges for operating costs, including insurance, maintenance, taxes and other costs incurred, which are billed based on both usage and as a percentage of the Company's share of total square footage.

As of March 31, 2023, the maturities of the Company's operating lease liabilities and future minimum lease payments were as follows (in thousands):

Total undiscounted lease payments for the remainder of the year ending December 31, 2023	4,111
Less: present value adjustment	(38)
Present value of lease liabilities	$ 4,073

In July 2022, the Company entered into an operating lease agreement, or the 2024 Lease Agreement, for its corporate office space and facilities at 333 Oyster Point Blvd., South San Francisco, California, which the Company currently occupies pursuant to a sublease agreement that is scheduled to expire on December 31, 2023. Pursuant to the 2024 Lease Agreement, the lease term with the new landlord begins on January 1, 2024 and expires on December 31, 2033, and the Company will pay an initial monthly base rent of approximately $0.9 million for the first year, which is subject to increase at an annual rate of 3.5% each year thereafter, plus certain operating and tax expenses. Base rent during the initial ten-year term of the 2024 Lease Agreement will total $124.1 million. The 2024 Lease Agreement provides a tenant improvement allowance of approximately $4.9 million. The Company has an option to extend the 2024 Lease Agreement for a period of either eight or ten years after the initial term. In July 2022, pursuant to the 2024 Lease Agreement, the Company provided the landlord with a letter of credit in the amount of $2.5 million that was reported as restricted cash in non-current assets on the Company's condensed consolidated balance sheets as of March 31, 2023 and December 31, 2022.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and may provide for indemnification of the counterparty. The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made.

In accordance with the Company's amended and restated certificate of incorporation and its amended and restated bylaws, the Company has indemnification obligations to its officers and directors, subject to some limits, with respect to their service in such capacities. The Company has also entered into indemnification agreements with its directors and certain of its officers. To date, the Company has not been subject to any claims, and it maintains director and officer insurance that may enable it to recover a portion of any amounts paid for future potential claims.

The Company's exposure under these agreements is unknown because it involves claims that may be made against it in the future but have not yet been made. The Company believes that the fair value of these indemnification obligations is minimal and, accordingly, it has not recognized any liabilities relating to these obligations for any period presented.

7. Stock-Based Compensation

Stock Option Activity

A summary of the activity under the 2008 Plan and the 2018 Plan is as follows:

	Outstanding Options		Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In Thousands)
	Number of Options (In Thousands)	Weighted Average Exercise Price		
Balances at December 31, 2022	14,215	$ 14.74	6.89	$ 1,749
Options granted	4,292	4.38		
Options exercised	(171)	1.63		
Options forfeited	(228)	12.13		
Options expired	(122)	12.87		
Balances at March 31, 2023	17,986	$ 12.44	6.82	$ 555
Vested and expected to vest at March 31, 2023	17,224	$ 12.55	6.70	$ 555
Exercisable at March 31, 2023	9,294	$ 14.35	4.99	$ 555

The aggregate intrinsic values of options outstanding, vested and expected to vest, and exercisable were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock.

The weighted-average grant date fair value of stock options granted during the three months ended March 31, 2023 was $3.18 per share.

Employee Stock Purchase Plan

Under the ESPP, eligible employees are granted the right to purchase shares of the Company's common stock through payroll deductions that cannot exceed 15% of each employee's salary. The ESPP provides for a 24-month offering period, which includes four six-month purchase periods. At the end of each purchase period, eligible employees are permitted to purchase shares of common stock at the lower of 85% of fair market value at the beginning of the offering period or fair market value at the end of the purchase period. The ESPP is considered a compensatory plan. As of March 31, 2023, 736,170 shares of common stock had been purchased under the ESPP.

Restricted Stock Units

During the three months ended March 31, 2023, the Company granted 1.0 million RSUs covering an equal number of shares of the Company's common stock to employees with a weighted-average grant date fair value of $4.36 per RSU. The fair value of RSUs is determined on the date of grant based on the market price of the Company's common stock as of that date. The fair value of the RSUs is recognized as an expense ratably over the vesting period of four years. No shares underlying the RSUs have vested or been released as of March 31, 2023.

Stock-Based Compensation Expense

Stock-based compensation expense was calculated based on awards previously granted to employees, directors and non-employees that are ultimately expected to vest and has been reduced for estimated forfeitures.

Stock-based compensation expense was allocated as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 4,814	$ 4,211
General and administrative	3,723	3,609
Total stock-based compensation expense	$ 8,537	$ 7,820

As of March 31, 2023, total compensation cost not yet recognized related to unvested stock options was $58.5 million, which is expected to be recognized over a weighted-average period of 2.3 years. As of March 31,

2023, total compensation cost not yet recognized related to unvested RSUs was $3.7 million, which is expected to be recognized over a weighted-average period of 3.8 years.

8. Income Taxes

Since inception, the Company has incurred net losses, and the Company expects to record a net loss for the year ending December 31, 2023. Additionally, the Company's net deferred tax assets have been fully offset by a valuation allowance. Therefore, the Company did not record a tax provision for income taxes for the three months ended March 31, 2023 and 2022.

9. Subsequent Event

On April 3, 2023, the Company's board of directors approved a restructuring of the Company's workforce pursuant to which the Company's workforce will be reduced by 75 people, or approximately 33% of the Company's existing headcount as of such date. The restructuring was communicated to employees on April 4, 2023. The Company estimated that it will incur approximately $5.0 million in restructuring charges in connection with the restructuring, consisting of (i) approximately $4.5 million in cash-based expenses related to employee severance and notice period payments, benefits and related costs, and (ii) approximately $0.5 million in non-cash stock-based compensation expense related to the vesting of share-based awards. The Company expects that the majority of the restructuring charges will be incurred in the second quarter of 2023 and that the execution of the restructuring, including cash payments, will be substantially complete by the end of the second quarter of 2023.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with (1) the condensed consolidated financial statements and notes to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and (2) the audited consolidated financial statements and related notes and management's discussion and analysis of financial condition and results of operations for the fiscal year ended December 31, 2022 included in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission, or SEC, on February 28, 2023, or the 2022 Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors that could impact our business, including those set forth in the section titled "Risk Factors" under Part II, Item 1A in this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "aspire," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "should," "will" or the negative of these terms or other similar expressions.

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 on Form 10-Q, 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 we have conducted exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Overview of Our Business

We are a biopharmaceutical company focused on discovering and developing novel, potentially life-changing medicines based on scientific understanding of key biological pathways underlying grievous diseases with critical unmet or underserved patient need. These diseases represent a significant burden for patients and healthcare systems and, in some cases, are leading causes of morbidity and mortality. Since the commencement of our operations in 2008, we have generated a portfolio of product candidates ranging from early discovery to Phase 2b development. Currently, we have four programs in active ongoing clinical development. Our biology-centric drug discovery approach is therapeutic area agnostic and aims to seamlessly integrate interrogation of complex disease-associated biology and protein engineering expertise to unlock proprietary insights that are leveraged to generate promising product candidates and enable their rapid advancement into proof-of-concept studies. As explorers on the frontier of life-changing science, we aspire to operate one of the most productive research and development engines in the biopharmaceutical industry. All therapeutic candidates in our pipeline have been generated by our in-house discovery engine, led by biology and motivated by patient need.

Our pipeline is currently divided into two categories with separate approaches to development strategy and resource allocation in an effort designed to enable more of the product candidates in our pipeline to be advanced as effectively and efficiently as possible. To that end, we are currently focusing most of our execution efforts and resources on advancing our clinical-stage solid tumor oncology programs to potentially rapid proof of concept. For our other programs that are in therapeutic areas where clinical development is relatively resource intensive and can have long timelines to generate proof-of-concept data, due to the need to conserve capital and prioritize focused execution, we are actively seeking, or intend to seek, as applicable, collaboration, out licensing, partnership or other business development arrangements, or BD Arrangements, with third-party partners with sufficient resources and relevant domain expertise in order to further their development.

Pipeline Programs and Operational Updates

Key Programs in Active Development

Our pipeline includes four solid tumor oncology programs in active ongoing clinical development. We are currently focusing most of our execution efforts and resources on these key programs. We have intentionally built our clinical capabilities primarily in areas such as solid tumor oncology that offer development paths that are relatively resource efficient and have the potential to generate clinical proof-of-concept data more rapidly than certain other indications, although we may in the future pursue development of programs in other therapeutic areas. While we will opportunistically consider BD Arrangements to advance development of our key programs, we intend to invest our resources in their development even in the absence of BD Arrangements.

- **Solid Tumor Oncology**. Our solid tumor oncology product candidates NGM707, NGM831, NGM438 and NGM120 and their related compounds are wholly-owned by us.
    - **NGM707**. NGM707, the lead asset in our myeloid reprogramming and checkpoint inhibition portfolio, is a dual antagonist monoclonal antibody that is designed to improve patient immune responses to tumors by inhibiting both Immunoglobulin-like transcript 2, or ILT2 (also known as LILRB1), and Immunoglobulin-like transcript 4, or ILT4 (also known as LILRB2) receptors. We believe NGM707 has the potential to reprogram ILT4- and ILT2-expressing myeloid cells to shift them from a suppressive state that restricts anti-tumor immunity to a stimulatory state that may promote anti-tumor immunity. Blocking ILT2 also may reverse inhibition of ILT2-expressing lymphoid cells to further stimulate anti-tumor immune responses.
        - We are conducting an open-label Phase 1/2 clinical trial evaluating NGM707 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with advanced or metastatic solid tumors. We expect to enroll approximately 220 patients in this trial.
        - A Phase 1, Part 1a cohort evaluating NGM707 as a monotherapy was initiated in 2021 and a Phase 1, Part 1b cohort evaluating NGM707 in combination with pembrolizumab was initiated in 2022. Two Phase 2 expansion cohorts evaluating NGM707 in combination with pembrolizumab in specific tumor types were initiated in the first quarter of 2023.
    - **NGM831**. NGM831 is an antagonist antibody that is designed to block the interaction of the Immunoglobulin-like transcript 3, or ILT3 (also known as LILRB4) receptor, with fibronectin, as well as other cognate ligands. For tumors in which both ILT3 and fibronectin are upregulated, the ILT3-fibronectin signaling pathway may act as a stromal checkpoint to repress myeloid cell function and inhibit anti-tumor immunity. By inhibiting ILT3's interaction with fibronectin and its other ligands, we believe NGM831 has the potential to mobilize a patient's own immune system to fight tumors by shifting myeloid cells from a suppressive state to a stimulatory state and promoting anti-tumor activity.
        - We are conducting an open-label Phase 1/1b clinical trial to evaluate NGM831 as a monotherapy and in combination with pembrolizumab for the treatment of patients with advanced or metastatic solid tumors. A Phase 1, Part 1a cohort evaluating NGM831 as a monotherapy and a Phase 1, Part 1b cohort evaluating NGM831 in combination with pembrolizumab were initiated in 2022. Both cohorts are ongoing, and the protocol allows us to enroll up to 80 patients in these two cohorts.
    - **NGM438**. NGM438 is an antagonist antibody that is designed to inhibit leukocyte-associated immunoglobulin-like receptor 1, or LAIR1, and thereby promote anti-tumor immune responses. NGM438 has the potential to potently block the binding of all collagens to LAIR1, including tumor-derived collagens. Collagens produced by the tumor stroma, meaning the non-malignant, non-immune components of the tumor, are believed to bind LAIR1 to create an immuno-suppressive tumor microenvironment. The interaction of collagens from the tumor stroma with LAIR1 on immune cells represents a “stromal checkpoint” that restrains anti-tumor immune responses. Reinvigoration of these collagen-suppressed immune cells by blocking the binding of collagens to LAIR1 may address a key resistance mechanism that limits tumor responses to current immunotherapies.
        - We are conducting an open-label, Phase 1/1b clinical trial to evaluate NGM438 as a monotherapy and in combination with pembrolizumab for the treatment of patients with advanced or metastatic solid tumors. A Phase 1, Part 1a cohort evaluating NGM438 as a monotherapy and a Phase 1, Part 1b cohort evaluating NGM438 in combination with pembrolizumab were initiated in 2022. Both cohorts are ongoing, and the protocol allows us to enroll up to 80 patients in these two cohorts.
    - **NGM120**. NGM120 is an antagonist antibody that binds to glial cell-derived neurotrophic factor receptor alpha-like, or GFRAL, and is designed to block the effects of elevated serum levels of growth differentiation factor 15, or GDF15. We designed NGM120 as a potent, humanized monoclonal antibody inhibitor of GFRAL with the potential for once-monthly or less frequent dosing. Preclinical studies suggest that NGM120 may reduce tumor growth and improve survival in syngeneic orthotopic pancreatic tumor models in mice.

- We are conducting a Phase 1/2 clinical trial to assess NGM120's effect on cancer and cancer-related cachexia in patients with select advanced solid tumors, metastatic pancreatic cancer and metastatic castration-resistant prostate cancer, or mCRPC.

  The trial includes:

  - a Phase 1a cohort evaluating NGM120 as a monotherapy in patients with select advanced solid tumors,
  - a Phase 1b cohort evaluating NGM120 in combination with gemcitabine and Nab-paclitaxel in patients with metastatic pancreatic cancer,
  - an additional Phase 1b cohort testing NGM120 in combination with one or more lines of hormone therapies in patients with mCRPC, and
  - a Phase 2 cohort evaluating NGM120 in combination with gemcitabine and Nab-paclitaxel as first-line treatment in patients with metastatic pancreatic cancer (referred to as the PINNACLES trial).

  All four cohorts have completed enrollment.

Additional Programs Currently Without Significant Resource Allocation

Due to the need to conserve capital and prioritize focused execution, the remainder of our pipeline includes programs whose further development is primarily dependent on our ability to secure potential future BD Arrangements. These programs are in therapeutic areas where clinical development is relatively resource intensive and can have long timelines to generate proof-of-concept data. As a result, we are actively seeking, or intend to seek, as applicable, BD Arrangements with third-party partners possessing sufficient resources and relevant domain expertise in the relevant therapeutic area in order to further clinical development of these programs. In the absence of such BD Arrangements for these programs, we are unlikely to be able to advance their development unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development. These programs are set forth below:

- **NGM621**. NGM621 is a humanized Immunoglobulin 1, or IgG1, monoclonal antibody administered via intravitreal, or IVT, injection. NGM621 was engineered to potently bind to, and be a long-acting inhibitor of, complement C3 with the treatment goal of reducing the rate of disease progression in patients with geographic atrophy, or GA, secondary to age-related macular degeneration, or AMD.
- **Aldafermin.** Aldafermin is an engineered analog of human hormone fibroblast growth factor 19, or FGF19, that is administered through a once-daily subcutaneous injection. Aldafermin is wholly-owned by us. In May 2023, we reported topline data from the Phase 2b ALPINE 4 trial of aldafermin in 160 patients with compensated cirrhosis due to non-alcoholic steatohepatitis, or NASH (liver fibrosis stage 4, or F4, by the NASH Clinical Research Network classification). The 48-week trial assessed the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg doses of aldafermin compared to placebo. The primary objective of the ALPINE 4 study was to evaluate the impact on Enhanced Liver Fibrosis, or ELF, score at week 48. The ELF score is a reproducible, quantitative non-invasive liver prognostic test that evaluates liver fibrosis and correlates to liver-related outcomes. The study met its primary endpoint with a statistically significant reduction in ELF score from baseline to week 48 in patients treated with 3 mg of aldafermin versus patients receiving placebo. Patients receiving 3 mg of aldafermin had a 0.5 point greater reduction in ELF at week 48 compared to patients receiving placebo (p-value=0.0003). On the secondary endpoint of fibrosis improvement of ≥1 stage (for which the trial was not statistically powered), 21% (p-value=0.39) and 23% (p-value=0.36) of patients in the 1 mg and 3 mg cohorts, respectively, achieved fibrosis improvement versus 15% in the placebo cohort at week 48. A 0.3 mg aldafermin cohort was part of the original design of the trial and enrolled 7 patients prior to being discontinued in favor of enrolling more patients in the 1 mg and 3 mg arms of the trial. Patients in the 0.3 mg arm were primarily evaluated for safety. Aldafermin was generally well tolerated with no treatment-related serious adverse events and a safety and tolerability profile generally consistent with prior trials of aldafermin, including higher levels of gastrointestinal events in patients treated with aldafermin as compared to patients treated with placebo.
- **MK-3655 (NGM313)**. MK-3655 (NGM313) is an agonistic antibody discovered by us that selectively activates fibroblast growth factor receptor 1c-beta-klotho, or FGFR1c/KLB, which regulates insulin sensitivity, blood glucose and liver fat and is administered every four weeks through a subcutaneous injection. MK-3655 (NGM313) was licensed by Merck in November 2018 and was being developed by

Merck in patients with NASH and liver fibrosis stage 2 or 3. In April 2023, the license rights granted to Merck with respect to MK-3655 (NGM313) reverted to us and the program is now wholly-owned by us.

- **NGM936.** NGM936 is a bispecific T cell engager therapeutic candidate for the treatment of hematologic malignancies that targets ILT3 and cluster of differentiation 3, or CD3. NGM936 is designed to direct T cell mediated killing of ILT3-positive cancer cells while sparing normal hematopoietic stem cells, or HSCs, and minimizing CD3-driven cytokine release. ILT3, a myeloid-cell restricted receptor, has enriched expression in myelomonocytic leukemia, monocytic leukemia and leukemia stem cells but is not expressed on healthy HSCs. This expression profile of ILT3 may make it an effective target for the treatment of monocytic acute myeloid leukemia, or AML, and multiple myeloma. NGM936 has been evaluated in preclinical studies, where it has demonstrated the ability to potently kill ILT3+ AML cells, kill ILT3+ multiple myeloma cells and preserve healthy bone marrow cells.

We have additional programs that are in various stages of development ranging from functional validation to preclinical development.

The success of each of our product candidates may be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability, sales capability, any future partners, the sufficiency of our cash resources, regulatory matters, third-party payor matters and commercial viability. We do not have any products approved for sale and do not anticipate generating revenue from product sales for the foreseeable future, if ever.

Business Development and Merck Collaboration Updates

Pursuing BD Arrangements has been and is expected to continue to be a key component of our strategy. Given the breadth of opportunities that have been, and may in the future be, produced by our discovery engine, we are actively seeking, or intend to seek, as applicable, BD Arrangements with third-party partners to progress, in whole or in part, the development of one or more of our product candidates. We believe that this strategy, if successfully implemented, may enable more of the programs in our pipeline, including those in active development by us, to be advanced as effectively and efficiently as possible. As described above, further development of NGM621, aldafermin, MK-3655 (NGM313) and NGM936 is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of those programs unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development.

Our collaboration with Merck, described in "Business - Licensing and Collaboration Arrangements - Merck Collaboration" in Part I, Item 1 of the 2022 Annual Report on Form 10-K and Note 5, “Research Collaboration and License Agreements - Merck,” in our notes to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, historically provided us with robust financial support that enabled us to broaden and accelerate our research efforts and to develop more product candidates for major indications than we likely could have advanced on our own. We do not have any committed external source of funds, other than pursuant to our collaboration with Merck under the amended and restated research collaboration, product development and license agreement we entered into with Merck on June 30, 2021, or the Amended Collaboration Agreement. Currently, the only ongoing activities funded under the Amended Collaboration Agreement are ongoing cardiovascular or metabolic-, or CVM-, related activities. In 2023, the R&D funding we receive from Merck under the Amended Collaboration Agreement will be limited and continue to be substantially lower on an annual basis than the research funding previously provided by Merck. In this regard, for the period that started on April 1, 2023 and ends on March 31, 2024, we expect to receive funding of only approximately $4.0 million in the aggregate from Merck for the ongoing CVM-related activities and for certain costs and reimbursements related to the NGM621 program. Funding from Merck after December 31, 2023 is expected to be minimal. The research phase for the CVM-related programs under the Amended Collaboration Agreement will continue through March 31, 2024, unless the parties mutually agree to extend the research phase through March 31, 2026, in which case Merck would provide up to a total of $20.0 million in R&D funding during the additional two years of the CVM program research phase.

Restructuring

On April 4, 2023, we announced a restructuring of our workforce pursuant to which our workforce will be reduced by 75 people, or approximately 33% of our existing headcount as of such date. We estimated that we will incur approximately $5.0 million in restructuring charges in connection with the restructuring, consisting of (i) approximately $4.5 million in cash-based expenses related to employee severance and notice period payments, benefits and related costs, and (ii) approximately $0.5 million in non-cash stock-based compensation expense related to the vesting of share-based awards. We expect that the majority of the restructuring charges will be incurred in the second quarter of 2023 and that the execution of the restructuring, including cash payments, will be substantially complete by the end of the second quarter of 2023.

Operational Updates

We do not own, and have no plans to establish, any manufacturing facilities. All of our manufacturing activities are outsourced to third-party contract development and manufacturing organizations or third-party contract manufacturing organizations, which we refer to collectively as CMOs, which are generally single-source suppliers of the drug product or drug substance they are manufacturing for us. We also utilize third-party contract research organizations, or CROs, to carry out many of our clinical development activities. We expect to be reliant on CMOs and CROs for these activities for the foreseeable future. Significant portions of our research and development, or R&D, resources are focused, and will continue to be focused, on the manufacture and testing of clinical trial materials. If our CROs and CMOs fail to satisfy their contractual duties to us or meet expected deadlines or if our CMOs experience difficulties in scaling production, higher than anticipated costs or lower than anticipated yields, product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, turnover of qualified staff or improper storage conditions, difficulties with quality control, product stability or quality assurance testing, or difficulties procuring raw materials or components as a result of the ongoing COVID-19 pandemic or otherwise, our ongoing and planned trials and possible acceleration or expansion of those trials may be delayed, perhaps substantially, or abandoned, which could materially and adversely affect our business. For example, in 2022, our planned individual new drug application, or IND, submissions for NGM831 and NGM438 were delayed due to challenges at one of our CMOs with respect to the manufacture of those product candidates, primarily related to analytical method qualification and release testing. It is possible that we could experience further supply-related delays that would create supply challenges and possible timing delays for ongoing and planned clinical trials or delay the commencement of first-in-human testing of future product candidates. In addition, there is increased competition in the biotechnology industry for CMO manufacturing slots and other capabilities generally, which has had, and may continue to have, a negative impact on the availability of manufacturing capacity and therefore our ability to supply clinical trial materials for planned, ongoing, accelerated or expanded clinical trials. Our CMOs' facilities and operations have also been adversely affected by labor, raw material and component shortages, high turnover of staff and difficulties in hiring trained and qualified replacement staff. Changes in economic conditions, supply chain constraints, labor, raw material and component shortages and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, could lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs. These supply chain effects, increased competition and higher costs of acquired goods and services may negatively impact our business operations and our financial results.

In addition, all of our product candidates other than NGM621 and aldafermin are currently manufactured solely at a facility in Lithuania. Following Russia's invasion of Ukraine in February 2022, NATO deployed additional military forces to Eastern Europe, including to Lithuania. The ongoing conflict between Russia and Ukraine and the retaliatory measures taken or that may be taken by the United States, NATO and others, including significant sanctions against Russia, create global security concerns and regional instability, including due to the possibility of expanded regional or global conflict, and are likely to have short-term and likely longer-term negative impacts on regional and global economies, any or all of which could disrupt our supply chain and adversely affect our ability to conduct ongoing and future clinical trials of our product candidates and our ability to raise capital on favorable terms.

In July 2022, we entered into an operating lease agreement, or the 2024 Lease Agreement, for our existing corporate office space and facilities at 333 Oyster Point Blvd., South San Francisco, California, which allows us to remain in our existing facilities through December 31, 2033, subject to our compliance with the 2024 Lease Agreement. We also have an option to extend the 2024 Lease Agreement for a period of either eight or ten years after the initial ten-year term of January 1, 2024 to December 31, 2033.

We seek to allocate our capital efficiently and strategically and fund our active development portfolio based on each program's scientific and other merits. Our discipline has been demonstrated by our decision not to proceed with development activities on multiple potentially viable product candidates for portfolio management and capital conservation reasons to concentrate our resources and focus our execution on our solid tumor oncology programs. Given the substantial decrease in research funding we now receive from Merck as compared to historical periods commensurate with the decreased scope of the collaboration, we need to devote a substantial amount of our own financial resources to fund our R&D programs, and we may need to delay or suspend development activities on product candidates that we consider promising unless and until we are able to raise sufficient additional capital and/or we need to enter into additional BD Arrangements in order to proceed with such development through to regulatory approval.

Financial Highlights

Since inception, we have funded our operations primarily through:

- fees received from collaboration partners, which since inception through March 31, 2023 includes reimbursement of R&D expenses of $541.6 million and upfront cash licensing fees of $123.0 million, primarily from Merck, and a payment of $20.0 million from Merck to license MK-3655 (NGM313) and related compounds;
- proceeds from private placements of convertible preferred stock prior to our initial public offering, or IPO, including approximately $106.0 million of our Series E convertible preferred stock purchased by Merck;
- net proceeds from our IPO in 2019 of approximately $107.8 million, together with proceeds from the concurrent private placement of shares of common stock to Merck of $65.9 million;
- net proceeds of $134.6 million from the sale of 5,324,074 shares of our common stock in January 2021 upon completion of an underwritten public offering of our common stock, or the follow-on offering, which included the full exercise by the underwriters of their option to purchase additional shares; and
- net proceeds of $71.5 million through March 31, 2023 from sales of approximately 4.1 million shares of our common stock under an Open Market Sale Agreement℠, or the Sales Agreement, we entered into with Jefferies LLC, or Jefferies, in June 2020.

At March 31, 2023, we had $231.0 million in cash, cash equivalents and short-term marketable securities.

We have incurred net losses each year since our inception. As of March 31, 2023, we had an accumulated deficit of $629.3 million. Substantially all of our net losses have resulted from costs incurred in connection with our R&D programs and general and administrative, or G&A, costs associated with our operations. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenses on other R&D activities, and the amount of R&D funding we receive from future BD Arrangements, if any. For further discussion of our financial position and future sources of funding, see “Liquidity and Capital Resources” below.

Financial Operations Overview

Related Party Revenue

Our revenue to date has been generated primarily from recognition of license fees and R&D service funding pursuant to our collaboration with Merck. Merck is also a significant stockholder and, as such, collaboration revenue from Merck is referred to as related party revenue.

Since the Company's inception through March 31, 2023, Merck paid us $616.8 million pursuant to the terms of our collaboration. Due to the nature of our collaboration with Merck and the timing of related revenue recognition, our revenue has fluctuated from period to period in the past and we expect that it will continue to decrease in 2023 given the substantial reduction in the level of funding we will receive from Merck in 2023. After December 31, 2023, we expect funding, and revenue recognized, from Merck to be minimal. As a result, we believe that period-to-period comparisons of our revenue may not be meaningful and should not be relied upon as being indicative of future performance.

We use the cost-based input method in accordance with Accounting Standards Codification 606, or ASC 606, to calculate the corresponding amount of revenue to recognize at each reporting period. In applying the cost-based input measure of revenue recognition, we measure actual costs incurred relative to budgeted costs to fulfill our performance obligation. We apply considerable judgment when we re-evaluate the estimate of expected costs to satisfy the performance obligation each reporting period and make adjustments for any significant changes. A significant change in the estimate of expected costs under the Amended Collaboration Agreement could have a material impact on revenue recognized (including the possible reversal of previously recognized revenue) at each reporting period.

Our related party revenue was as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Related party revenue	$ 2,247	$ 20,948

Research and Development Expenses

R&D efforts include drug discovery and other research activities and development activities relating to our product candidates, such as manufacturing drug substance, drug product and other clinical trial materials, conducting preclinical studies and clinical trials and providing support for these operations. Our R&D expenses consist of both internal and external costs. Our internal costs include employee, consultant, facility and other R&D operating expenses. Our external costs include fees paid to CROs and other service providers in connection with our clinical trials and preclinical studies, third-party license fees and CMO costs related to manufacturing drug substance, drug product and other clinical trial materials.

Our R&D efforts are extensive and costly. Our R&D expenses related to the development of our product candidates consist primarily of:

- fees paid to our CROs in connection with our clinical trials and other related clinical trial fees, when applicable;
- costs related to acquiring and manufacturing drug substance, drug product and clinical trial materials, and the costs of continued testing, such as process validation testing and stability testing, of drug substance and drug product;
- costs related to toxicology testing and other research- and preclinical-related studies;
- salaries and related overhead expenses, which include stock-based compensation and benefits, for personnel in R&D functions;
- fees paid to consultants for R&D activities;
- R&D operating expenses, including facility costs and depreciation expenses; and
- costs related to compliance with regulatory requirements.

We need to devote a substantial amount of our own financial resources to our wholly-owned development programs, primarily our solid tumor oncology programs in active ongoing clinical development. As a result, further development of NGM621, aldafermin, MK-3655 (NGM313) and NGM936 is currently primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of those programs unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development. For the foreseeable future, we anticipate a significant portion of our financial resources, other than those received from Merck which are dedicated to activities under the Amended Collaboration Agreement, will be directed to activities required to initiate and advance clinical trials of our solid tumor oncology programs.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of our product candidates or if we will be able to enter into BD Arrangements or otherwise raise adequate additional capital to meet our funding requirements to support such efforts, particularly outside of our key solid tumor oncology programs. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainty of:

- the scope, rate of progress, results and expense of our ongoing, as well as any future, clinical trials and other R&D-related activities;
- the impact and timing of any interactions with regulatory authorities, including timing and receipt of regulatory approvals;
- our ability to hire and retain key R&D personnel;
- manufacturing scale-up challenges, production shortages or other supply disruptions for clinical trial materials, including raw materials and components;
- the effects of the continuing COVID-19 pandemic on our employees, patients, clinical trial sites and our CROs, CMOs and other service providers;

- the timely and quality performance of our CROs, CMOs and other service providers;
- the effect of products that may compete with our product candidates or other market developments; and
- our ability to expand and enforce our intellectual property portfolio.

A change in the outcome of any of the risks and uncertainties associated with the development of a product candidate could mean a significant change in the costs, as well as the timing, associated with the development of that product candidate. For example, if the FDA or a comparable foreign health authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. For additional discussion of the risks and uncertainties associated with our R&D efforts, see “Risk Factors—Risks Related to Our Business and Industry,” “—Risks Related to Our Dependence on Third Parties,” “—Risks Related to Regulatory Approvals” and "—Risks Related to Our Intellectual Property” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

General and Administrative Expenses

G&A expenses consist primarily of salaries and other related costs, including stock-based compensation and benefits. Other significant costs include legal fees relating to patent and corporate matters, facility costs not otherwise included in R&D expenses and fees for accounting and other consulting services.

We anticipate that our G&A expenses in 2023 will decrease moderately compared to 2022 primarily due to the workforce restructuring implemented in the second quarter of 2023. Beginning in 2024, our G&A expenses will include an increase in operating lease expenses under the 2024 Lease Agreement. Additionally, we anticipate continued costs associated with being a public company, including expenses related to services associated with maintaining compliance with Nasdaq listing rules and related SEC requirements and costs related to insurance, investor relations and compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. In addition, we may continue to incur expenses associated with negotiating and entering into BD Arrangements.

Results of Operations

Our results of operations were as follows (in thousands):

	Three Months Ended March 31,		
	2023	2022	Change
Related party revenue	$ 2,247	$ 20,948	$ (18,701)
Operating expenses:			
Research and development	40,857	42,806	(1,949)
General and administrative	11,584	10,723	861
Total operating expenses	52,441	53,529	(1,088)
Loss from operations	(50,194)	(32,581)	(17,613)
Interest income, net	2,584	176	2,408
Other expense, net	(37)	(45)	8
Net loss	$ (47,647)	$ (32,450)	$ (15,197)

Related Party Revenue from Merck

Revenue decreased $18.7 million in the three months ended March 31, 2023 compared to the same period in 2022 due to a decrease in R&D revenue under the Amended Collaboration Agreement with Merck.

Due to the nature of our collaboration with Merck and the timing of related revenue recognition, our revenue has fluctuated from period to period in the past and we expect that it will continue to decrease in 2023 given the substantial reduction in the level of funding we will receive from Merck. In this regard, for the period that started on April 1, 2023 and ends on March 31, 2024, we expect to receive funding of only approximately $4.0 million in the aggregate from Merck for the ongoing CVM-related activities and for certain costs and reimbursements related to the NGM621 program. After December 31, 2023, we expect funding, and revenue recognized, from Merck to be minimal.

Research and Development Expenses

Our R&D expenses by program were as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
External R&D expenses:		
NGM707 (Anti-ILT2/ILT4 dual antagonist)	$ 6,876	$ 3,678
NGM438 (LAIR1 antagonist)	2,965	2,022
Aldafermin (FGF19 analog)	2,286	4,362
NGM831 (ILT3 antagonist)	1,642	1,739
NGM120 (GFRAL antagonist)	1,168	1,479
NGM621 (C3 inhibitor)	1,136	5,486
Other external R&D expenses	251	120
Total external R&D expenses	16,324	18,886
Personnel-related expenses	17,195	15,895
Internal and unallocated R&D expenses (1)	7,338	8,025
Total R&D expenses	$ 40,857	$ 42,806

(1) Internal and unallocated R&D expenses consist primarily of research supplies and consulting fees, which we deploy across multiple R&D programs.

R&D expenses decreased $1.9 million in the three months ended March 31, 2023 compared to the same period in 2022 primarily due to our completed trial of NGM621 and a decrease in expenses for our manufacturing activities and our clinical trials of aldafermin, partially offset by increases in external expenses for our ongoing clinical trials of our solid tumor oncology portfolio and personnel-related expenses.

We expect our R&D expenses will decrease moderately in 2023 compared to 2022 as we suspend development activities related to NGM621 and our other preclinical ophthalmology programs, complete activities related to ALPINE 4 and focus on the continued advancement of our solid tumor oncology portfolio.

General and Administrative Expenses

G&A expenses increased $0.9 million in the three months ended March 31, 2023 compared to the same period in 2022 primarily due to an increase of $1.2 million in legal-related expenses and $0.5 million in compensation-related expenses, partially offset by a decrease of $0.8 million in depreciation expense.

We anticipate that our G&A expenses in 2023 will decrease moderately compared to 2022 primarily due to the workforce restructuring implemented in the second quarter of 2023.

Interest Income, net

Interest income, net, increased $2.4 million in the three months ended March 31, 2023 compared to the same period in 2022 primarily due to higher yielding investments.

Liquidity and Capital Resources

Funding Requirements

We have no products approved for commercial sale, have not generated any revenue from product sales to date and we are not and may never be profitable. We have incurred losses in each year since commencing operations, and we expect to incur significant operating losses in 2023 and over the next several years. As of March 31, 2023, we had an accumulated deficit of $629.3 million, and we expect our accumulated deficit will continue to increase over time.

We have an active discovery research group and have spent significant resources to fund R&D of multiple pipeline programs. Our pipeline includes four solid tumor oncology programs, NGM707, NGM831, NGM438 and NGM120, in active ongoing clinical development. We are currently focusing most of our execution efforts and

resources on these programs as our substantial research, development, clinical trial and related activities continue. While we will opportunistically consider BD Arrangements to advance development of these key programs, we intend to invest our resources in their development even in the absence of BD Arrangements.

Due to the need to conserve capital and prioritize focused execution, the remainder of our pipeline includes programs whose further development is primarily dependent on our ability to secure potential future BD Arrangements. We are actively seeking, or intend to seek, as applicable, BD Arrangements with third-party partners possessing sufficient resources and relevant domain expertise in the relevant therapeutic area in order to further clinical development of these programs. In the absence of such BD Arrangements for these programs, we are unlikely to be able to advance their development unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development.

Prior to 2022, we received substantial R&D funding from our collaboration with Merck. However, under the narrower scope of the Amended Collaboration Agreement, R&D funding from Merck beginning April 2022 was and is expected to continue to be substantially lower than the R&D funding previously provided by Merck. For the period that started on April 1, 2023 and ends on March 31, 2024, we expect to receive funding of only approximately $4.0 million in the aggregate from Merck for activities remaining under the Amended Collaboration Agreement and for certain costs and reimbursements related to the NGM621 program. Funding from Merck after December 31, 2023 is expected to be minimal.

Our cash requirements for fiscal year 2023 will continue to be driven by our R&D and G&A expenses. In 2022 and 2021, our R&D expenses were $181.1 million and $161.7 million, respectively. In 2023, we expect our R&D expenses to decrease moderately compared to 2022 as we suspend development activities related to NGM621 and our other preclinical ophthalmology programs, complete activities related to ALPINE 4 and focus on the continued advancement of our solid tumor oncology portfolio. In 2022 and 2021, our G&A expenses were $40.5 million and $36.9 million, respectively. In 2023, we expect our G&A expenses will decrease moderately compared to 2022 primarily due to the workforce restructuring implemented in the second quarter of 2023. Beginning in 2024, our operating lease costs will increase pursuant to the 2024 Lease Agreement we entered into in July 2022 for our current corporate office space and facilities in South San Francisco, California. Our current sublease will expire on December 31, 2023. The 2024 Lease Agreement will commence on January 1, 2024 and expire on December 31, 2033. We will pay an initial monthly base rent of approximately $0.9 million for the first year, which is subject to increase at an annual rate of 3.5% each year thereafter, plus certain operating and tax expenses.

We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to fund our operations for at least twelve months from the date this Quarterly Report on Form 10-Q is filed. Moreover, based on our current development plans and related assumptions, we believe our current cash position is sufficient to fund our key solid tumor oncology programs through generation of proof-of-concept data. We have based these estimates on plans and assumptions that may prove to be insufficient or inaccurate (for example, with respect to anticipated costs, timing or success of certain activities), and we could utilize our available capital resources sooner than we currently expect. For example, although we implemented a workforce restructuring in the second quarter of 2023 as part of our broader efforts designed to reduce our operating expenses, we may not achieve the expected benefits of our cost preservation efforts on the expected timeline, or at all, and we could otherwise consume capital more rapidly than we currently anticipate. In addition, our forecast of 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 as a result of a number of factors, including the factors discussed under “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q. Nonetheless, in order to advance our current and potential future product candidates through development and to regulatory approval and commercialization, we need to raise significant additional capital and/or we need to enter into BD Arrangements to obtain funding or other resources for one or more of our wholly-owned programs. Neither may be possible and, as a result, we may need to significantly delay, scale back or discontinue development of or abandon some or all of our product candidates, or scale back or discontinue our discovery research efforts, any of which could have a material adverse effect on our business, operating results and prospects, or we may be required to cease operations altogether.

Sources of Liquidity

Cash and Investments

As of March 31, 2023, we had cash and cash equivalents of $67.5 million and short-term marketable securities of $163.5 million.

Merck Collaboration

The revenue we receive under the Amended Collaboration Agreement with Merck is currently our only source of revenue. For the period that started on April 1, 2023 and ends on March 31, 2024, we expect to receive funding of only approximately $4.0 million in the aggregate from Merck for the ongoing CVM-related activities and for certain costs and reimbursements related to the NGM621 program. See "Overview of Our Business – Business Development and Merck Collaboration Updates" above.

Other Sources of Capital

In June 2020, we entered into the Sales Agreement with Jefferies. In accordance with the terms of the Sales Agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $150.0 million from time to time through Jefferies, acting as our sales agent. As of December 31, 2022 and March 31, 2023, $76.2 million of our common stock remained available to be sold under the Sales Agreement, subject to conditions specified in the Sales Agreement.

We plan to finance our future cash needs through public or private equity or debt offerings, including under the Sales Agreement, BD Arrangements or a combination of these potential financing sources. Additional capital may not be available in sufficient amounts, on reasonable terms or when we need it, if at all.

Our ability to raise additional capital through public or private equity or debt offerings may be adversely impacted by worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, and in the biotechnology industry specifically. While the long-term economic impact of either the COVID-19 pandemic or the conflict between Russia and Ukraine is difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, inflation rates across the globe have increased to levels not seen in decades. Increased inflation may result in increased operating costs (including labor costs) and may affect our operating budgets. In addition, the U.S. Federal Reserve has raised, and is expected to further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Moreover, the recent closures of Silicon Valley Bank, or SVB, and Signature Bank have resulted in broader financial institution liquidity risk and concerns. Although as of March 31, 2023, we had only approximately $6.0 million in deposits and other accounts with SVB, which is now a division of First Citizens Bank, consisting of $4.0 million in letters of credit related to our facilities leases and approximately $1.9 million held in a sweep account used to purchase shares in money-market funds through SVB, and we incurred no losses as a result of the closure of SVB, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages that could materially harm our business and financial condition. In this regard, we continue to maintain our cash at SVB and other banks, often in balances that exceed the current FDIC insurance limits, and the failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and/or custodial financial institutions. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions fail or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash, cash equivalents and investments, including transferring funds, making payments or receiving funds may be threatened and our ability to raise additional capital could be substantially impaired, any of which could materially and adversely affect our business and financial condition. In any event, if the financial market disruptions and economic slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could negatively affect our financial condition and our ability to pursue our business strategy.

In addition, if we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Furthermore, any securities that we may issue may have rights senior to those of our common stock and could contain covenants or protective rights that would lead to restrictions on our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

While we may opportunistically consider BD Arrangements to advance development of our key solid tumor oncology programs, we are actively seeking, or intend to seek, as applicable, BD Arrangements with third-party partners to progress, in whole or in part, the development of one or more of our other programs whose further

development is primarily dependent on our ability to secure potential future BD Arrangements. We believe that this strategy, if successfully implemented, may enable more of the product candidates in our pipeline to be advanced as effectively and efficiently as possible. If we are unable to secure BD Arrangements for NGM621 and our preclinical ophthalmology programs, aldafermin, MK-3655 (NGM313) and NGM936, we may discontinue or abandon any or all of them altogether, in which case we will not realize any return on our investments in these programs. Even if we are successful in securing BD Arrangements for these programs, we will likely have limited control over the amount and timing of resources that our partners dedicate to the development or commercialization of the applicable product candidates. Our ability to generate revenue from any such BD Arrangement will depend on the specific terms of the BD Arrangement.

If we are unable to raise adequate additional capital through public or private equity or debt offerings, BD Arrangements or otherwise, on acceptable terms or at all, we may be delayed in or prevented from pursuing our planned and any future development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects, or we may be required to cease operations altogether.

Cash Flow Activity

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

	Three Months Ended March 31,	
	2023	2022
Net cash provided by (used in):		
Operating activities	$ (41,827)	$ (35,738)
Investing activities	35,641	(6,853)
Financing activities	279	668
Net decrease in cash, cash equivalents and restricted cash	$ (5,907)	$ (41,923)

Operating Activities

In the three months ended March 31, 2023, net cash used in operating activities was $41.8 million, which consisted of a net loss of $47.6 million, adjusted for non-cash charges of $8.7 million and a change in operating assets and liabilities of $2.9 million. The non-cash charges consisted primarily of stock-based compensation expense of $8.5 million. The change in operating assets and liabilities was mainly driven by a decrease in accrued liabilities of $13.4 million partially offset by an increase in the related party receivable of $6.3 million and an increase in accounts payable of $4.8 million.

In the three months ended March 31, 2022, net cash used in operating activities was $35.7 million, which consisted of a net loss of $32.5 million, adjusted for non-cash charges of $10.7 million and a change in operating assets and liabilities of $14.0 million. The non-cash charges consisted primarily of stock-based compensation expense of $7.8 million, depreciation expense of $1.4 million and amortization of a premium on marketable securities of $0.5 million. The change in operating assets and liabilities was mainly driven by decreases in contract liabilities of $12.7 million and accrued liabilities of $4.7 million, partially offset by an increase in the related party receivable of $4.8 million.

Investing Activities

In the three months ended March 31, 2023, net cash provided by investing activities was $35.6 million, which consisted primarily of $50.8 million in net proceeds on maturity of marketable securities offset by purchases of marketable securities of $14.5 million.

In the three months ended March 31, 2022, net cash used in investing activities was $6.9 million, which consisted primarily of purchases of marketable securities of $86.9 million partially offset by $80.3 million in net proceeds on maturity of marketable securities.

Financing Activities

In both the three months ended March 31, 2023 and March 31, 2022, net cash provided by financing activities consisted of proceeds from our employee equity incentive plans.

Contractual Obligations

We have contractual obligations related to our lease liabilities. In July 2022, we entered into the 2024 Lease Agreement for the corporate office space and facilities in South San Francisco, California that we currently occupy pursuant to a sublease agreement scheduled to expire on December 31, 2023. The initial term of the 2024 Lease Agreement will commence on January 1, 2024 and expire on December 31, 2033. Base rent during the initial ten-year term of the 2024 Lease Agreement will total $124.1 million. See Note 6 to our condensed consolidated financial statements included in Part I, Item 1,“Financial Statements” of this Quarterly Report on Form 10-Q for additional information.

We enter into agreements in the normal course of business with CROs for clinical trials, CMOs and other vendors for preclinical studies, supplies, manufacturing and other services and products for operating purposes. These agreements are generally cancellable at any time by us, upon prior written notice, and may or may not include cancellation fees. Given that the amount and timing related to such payments are uncertain, they are not considered to be contractual obligations. As of March 31, 2023, we had not accrued for any termination or cancellation charges for any of these agreements as these were not considered probable. Significant portions of our R&D resources are focused, and will continue to be focused, on the manufacture and testing of clinical trial materials. See "Liquidity and Capital Resources - Funding Requirements" above for information regarding our expected R&D spend.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, low single-digit royalties and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our condensed consolidated balance sheets and are not considered to be contractual obligations. See "Business - Licensing and Collaboration Arrangements" in Part I, Item 1 of our 2022 Annual Report on Form 10-K for additional information regarding our current in-license agreements.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our condensed consolidated financial statements, as well as revenue and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. In accordance with U.S. GAAP, we base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions. We believe that there have been no significant changes in our critical accounting policies and estimates disclosed in our 2022 Annual Report on Form 10-K.

Recent Accounting Pronouncements

See Note 2 to our condensed consolidated financial statements included in Part I, Item 1, “Financial Statements,” of this Quarterly Report on Form 10-Q for a description of recent accounting pronouncements applicable to our business.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the three months ended March 31, 2023, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A “Quantitative and Qualitative Disclosures About Market Risk” in our 2022 Annual Report on Form 10-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of March 31, 2023, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and

procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2023, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 2023, there have been no changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material litigation or other material legal proceedings.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before deciding whether to make an investment decision with respect to our common stock. You should also refer to the other information contained in this Quarterly Report on Form 10-Q, including in Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our condensed consolidated financial statements and related notes, as well as our other filings with the U.S. Securities and Exchange Commission, or SEC. Our business, financial condition, results of operations, stock price and prospects could be materially and adversely affected by any of these risks or uncertainties. In any such case, the trading price of our common stock could decline, and you could lose all or part of your investment. We caution you that the risks, uncertainties and other factors referred to below and elsewhere in this Quarterly Report on Form 10-Q may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock. Moreover, new risks will emerge from time to time. It is not possible for our management to predict all risks.

Risk Factor Summary

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found immediately following this risk factor summary. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should carefully consider the risks and uncertainties described immediately following this risk factor summary as part of your evaluation of an investment in our common stock.

- We need to successfully complete rigorous preclinical and clinical testing of our product candidates before we can seek regulatory approval, and the regulatory approval processes of the U.S. Food and Drug Administration, or FDA, and comparable foreign health authorities are lengthy and inherently unpredictable, and if we are not successful at each step of the process, commercialization of our product candidates will be delayed or prevented.
    - Our product candidates are in early stages of development, with our most advanced product candidates only in Phase 2 development.
    - Our product candidates may fail to demonstrate safety and efficacy in ongoing and future clinical trials, may never achieve regulatory approval and may not be able to be successfully commercialized due to competition or other factors.
- We have incurred net losses every year since our inception, we have no source of product revenue, we expect to continue to incur significant operating losses and we may never become profitable.
- All of our revenue for recent periods has been received from a single collaboration partner, Merck Sharp & Dohme LLC, or Merck, and that revenue will continue to be substantially lower in 2023 and minimal thereafter.
- We need significant additional capital to proceed with development and commercialization of our current and potential future product candidates and to finance our other operations, and that additional capital may not be available to us on acceptable terms, or at all; as a result, we may need to significantly delay, scale back or discontinue development of or abandon some or all of our product candidates, or scale back or discontinue our discovery research efforts, or we may be required to cease operations altogether.
- We may depend in the future on collaboration, out licensing, partnership or other business development arrangements, or BD Arrangements, with third-party partners for the development and commercialization of our product candidates and for revenue and, if we are unable to secure those BD Arrangements, or if any future BD Arrangements are not successful, we may not be able to capitalize on the market potential of our product candidates or continue their development. BD Arrangements involve numerous risks, any of which could materially and adversely affect our business and financial condition.

- While we may opportunistically consider BD Arrangements to advance development of our key solid tumor oncology programs, we are actively seeking, or intend to seek, as applicable, BD Arrangements with third-party partners to progress, in whole or in part, the development of one or more of our other programs whose further development is primarily dependent on our ability to secure potential future BD Arrangements, and if we are unable to secure BD Arrangements to support these programs, which include NGM621, aldafermin, MK-3655 (NGM313) and NGM936, we are unlikely to be able to advance their development unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development, and may discontinue or abandon any or all of these programs altogether, in which case we will not realize any return on our investments in those programs.
- We may not be able to obtain and maintain other relationships with third-party partners and service providers that are necessary to develop, manufacture and commercialize some or all of our product candidates.
- We rely completely on contract manufacturers for the manufacture of our product candidates and the process of manufacturing, and conducting release testing for, our biologic product candidates is complex, highly regulated and subject to many risks, any of which could substantially increase our costs and limit supply of our product candidates and any future products needed for clinical trials and commercialization.
- Our product candidates other than NGM621 and aldafermin are currently manufactured at a facility in Lithuania. The ongoing conflict between Russia and Ukraine and the retaliatory measures taken or that may be taken by the United States, NATO and others against Russia create global security concerns, any or all of which could disrupt our supply chain and adversely affect our ability to conduct ongoing and future clinical trials of our product candidates and our ability to raise capital on favorable terms.
- We may not successfully identify new product candidates to expand our development pipeline.
- Our future success depends in part on our ability to attract and retain highly skilled employees, including members of our current senior management team.
- We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, us.
- Our business could be materially and adversely affected in the future by effects of disease outbreaks, epidemics and pandemics, including the COVID-19 pandemic.
- Our success depends in significant part upon our ability to obtain and maintain intellectual property protection for our products and technologies.
- Our principal stockholders, including entities affiliated with The Column Group, Merck and our management, own a substantial percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.
- We or third parties we rely on or partner with could experience a cybersecurity incident that could harm our business.
- The market price of our common stock has been and may continue to be volatile, and you could lose all or part of your investment.
- We continue to incur increased costs as a result of operating as a public company and our management devotes substantial time to public company compliance initiatives; for example, we are obligated to develop and maintain proper and effective internal control over financial reporting and to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act.

Risks Related to Our Financial Condition and Capital Needs

We have incurred net losses every year since our inception and have no source of product revenue. We expect to continue to incur significant operating losses and may never become profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. As a result, we are not profitable and have incurred losses in each year since commencing operations. Our net losses were $162.7 million, $120.3 million and $102.5 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of March 31, 2023, we had an accumulated deficit of $629.3 million.

We expect to continue to incur significant research and development, or R&D, and other expenses related to our ongoing operations for the foreseeable future, particularly to fund R&D of, and seek regulatory approvals for, our product candidates. We incurred substantial net operating losses in 2022 and expect to continue to incur significant operating losses in 2023 and over the next several years as our research, development, manufacturing, preclinical studies, clinical trial and related activities increase. We expect our accumulated deficit will also increase

in future periods. The size of our future net losses will depend, in part, on the amount of our expenses and our ability to generate revenue. All of our revenue from recent periods has been provided under our collaboration with Merck under the amended and restated research collaboration, product development and license agreement we entered into with Merck on June 30, 2021, or the Amended Collaboration Agreement. That revenue will be substantially lower in 2023 than in 2022 and prior years and minimal thereafter. See the risk factor titled "*All of our revenue for recent periods has been received from a single collaboration partner, and that revenue will continue to be substantially lower going forward as compared to historical periods.*"

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

In addition, we will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials, receives regulatory approval and is successfully commercialized. As our product candidates are in Phase 2 trials or in earlier stages of development, we do not expect to receive product revenue from our product candidates for a number of years, if ever.

Our ability to generate any product revenue from our current or future product candidates also depends on a number of additional factors, including our ability or the ability of any potential future third-party partner to:

- successfully complete research and clinical development of current and future product candidates and obtain regulatory approval for those product candidates;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate, scaled up and legally compliant manufacturing of bulk drug substances and drug products to maintain sufficient supply;
- launch and commercialize any product candidates for which marketing approval is obtained, if any, and, if launched independently by us without a partner, successfully establish a sales force and marketing and distribution infrastructure;
- demonstrate the necessary safety data (and, if accelerated approval is obtained, verify the clinical benefit) post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors, for any approved products;
- achieve market acceptance for any approved products;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance through development or be approved for commercial sale, we are unable to predict if or when we will generate product revenue or achieve or maintain profitability.

Even if we successfully complete development and regulatory processes for any product candidates that we take forward, we anticipate incurring significant costs associated with launching and commercializing any products. If we fail to become profitable or do not sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or cease our operations.

All of our revenue for recent periods has been received from a single collaboration partner, and that revenue will continue to be substantially lower going forward as compared to historical periods.

We do not have any committed external source of funds, other than pursuant to our collaboration with Merck, which has provided us with substantial financial support since 2015. However, as described under "Management's Discussion and Analysis of Financial Condition and Results of Operations-Overview of Our Business-Business Development and Merck Collaboration Updates" in Part I, Item 2 of this Quarterly Report on Form 10-Q, in 2023 the R&D funding we receive from Merck under the collaboration will continue to be substantially lower on an annual basis than the research funding previously provided by Merck. In this regard, for the period that started on April 1, 2023 and ends on March 31, 2024, we expect to receive funding of only approximately $4.0 million in the aggregate from Merck for the ongoing activities under the Amended Collaboration Agreement and for certain costs and reimbursements related to the NGM621 program. Funding from Merck after December 31, 2023 is expected to be minimal.

In any event, we need to devote a substantial amount of our own financial resources to our R&D programs, particularly with respect to our wholly-owned programs that now include all of our ophthalmology programs and MK-3655 (NGM313). In addition, our funding requirements would increase for any preclinical programs that remain within the scope of the collaboration in the event Merck does not elect to license these programs and we decide to continue them, in the event Merck elects to terminate its license to any program it licenses and we decide to continue it or in the event we opt to co-develop any Merck-licensed programs. For example, as a result of Merck's decision not to exercise its option to license NGM621 and its related compounds, as described below, NGM621 and its related compounds are now wholly-owned by us. Further development of NGM621 is primarily dependent on our ability to secure potential future BD Arrangements with third-party partners and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of NGM621 unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development. In addition, as a result of Merck's decision to terminate its license to MK-3655 (NGM313) and its related compounds, the license rights granted to Merck in 2018 with respect to MK-3655 (NGM313) reverted to us and the program is now wholly-owned by us. Further development of MK-3655 (NGM313) is also primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of MK-3655 (NGM313) unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development.

Other than our Amended Collaboration Agreement with Merck, which is limited in scope and duration, and may be unilaterally terminated by Merck under certain circumstances, we are not party to any agreements that could provide us with future revenue. Accordingly, in order to advance our current and potential future product candidates through development and to regulatory approval and commercialization, we need to raise significant additional capital and/or we will need to enter into BD Arrangements to obtain funding or other resources for one or more of our wholly-owned programs. Neither may be possible and, as a result, we may need to significantly delay, scale back or discontinue development of or abandon some or all of our product candidates, or scale back or discontinue our discovery research efforts, any of which could have a material adverse effect on our business, operating results and prospects, or we may be required to cease operations altogether.

We need significant additional capital to proceed with development and commercialization of our current and potential future product candidates and our other operations. We may not be able to access sufficient capital on acceptable terms, if at all, and, as a result, we may need to significantly delay, scale back or discontinue development of or abandon some or all of our product candidates, or scale back or discontinue our discovery research efforts, any of which could have a material adverse effect on our business, operating results and prospects, or we may be required to cease operations altogether.

As an R&D company, our operations have consumed substantial amounts of cash since inception, and we need substantial additional capital to finance our operations and pursue our strategy, both in the short and the long term, and the amount of funding we will need depends on many factors, including:

- the initiation, progress, timing, delays, costs and results of preclinical studies and clinical trials for our current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign health authorities, including the potential for such authorities to require that we perform more studies than those that we currently expect or to change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for later-stage clinical and commercial-scale manufacturing;
- the effect of products that may compete with our product candidates or other market developments;
- market acceptance of any approved product candidates, including product pricing and product reimbursement by third-party payors;
- whether Merck exercises its option to license any preclinical candidates that remain within the scope of the collaboration at the license option point as specified in the Amended Collaboration Agreement for each such candidate;

- whether Merck terminates the research phase of the collaboration under pre-specified circumstances set forth in the Amended Collaboration Agreement or terminates a program that it has licensed, such as its decision to terminate its license for MK-3655 (NGM313) and its related compounds;
- the cost of potentially acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and
- the cost of establishing sales, marketing and distribution capabilities for any of our product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with partners.

We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to fund our operations for at least twelve months from the date this Quarterly Report on Form 10-Q is filed. Moreover, based on our current development plans and related assumptions, we believe our current cash position is sufficient to fund our key solid tumor oncology programs through generation of proof-of-concept data. We have based these estimates on plans and assumptions that may prove to be insufficient or inaccurate (for example, with respect to anticipated costs, timing or success of certain activities), and we could utilize our available capital resources sooner than we currently expect. For example, although we implemented a workforce restructuring in the second quarter of 2023 as part of our broader efforts designed to reduce our operating expenses, we may not achieve the expected benefits of our cost preservation efforts on the expected timeline, or at all, and we could otherwise consume capital more rapidly than we currently anticipate. In addition, our forecast of 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 as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section.

We plan to finance our future cash needs through public or private equity or debt offerings, including under the Open Market Sale Agreement℠, or the Sales Agreement, we entered into with Jefferies LLC in June 2020, BD Arrangements or a combination of these potential financing sources. Additional capital may not be available in sufficient amounts, on reasonable terms or when we need it, if at all. While the long-term economic impact of either the COVID-19 pandemic or the conflict between Russia and Ukraine is difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, inflation rates, particularly in the United States and the U.K., have increased recently to levels not seen in decades. Increased inflation may result in increased operating costs (including labor costs) and may affect our operating budgets. In addition, the U.S. Federal Reserve has raised, and is expected to further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Moreover, the recent closures of Silicon Valley Bank, or SVB, and Signature Bank have resulted in broader financial institution liquidity risk and concerns. Although as of March 31, 2023, we had only approximately $6.0 million in deposits and other accounts with SVB, which is now a division of First Citizens Bank, consisting of $4.0 million in letters of credit related to our facilities lease and approximately $1.9 million held in a sweep account used to purchase shares in money-market funds through SVB, and we incurred no losses as a result of the closure of SVB, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages that could materially harm our business and financial condition. In this regard, we continue to maintain our cash at SVB and other banks, often in balances that exceed the current FDIC insurance limits, and the failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or delay our ability to access such funds. Any such failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and/or custodial financial institutions. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions fail or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash, cash equivalents and investments, including transferring funds, making payments or receiving funds may be threatened and our ability to raise additional capital could be substantially impaired, any of which could materially and adversely affect our business and financial condition. In any event, if the financial market disruptions and economic slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could negatively affect our financial condition and our ability to pursue our business strategy.

If adequate funds are not available from public or private equity or debt offerings on acceptable terms, in order to continue the development of product candidates outside of the scope of the collaboration with Merck we may need to:

- seek strategic alliances for R&D programs when we otherwise would not, at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or
- enter into BD Arrangements that could require us to relinquish, or license, on potentially unfavorable terms, our rights to intellectual property, product candidates or products that we otherwise would develop or seek to commercialize ourselves.

In this regard, due to the need to conserve capital and prioritize focused execution, we are actively seeking, or intend to seek, as applicable, BD Arrangements with third-party partners with sufficient resources and relevant domain expertise in order to further the clinical development, if any, of NGM621, aldafermin, MK-3655 (NGM313) and NGM936. Further development of these programs, which are in therapeutic areas where clinical development is relatively resource intensive and can have long timelines to generate proof-of-concept data, is primarily dependent on our ability to secure potential future BD Arrangements. However, we may not be able to enter into such BD Arrangements on acceptable terms, if at all. We face significant competition in seeking appropriate partners. Whether we reach a definitive agreement for a BD Arrangement will depend, among other things, upon the potential partner's evaluation of the subject product candidate and its market opportunity, our assessment of the partner's resources and expertise and the terms and conditions of the potential BD Arrangement. In the absence of such BD Arrangements for these programs, we are unlikely to be able to advance their development unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development.

We are also restricted under our existing Amended Collaboration Agreement with Merck, and may be restricted under future BD Arrangements, from entering into additional agreements on certain terms with potential partners. For example, under the current terms of the Amended Collaboration Agreement, we may not directly or indirectly research, develop, manufacture or commercialize, except pursuant to the Amended Collaboration Agreement, any medicine or product candidate that modulates a target then subject to the collaboration with specified activity. In addition, under the Amended Collaboration Agreement, we are prohibited from, directly or indirectly, researching, developing or commercializing any product for the treatment of heart failure with preserved ejection fraction, or HFpEF, during the research phase for the cardiovascular or metabolic-, or CVM-, related programs.

We may not be able to raise adequate additional capital or negotiate potential future BD Arrangements on a timely basis, on acceptable terms or at all. If we are unable to do so, we may need to significantly delay, scale back or discontinue development of or abandon some or all of our product candidates, or scale back or discontinue our discovery research efforts, any of which could have a material adverse effect on our business, operating results and prospects, or we may be required to cease operations altogether.

Raising additional capital may cause dilution to our existing stockholders, lead to restrictions on our operations or require us to relinquish rights to our product candidates or intellectual property.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Our ability to raise capital may be adversely impacted by the trading prices of our common stock following the announcement in October 2022 that the CATALINA trial did not meet its primary endpoint. Furthermore, any securities that we may issue may have rights senior to those of our common stock and could contain covenants or protective rights that would lead to restrictions on our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

Risks Related to Our Dependence on Third Parties

Funding from Merck under the collaboration after December 31, 2023 is expected to be minimal, and we may never realize the anticipated benefits to us of the collaboration.

As described in more detail under "Business-Licensing and Collaboration Arrangements-Merck Collaboration" in Part I, Item 1 of our 2022 Annual Report on Form 10-K and under "Management's Discussion and Analysis of Financial Condition and Results of Operations-Overview of Our Business-Business Development and Merck Collaboration Updates" in Part I, Item 2 of this Quarterly Report on Form 10-Q, our continuing Merck collaboration involves a complex allocation of rights, provides for certain limited R&D funding and, for remaining collaboration preclinical candidates for which Merck exercises its license option, if any, provides us with either milestone payments based on the achievement of specified clinical development, regulatory and commercial milestones and royalty-based revenue if certain product candidates are successfully commercialized or a cost and

profit share arrangement with the possibility that we would provide sales representatives to co-detail the product candidates that Merck elects to advance in the United States.

The level of R&D funding we expect to receive from Merck will be limited and will continue to be substantially lower on an annual basis than the funding previously provided by Merck. In this regard, for the period that started on April 1, 2023 and ends on March 31, 2024, we expect to receive funding of only approximately $4.0 million in the aggregate from Merck for the ongoing activities under the Amended Collaboration Agreement and for certain costs and reimbursements related to the NGM621 program. Funding from Merck after December 31, 2023 is expected to be minimal.

In addition, in January 2023, we announced that Merck notified us of its decision to terminate the Phase 2b trial of MK-3655 (NGM313) in patients with nonalcoholic steatohepatitis, or NASH, and liver fibrosis stage 2 or 3, or F2/F3, and Merck subsequently provided us with the required 90-days' notice of partial termination of the Amended Collaboration Agreement as it relates to MK-3655 (NGM313)and its related compounds. As a result, in April 2023, the license rights granted to Merck in 2018 with respect to MK-3655 (NGM313) reverted to us and the program is now wholly-owned by us. Further development of MK-3655 (NGM313) is primarily dependent on our ability to secure potential future BD Arrangements. We have not yet received the full set of clinical data from the terminated Phase 2b trial from Merck, other than the topline data previously disclosed, and we will need to access and analyze that data in order to pursue such BD Arrangements. In the absence of such BD Arrangements, we are unlikely to be able to advance development of MK-3655 (NGM313) unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development.

Similarly, in October 2022, we announced that our Phase 2 CATALINA trial evaluating NGM621 in patients with geographic atrophy, or GA, secondary to age-related macular degeneration, or AMD, did not meet its primary endpoint and, in December 2022, Merck notified us that it would not exercise its option to license NGM621 and its related compounds or the related ophthalmology bundle option and, as a result, those options expired unexercised in January 2023. Further, Merck did not elect for us to continue to conduct R&D on any compounds from our other ophthalmology programs that were subject to the collaboration, which are preclinical and directed to undisclosed targets. Such an election would have resulted in an extended or tail period in which Merck would continue to fund our R&D of such ophthalmology compounds. Because Merck did not make such an election, we do not have any funding from Merck to pursue such ophthalmology programs after we complete certain wind down activities related to NGM621, and if we choose to develop these programs further, we will be responsible for funding them. As a result, while our ophthalmology programs, including NGM621, are now wholly-owned by us, further development of those programs is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of NGM621 or the preclinical ophthalmology programs unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development.

We do not know whether Merck will elect to exercise its option to license any CVM-related preclinical candidates that remain subject to the collaboration. Accordingly, the anticipated benefits to us of the collaboration with Merck may never be realized and it is possible that the Amended Collaboration Agreement will be terminated without Merck exercising its option to license any other programs or product candidates.

Moreover, under the Amended Collaboration Agreement, Merck has the unilateral right to terminate all or part of the agreement at certain times and under certain circumstances. Merck also may unilaterally terminate its R&D funding for programs that remain within the scope of the collaboration if we are acquired by a third party or in the event of an uncured material breach by us. Subject to certain limitations, Merck may partially terminate the Amended Collaboration Agreement for convenience as it relates to any future licensed program, as they did with respect to MK-3655 (NGM313) in April 2023 and with respect to our growth differentiation factor 15, or GDF15, agonist program, which included product candidates NGM395 and NGM386, in 2019. Merck may also unilaterally terminate the Amended Collaboration Agreement as it relates to its rights to research and develop small molecule compounds. It may also unilaterally terminate the Amended Collaboration Agreement with respect to a specific licensed program in the event of an uncured material breach by us. If Merck terminates a program as a result of our uncured material breach, then we would lose our option to participate in a global cost and profit share arrangement if not yet exercised as of the time of termination and lose our co-detailing option (whether or not exercised as of that time) for the relevant licensed program.

If Merck terminates funding or terminates the Amended Collaboration Agreement, it could delay or preclude our ability to further our CVM-related research programs, which could materially and adversely affect our business. In addition, in the event that Merck decides to take over any CVM-related preclinical candidates that remain within the scope of the collaboration for development during any tail period, or exercises its license option for any such preclinical candidate, we could be subject to disputes with Merck with respect to their obligation to use commercially

reasonable efforts with respect to the development and commercialization of the affected product candidate, and we could otherwise be subject to disputes with Merck over the scope of the parties' respective rights under the Amended Collaboration Agreement, any of which could delay or preclude the development or commercialization of the affected product candidate and involve us in costly and time-consuming arbitration and litigation, which could divert management attention and resources and otherwise negatively affect our business and operations.

We may depend in the future on BD Arrangements with third-party partners for the development and commercialization of our product candidates and for revenue. If we are unable to secure those BD Arrangements on beneficial terms, if at all, or if any such future arrangements are not successful, we may not be able to capitalize on the market potential of our product candidates or continue their development.

Pursuing BD arrangements has been and is expected to continue to be a key component of our strategy, and we are actively seeking, or intend to seek, as applicable, BD Arrangements with third-party partners to progress, in whole or in part, the development of one or more of our product candidates. While we may opportunistically consider BD Arrangements to advance development of our key solid tumor oncology programs, the further development of other programs in our pipeline, including NGM621, aldafermin, MK-3655 (NGM313) and NGM936, is primarily dependent on our ability to secure potential future BD Arrangements for these programs. Due to the need to conserve capital and prioritize focused execution and unless our portfolio prioritization changes, if we are unable to secure BD Arrangements for these programs on beneficial terms, if at all, we are unlikely to be able to advance their development unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development, and may discontinue or abandon any or all of these programs altogether, in which case we will not realize any return on our investments in these programs. Even if we are successful in entering into any BD Arrangements with third-party partners for our programs, we will likely have limited control over the amount and timing of resources that our partners dedicate to the development or commercialization of the applicable product candidates. Our ability to generate revenue from any such arrangement will depend on the specific financial terms we reach with any partner, as well as each of our partners' abilities to successfully perform the functions assigned to them in such arrangement towards developing, seeking regulatory approval for and commercializing our product candidates.

BD Arrangements involving our product candidates pose risks to us, including the following:

- Partners have significant discretion in determining the efforts and resources that they will apply to these arrangements. For example, under the terms of the collaboration with Merck, if Merck exercises its option to acquire an exclusive license for any CVM-related preclinical candidate that remains within the scope of the collaboration, our ability to influence the resources Merck devotes to such candidate are substantially reduced until such time, if any, that we exercise our right to participate in a cost and profit share arrangement. Even after we exercise that right to participate in a cost and profit share arrangement, our ability to influence Merck will be limited.
- Partners might opt not to pursue development and commercialization of our product candidates or not to continue or renew development or commercialization programs based on clinical trial results, changes in the partner's strategic focus or available funding or external factors, such as an acquisition that diverts resources or creates competing priorities. For example, in June 2021, we and Merck entered into the Amended Collaboration Agreement that covers a narrower scope, focused primarily on ophthalmology- and CVM-related therapeutic areas, than had been covered under the original collaboration agreement we entered into with Merck in 2015. In addition, under the terms of the Amended Collaboration Agreement, it is possible for Merck to unilaterally terminate any other future licensed program, if any, (whether or not we have exercised our cost and profit share option) upon prior written notice, such as it did for NGM386 and NGM395 in 2019 and most recently for MK-3655 (NGM313), without triggering a termination of the remainder of the Amended Collaboration Agreement. Moreover, Merck might also opt not to designate any collaboration preclinical candidates for further development during the tail period following the end of the research phase or exercise any of its options to acquire a license to a product candidate, as it did with respect to the preclinical ophthalmology product candidates.
- Partners may delay clinical trials, provide insufficient funding for a clinical trial program, request the suspension or termination of a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing.
- Partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the partners believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.

- A partner with marketing and distribution rights might not commit sufficient resources to the marketing and distribution of our product candidates.
- Partners might not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Disputes may arise between the partners and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our BD Arrangements, including, in the case of our collaboration with Merck, if we undergo a change in control.
- BD Arrangements might be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.
- BD Arrangements might not lead to development or commercialization of product candidates in the most efficient manner, or at all. If a present or future partner of ours were to be involved in a business combination, the continued pursuit of and emphasis on our product development or commercialization program under such arrangement could be delayed, diminished or terminated.

We may not be able to obtain and maintain the relationships with third parties that are necessary to develop, commercialize and manufacture some or all of our product candidates.

In addition to our dependence on any potential future partners, we expect to depend on other third parties, including contract research organizations, or CROs, clinical data management organizations, clinical investigators, contract manufacturing organizations/contract development and manufacturing organizations, or CMOs, and other third-party partners and service providers to support our discovery efforts, to formulate product candidates, to conduct our clinical trials and certain aspects of our research and preclinical studies, to manufacture clinical and commercial-scale quantities of our drug substances and drug products and to market, sell and distribute any products we successfully develop and for which we obtain regulatory approval. Any problems we experience with any of these third parties could delay our research efforts or the development, manufacturing or commercialization of our product candidates or any future products, which could harm our results of operations. For more information, see the risk factors titled *"We rely completely on CMOs for the manufacture of our product candidates, and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates and any future products"* and *"We have no experience in sales, marketing and distribution and may have to enter into agreements with third parties to perform these functions, which could prevent us from successfully commercializing our product candidates."*

We cannot guarantee that we or, as applicable, any of our partners will be able to successfully negotiate agreements for, and maintain relationships with, third-party partners and service providers on favorable terms, if at all. If we or any of our partners are unable to obtain and maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates, which will, in turn, adversely affect our business. If we or any of our partners need to enter into alternative arrangements, it would delay our product development and, if applicable, commercialization activities and such alternative arrangements may not be available on terms acceptable to us.

We expect to continue to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, our reliance on these third parties for R&D activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. However, we cannot control the amount or timing of resources our partners will devote to our R&D programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials or other R&D activities in accordance with regulatory requirements, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize any approved products. In addition, we base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf and, if their estimates are not accurate, it could negatively affect the accuracy of our financial statements.

Any agreements we have or may enter into with third-party partners and service providers may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of R&D, the approach for regulatory approvals or commercialization strategy. We are conducting research programs in a range of therapeutic areas, and our pursuit of these opportunities could result in conflicts with the other parties to these agreements that may be developing or selling pharmaceuticals or conducting other activities in these same therapeutic areas. Any disputes or commercial conflicts could lead to the termination of our agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly and time-consuming arbitration or litigation.

In addition, we are less knowledgeable about the reputation and quality of third-party contractors in countries outside of the United States where we conduct discovery research or preclinical and clinical development and manufacturing of our product candidates and, therefore, we may not choose the best parties for these relationships.

We rely completely on CMOs for the manufacture of our product candidates, and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates and any future products.

We have limited process development capabilities and require the services of third-party CMOs to provide additional process development and manufacturing capabilities. We do not have, and we do not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in clinical trials or commercialization. As a result, we rely completely on CMOs, which entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including risks related to reliance on third parties for availability of drug product to use in our clinical trials and for regulatory compliance and quality assurance with respect to such drug product, the possibility of breach of the manufacturing agreement by third parties because of factors beyond our control (including a failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of agreements by third parties, based on their own business priorities, at a time that is costly or damaging to us.

Our product candidates are biologics, and the manufacture of biologic products is complex, highly regulated and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. As a result, the manufacture of our product candidates is subject to many risks, including the following, some of which we have experienced:

- product loss or other negative consequences due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, shortages of qualified personnel or improper delivery or storage conditions;
- difficulties with production costs and yields, quality control, product stability and quality assurance testing, including challenges related to bioanalytical method development and the qualification and implementation of those methods for release testing, which can delay availability of clinical trial materials;
- the negative consequences of failure to comply with strictly enforced federal, state and foreign regulations;
- minor deviations from normal manufacturing processes, which have in the past and may in the future result in reduced production yields, product defects and other supply disruptions;
- the presence of microbial, viral or other contaminants discovered in our product candidates or in the manufacturing facilities in which they are made, which can necessitate closure of facilities for an extended period of time to investigate and eliminate the contamination;
- the negative consequences of our CMOs' failure to qualify upon an audit by regulatory authorities, by us or by our collaborators;
- our CMOs' changing strategies and business priorities, which can affect the availability of facilities where we intend to manufacture our product candidates; and
- our CMOs or their manufacturing facilities being adversely affected by labor, raw material and component shortages, turnover of qualified staff or financial difficulties of their owners or operators, including as a result of the effects of financial market disruptions and economic slowdowns, the ongoing COVID-19 pandemic, or by natural disasters, power failures, local political unrest or other factors.

We cannot ensure that issues relating to the manufacture or testing of our product candidates, such as those described above, will not occur or continue to occur in the future and if we or our CMOs experience any such issues there could be a shortage of drug substance or drug product for use in our clinical trials, which could delay clinical and regulatory timelines significantly and have an adverse effect on our business.

In addition, to date our product candidates have been manufactured by CMOs solely for preclinical studies and relatively small clinical trials. We intend to continue to use CMOs for these purposes, and also for the supply of larger quantities that may be required to conduct accelerated or expanded early clinical trials or larger, later clinical trials and for commercialization if we advance any of our product candidates through regulatory approval and to commercialization. These manufacturers may not have sufficient manufacturing capacity and may not be able to scale up the production of drug substance or drug product in the quantities we need and at the level of quality required in a timely or effective manner, or at all. In particular, there is increased competition in the biotechnology industry for CMO manufacturing slots and other capabilities generally, which has had, and may continue to have, a negative impact on the availability of manufacturing capacity and therefore our ability to supply clinical trial materials for planned, ongoing or expanded clinical trials.

The transfer of our small-scale manufacturing processes to CMOs for scale up and validation and any later scale up and validation of the manufacturing process in the CMOs' facilities to manufacture larger quantities, involve difficult and complex processes. We may not be successful in transferring our production system to a CMO, either because it is unable to implement the process successfully in its facilities or for other reasons. Later scale-up activities are also difficult and costly and entail risks such as process reproducibility, stability, consistency and other technical challenges. If we are unable to adequately validate or scale up the manufacturing processes for our product candidates, we would need to undertake a transfer to another third party and repeat the manufacturing validation process, which can be expensive and time-consuming and could delay the initiation or completion of our clinical trials.

Similarly, we or our CMOs may make changes to our product candidates' manufacturing processes at various points in product development for many reasons, including scaling up, facility fit, raw material or component availability, decreasing costs or timing of production, improving processing robustness and reliability, decreasing processing times or others. Such changes require further validation and may have unintended consequences, which could include causing our product candidates to perform differently when administered in clinical trials and affecting clinical trial results. In some circumstances, we may be required to perform comparability or other studies to demonstrate that the product used in earlier clinical trials or at earlier stages of a trial are comparable to the product we intend to use in later trials or later stages of an ongoing trial. These efforts are expensive and there is no assurance that they will be successful, which could impact our ability to continue or initiate clinical trials in a timely manner, or at all.

Any future adverse developments affecting manufacturing operations or the scale up or validation of manufacturing processes for our product candidates may result in shipment delays, lot failures, clinical trial delays or discontinuations, or, if we are commercializing products, inventory shortages, product withdrawals or recalls or other interruptions in supply. We may also have to record inventory write-offs and incur other charges and expenses for drug substance or drug product that fails to meet specifications or cannot be used before its expiration date. In addition, for out of specification materials, we may need to undertake costly remediation efforts or manufacture new batches at considerable cost and time delays or, in the longer run, seek more expensive manufacturing alternatives.

We also have a single source of supply for most of our product candidates, including the drug substances used in manufacturing them. Single sourcing minimizes our leverage with our CMOs, who may take advantage of our reliance on them to increase the pricing of their manufacturing services or require us to change our intended manufacturing plans based on their strategies and priorities. Single sourcing also imposes a risk of interruption or delays in supply in the event of manufacturing, quality or compliance difficulties and/or other difficulties in timely supplying us with materials. For example, our investigational new drug application, or IND, submissions for NGM438 and NGM831 were delayed due to challenges at one of our CMOs, primarily related to analytical method qualification and release testing for those product candidates. It is possible that we could experience further supply-related delays that would adversely affect our ability to commence first-in-human testing of product candidates on our anticipated timing. Moreover, we do not currently have arrangements in place for redundant supply for drug substance or drug product. If one of our suppliers fails or refuses to supply us for any reason or we otherwise choose to engage a new supplier for one or more of our product candidates, including a second source supplier to mitigate the risks of single-source supply, it would take a significant amount of time and cost to implement and execute the necessary technology transfer to, and qualification of, a new supplier. The FDA or comparable foreign health authority must approve manufacturers of drug substance and drug product. If there are any delays in qualifying new suppliers or facilities or a new supplier is unable to meet the requirements of the FDA or comparable

foreign health authority for approval, there could be a shortage of drug substance or drug product for use in clinical trials with respect to the affected product candidates which would adversely affect our ability to continue and complete clinical trials on our anticipated timing or at all.

Our product candidates use certain raw materials for their production, such as reagents that support cell growth, purification materials and testing and manufacturing supplies. Some of these materials only have a single supplier and are purchased as necessary without a long-term supply agreement in place. In addition, our drug products may require the use of syringe or other components, some of which have been the subject of shortages amplified by the COVID-19 pandemic due to their use in, among other things, COVID-19 vaccine production. If our CMOs are required to obtain an alternative source of certain raw materials and components, additional testing, validation activities and regulatory approvals may be required, which may negatively impact manufacturing and other development timelines. For example, one of our CMOs experienced shortages of the specific cell culture media used to manufacture one of our products due to global supply chain challenges and, while we have been successful in obtaining a replacement product, these types of substitutions may require additional and unplanned testing, qualification or validation activities. Any significant delay in the acquisition or decrease in the availability of these materials, components or other items, or failure to successfully qualify or validate alternative materials or components, could considerably delay the manufacture of our product candidates, which could adversely impact the timing or completion of any ongoing and planned trials or the timing of regulatory approvals, if any, of our product candidates.

In addition, our CMOs' facilities and operations have been adversely affected by labor, raw material and component shortages, high turnover of staff and difficulties in hiring trained and qualified replacement staff and the operations of our CMOs may be requisitioned, diverted or allocated by U.S. or foreign government orders such as under emergency, disaster and civil defense declarations in connection with the COVID-19 pandemic or otherwise. For a discussion of how the COVID-19 pandemic has affected or may affect drug or related component supplies for our clinical trials, refer to the risk factor titled "*Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics, including the COVID-19 pandemic.*" Changes in economic conditions, supply chain constraints, labor, raw material and component shortages and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, could also lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs.

Our product candidates other than NGM621 and aldafermin are currently solely manufactured at a facility in Lithuania. Following Russia's invasion of Ukraine in February 2022, the response from the United States and its allies has included both significant sanctions and NATO's deployment of additional military forces to Eastern Europe, including to Lithuania. The ongoing conflict between Russia and Ukraine and the retaliatory measures taken or that may be taken by the United States, NATO and others, including significant sanctions against Russia, create global security concerns and regional instability, including due to the possibility of expanded regional or global conflict, and are likely to have short-term and likely longer-term negative impacts on regional and global economies, any or all of which could disrupt our supply chain and adversely affect our ability to conduct ongoing and future clinical trials of our product candidates and our ability to raise capital on favorable terms.

Any further delays or interruptions in the supply of clinical trial material could delay the completion or initiation of our clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense, terminate ongoing clinical trials or abandon planned clinical trials or expansions or accelerations of clinical trials completely.

We have no experience in sales, marketing and distribution and may have to enter into agreements with third parties to perform these functions, which could prevent us from successfully commercializing our product candidates.

We currently have no sales, marketing or distribution capabilities. To commercialize our product candidates outside of the Merck collaboration, or to commercialize products subject to the Merck collaboration for which we may in the future exercise our co-detailing rights in the United States, if any, or for which Merck decides not to exercise its license option, we must either develop our own sales, marketing and distribution capabilities or make arrangements with third parties to perform these services for us. If we exercise our co-detailing rights in the United States with respect to the Merck collaboration, we will be responsible for the costs of fielding such a sales force, subject to partial offset pursuant to the formula by which profits are allocated, and the risks of attracting, retaining, motivating and ensuring the compliance of such a sales force with the various requirements of the Merck collaboration and applicable law. If we decide to market any of our products on our own, we will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide

to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all. If we are not able to establish and maintain successful arrangements with third parties or build our own sales and marketing infrastructure, we may not be able to commercialize our product candidates, which would adversely affect our business, operating results and prospects.

Risks Related to Our Business and Industry

Our product candidates must undergo rigorous clinical trials before seeking regulatory approvals, and clinical trials may be delayed, suspended or terminated at any time for many reasons, any of which could delay or prevent regulatory approval and, if approval is granted, commercialization of our product candidates.

All of our product candidates are subject to rigorous and extensive clinical trials before we can seek regulatory approval from the FDA and comparable foreign health authorities such as the European Commission. Clinical trials may be delayed, suspended or terminated at any time for reasons including but not limited to:

- ongoing discussions with the FDA or comparable foreign health authorities regarding the scope or design of our clinical trials;
- delays in obtaining, or the inability to obtain, required approvals from IRBs and ethics committees or other governing entities at clinical trial sites selected for participation in our clinical trials;
- delays in patient enrollment and other key trial activities, including as a result of the effects of the ongoing COVID-19 pandemic and of the significant competition for recruiting patients with cancer in clinical trials;
- delays in reaching agreement on acceptable terms with prospective CROs and the failure of CROs, testing laboratories and other third parties to satisfy their contractual duties to us or meet expected deadlines;
- deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements;
- lower than anticipated retention rates of participants in clinical trials, including patients dropping out due to side effects, disease progression or concerns about the COVID-19 pandemic;
- failure of enrolled patients to complete treatment or to return for post-treatment follow-up;
- for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients and test any patient samples;
- implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign health authorities with respect to approval pathways for product candidates we are pursuing;
- the need to repeat clinical trials as a result of inconclusive or negative results, poorly executed testing or changes in required endpoints;
- insufficient supply or deficient quality of drug substance, drug product or other clinical trial material necessary to conduct our clinical trials, as well as delays in the testing, validation, manufacturing and delivery to clinical trial sites of such material;
- withdrawal of clinical trial sites or investigators from our clinical trials for any reason, including as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- unfavorable FDA or comparable foreign health authority inspection or review of a clinical trial site or records of any clinical or preclinical investigation;
- drug-related adverse effects or tolerability issues experienced by participants in our clinical trials;
- changes in government regulations or administrative actions;
- lack of adequate funding to continue the clinical trials;
- our ability to hire and retain key R&D personnel; or
- the placement of a clinical hold on a trial by the FDA or comparable foreign health authorities.

We cannot guarantee that we will be able to successfully accomplish required regulatory and/or manufacturing activities or all of the other activities necessary to initiate and complete clinical trials in a timely fashion, if at all. As a result, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approvals or successfully commercialize our products. In addition, we have only limited experience in conducting late-stage clinical trials required to obtain regulatory approval. In any event, we do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Our product development costs will increase if we continue to experience delays in clinical testing. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects. Our or our partners' inability to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenue or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

If clinical trials of our product candidates fail to produce positive results or to demonstrate safety and efficacy to the satisfaction of the FDA or comparable health authorities or sufficient to demonstrate differentiation from other approved therapies or therapies in development, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Our product candidates are in early stages of development, with our most advanced product candidates only in Phase 2 development. Before obtaining marketing approval from health authorities for the sale of our product candidates, we or our partners must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Preclinical studies and clinical trials are expensive, take several years to complete and may not yield results that support further clinical development or product approvals. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Because we have limited experience designing clinical trials, we may be unable to design and execute a clinical trial to support regulatory approval.

In addition, there is a high failure rate for drugs and biologic products proceeding through clinical trials and failure can occur at any stage of testing. For example, despite the results of preclinical and Phase 1 studies of NGM621, our Phase 2 CATALINA clinical trial evaluating NGM621 in patients with GA secondary to AMD did not meet its primary endpoint. Since Merck did not elect to exercise its option to license NGM621 and its related compounds, further development of NGM621 is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of NGM621 unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development.

Similarly, our Phase 2b ALPINE 2/3 trial evaluating aldafermin in patients with F2/F3 NASH did not meet its primary endpoint and, as a result, we decided to suspend further development of aldafermin in patients with F2/F3 NASH, allowing for the reallocation of resources to advancing our other programs. For more information, refer to the risk factor titled "*Aldafermin is, and MK-3655 (NGM313) was, being developed, for the treatment of NASH, an indication for which there are no approved products. This makes it difficult to predict the timing, cost and potential success of their continued clinical development, if any, and regulatory approval for the treatment of NASH, or otherwise.*" Further development of aldafermin is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of aldafermin unless our portfolio prioritization changes and we are able to secure the additional capital necessary to fund such development.

Further, we expect that certain of our current product candidates will, and future product candidates may, require chronic administration. The need for chronic administration increases the risk that participants in our clinical trials will fail to comply with our dosing regimens. If participants fail to comply, we may not be able to generate clinical data in our trials acceptable to the FDA or comparable foreign health authorities. The need for chronic administration also increases the risk that our clinical drug development programs may not uncover all possible adverse events that patients who take our products may eventually experience. The number of patients exposed to treatment with, and the average exposure time to, our product candidates in clinical development programs may be inadequate to detect rare adverse events or chance findings that may only be detected once our products are administered to more patients and for longer periods of time.

We may also not be successful in generating clinical data sufficient to differentiate our product candidates from other products in the same therapeutic area. If our competitors' products are, or are perceived to be, more effective, more convenient, less costly or safer than our products, or we are unable to demonstrate differentiation in any of those factors, we may not be able to achieve a competitive position in the market. For more information, refer to the risk factor titled "*We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us."*

In addition, data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In any event, it is impossible to predict when or if any of our product candidates will prove safe and effective in humans or will receive regulatory approval. If we are unable to successfully discover, develop or enable our partners to develop drugs that regulatory authorities deem effective and safe in humans, we will not have a viable business.

Success in preclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials.

To date, the data supporting our drug discovery and development programs are derived from laboratory and preclinical studies and earlier-stage clinical trials. Owing in part to the complexity of biological pathways, when used to treat human patients, our product candidates might not demonstrate the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier-stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. Success in preclinical studies and earlier-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of our product candidates. In this regard, the data supporting our drug discovery and development programs are derived from laboratory and preclinical studies, and future clinical trials in humans may show that one or more of our product candidates are not safe and effective, in which event we may need to abandon development of such product candidates. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical studies and earlier-stage clinical trials. Similarly, preliminary data and interim results from clinical trials may not be predictive of final results. For example, despite the results of preclinical and Phase 1 studies of NGM621, our Phase 2 CATALINA clinical trial evaluating NGM621 in patients with GA secondary to AMD did not meet its primary endpoint. Similarly, in spite of the results we had obtained in our Phase 1 trials of aldafermin and in our first Phase 2 trial, in May 2021, we announced that our Phase 2b ALPINE 2/3 trial evaluating aldafermin in patients with F2/F3 NASH did not meet its primary endpoint. For more information, refer to the risk factor titled "*If clinical trials of our product candidates fail to produce positive results or to demonstrate safety and efficacy to the satisfaction of the FDA or comparable health authorities or sufficient to demonstrate differentiation from other approved therapies or therapies in development, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates."* There can be no assurance that any clinical testing of our product candidates will be successful or will otherwise be supportive of continued development and/or regulatory approvals of such product candidates.

In addition, some of our earlier-stage clinical trials involve small patient populations, sometimes at single sites, and the results of these clinical trials may be subject to substantial variability and may not be indicative of either future interim results or final results. As a general matter, there is also a substantial risk that Phase 3 trials with larger numbers of patients and/or longer durations of therapy will fail to replicate efficacy and safety results observed in earlier clinical trials.

Our product candidates may cause undesirable side effects or adverse events or have other properties or safety risks, which could delay or prevent continued clinical development or their regulatory approval or limit the commercial profile of any approved label.

Adverse events, undesirable side effects or similar safety issues caused by our product candidates could cause us or health 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 FDA or other comparable foreign health authorities. Additional clinical trials may be required to further evaluate the safety profile of our product candidates. Patients in certain of our ongoing or planned clinical trials, particularly patients with cancer or with NASH with more advanced fibrosis, often enter our trials with significant comorbidities or advanced life-threatening illness and/or are treated in the trial with our product candidate in combination with other medications, including, in cancer patients, chemotherapy or other approved cancer treatments. As a result, patients in our clinical trials can be expected to experience some adverse events, including death, or side effects that are not or may not be related to treatment with our product candidates. Nonetheless, the occurrence of adverse events or side effects, whether or not related to our product candidates, could impact the success of our clinical trials.

Patients experienced, and we reported, serious adverse events, or SAEs, in the treatment arms of our completed trials of MK-3655 (NGM313), NGM621 and aldafermin. We expect that patients in our clinical trials, including those that are sham- or placebo-controlled with some patients not receiving study drug, will continue to experience adverse events and SAEs and we will continue to monitor those SAEs for any signals of concern regarding the safety and tolerability of our product candidates. For example, cancer patients enrolled in our ongoing

clinical trials of NGM120, NGM707, NGM831 and NGM438, many of whom are suffering from advanced life-threatening illness, have experienced, and we expect will continue to experience, SAEs and other adverse events, which may or may not be drug-related. If patients in any of our clinical trials experience a high or unacceptable severity and prevalence of side effects, including particularly SAEs, it could affect patient recruitment or the ability of enrolled patients to complete their treatment in a clinical trial, it may result in a regulatory authority putting a clinical hold on the clinical trial or it may result in failure to obtain regulatory approval for our product candidates or product liability claims.

In addition, significant increases in serum levels of low-density lipoprotein cholesterol, or LDL-C, were observed in clinical trials of aldafermin in patients with NASH and type 2 diabetes. Serum levels of LDL-C were brought back to baseline levels with concomitant statin use in patients with NASH; however, the impact of these drug-induced changes in LDL-C are unknown. Generally, sustained and prolonged LDL-C elevations in untreated patients are associated with cardiovascular disease through atherosclerotic plaque development. While data from our completed Phase 2b ALPINE 2/3 clinical trial and earlier trials of aldafermin demonstrated the ability of concomitant statin use to mitigate the serum LDL-C elevations driven by aldafermin activity, aldafermin's impact on LDL-C may negatively impact market acceptance of an approved aldafermin product.

Our product candidates are protein or antibody therapeutics. Protein and antibody therapeutics can sometimes induce host immune responses that can cause the production of anti-drug antibodies, or ADAs. In some cases, ADAs have no effect. In other cases, ADAs may neutralize the effectiveness of the product candidate, can require that higher doses be used to obtain a therapeutic effect or can cross react with substances naturally occurring in a subject's body, which can cause unintended effects, including potential impacts on efficacy and adverse events. Some patients treated with aldafermin in our completed clinical trials have developed ADAs against aldafermin and, in some cases, those antibodies were neutralizing or appeared to cross react with the patient's naturally occurring FGF19. We developed an assay to measure the presence of ADAs against aldafermin for our ongoing NASH program, which we are using to test patient samples and which will need to be evaluated by regulatory agencies. The presence of ADAs was also observed in our Phase 1 MK-3655 (NGM313) trial. If we are required to undertake substantial additional testing as a result of the detection of ADAs in subjects using aldafermin, MK-3655 (NGM313) or any other product candidate, the costs of our clinical trials may increase. If we determine that ADAs are causing safety or efficacy concerns when using any of our product candidates, we may need to delay or halt clinical trials of our product candidates and the affected product candidates may never obtain regulatory approval. We cannot provide assurance that the detection of ADAs will not be higher than we have observed historically or that observed rates will not later be found to limit drug exposure or cause adverse safety events, or that the detection of ADAs will not otherwise result in the non-approvability of any of our product candidates.

Future results of our trials could reveal a high and unacceptable severity and prevalence of side effects, SAEs, ADAs, safety issues or other negative or otherwise unexpected characteristics. The occurrence of those issues could affect patient recruitment or the ability of enrolled patients to complete their treatment in a clinical trial, result in failure to obtain regulatory approval for our product candidates or product liability claims or impact market acceptance of our products. Any of these occurrences could materially and adversely affect our business, financial condition and prospects.

Aldafermin is, and MK-3655 (NGM313) was, being developed for the treatment of NASH, an indication for which there are no approved products. This makes it difficult to predict the timing, cost and potential success of their continued clinical development, if any, and regulatory approval for the treatment of NASH, or otherwise.

We are developing aldafermin, and MK-3655 (NGM313) was in development by Merck, for the treatment of NASH, an indication for which there are no approved products. Implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign health authorities with respect to approval pathways, such as draft guidance documents from the FDA for the development of products for the treatment of NASH that issued in 2018 and 2019 and from the European Medicines Agency, or EMA, that issued in 2018, may impact the path for regulatory approval for NASH therapies. Further, as we and other companies advance clinical trials for potential NASH therapies, we expect that the path for regulatory approval for NASH therapies may continue to evolve as companies refine their regulatory approval strategies and interact with health authorities. Such evolution may impact our future clinical trial designs, including trial size and endpoints, in ways that we cannot currently predict. We updated the design of the ALPINE 4 trial of aldafermin, elevating the ELF test to be the primary endpoint for the trial. Neither the ELF test, nor any other surrogate biomarker endpoints, are currently endorsed by the FDA or EMA as sufficient for granting regulatory approval of products being developed for the treatment of compensated cirrhosis due to NASH (stage F4) and therefore may not be able to be used as a primary endpoint in potential future Phase 3 trials to support regulatory approval for aldafermin.

In addition, certain of our competitors have experienced regulatory setbacks for NASH therapies following communications from the FDA. We currently do not know the impact, if any, that these setbacks could have on the path for regulatory approval for NASH therapies generally or for aldafermin and MK-3655 (NGM313) in particular. If the clinical trials for aldafermin and MK-3655 (NGM313) are not designed in a manner that, even if successful, support regulatory approval due to shifting approval pathways or for other reasons, those product candidates may be delayed in obtaining approval or may never be approved, which could have a material adverse effect on our business, operating results and prospects. Moreover, the above factors could make it difficult or preclude altogether our ability to secure potential future partners necessary to further the development of aldafermin and MK-3655 (NGM313) in NASH or otherwise.

As a result of the above, the future development of aldafermin and MK-3655 (NGM313) in patients with NASH is substantially uncertain and could be discontinued altogether, in which case, we will not receive any return on our investments in these programs.

Aldafermin is a modified version of a human hormone that has been associated with liver cancer in rodent testing.

The IND application we filed for aldafermin in February 2014 for type 2 diabetes was placed on clinical hold by the FDA Division of Metabolism and Endocrinology Products pending receipt of additional information relating to the potential risk of proliferative effects of aldafermin in the livers of non-human primates and mice based on concerns relating to the observation that human FGF19 can induce hepatocellular proliferation in rodents. We withdrew this IND in January 2015, as we determined that we would not further study aldafermin in type 2 diabetes after we analyzed the results of the Phase 2 clinical trial of aldafermin in type 2 diabetes and made the determination to pursue NASH and other liver indications. To date, the FDA Division of Hepatology and Nutrition, which is responsible for the NASH indication, has not requested any additional information regarding the potential for aldafermin to induce hepatocellular proliferation. We have received feedback from the FDA Carcinogenicity Assessment Committee that our preclinical data through six-month chronic toxicology studies in mice and monkeys support a single species, two-year carcinogenicity assessment in rats. The human hormone and the rodent ortholog for FGF19 share a sequence identity of approximately 50%, which means that the results of these studies of aldafermin in rats are not necessarily predictive of the potential risk of carcinogenicity in humans. To our knowledge, neither FGF19 nor any variant thereof other than aldafermin has ever been tested in humans. Concerns about the association between FGF19 and liver cancer could have an adverse effect on our ability to develop and commercialize aldafermin.

We may not successfully identify new product candidates to expand our development pipeline.

The success of our business over the longer term depends upon our ability to identify and validate new potential protein and antibody therapeutics. Research programs to identify new product candidates require substantial technical, financial and human resources, and our research methodology may not successfully identify medically relevant protein or antibody therapeutics to be developed as product candidates. In this regard, the recent resignation of Jin-Long Chen, Ph.D., who served as our Chief Scientific Officer, may adversely affect our ability to successfully identify new product candidates and to attract and retain the key scientific personnel necessary to do so. In addition, our drug discovery efforts often identify and select novel, untested proteins in the particular disease indication we are pursuing, which we may fail to validate after further research work. Moreover, our research efforts may initially show promise in discovering potential new protein and antibody therapeutics yet fail to yield product candidates for clinical development for multiple reasons. For example, potential product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal drug profiles or other characteristics suggesting that they are unlikely to be commercially viable products. Our inability to successfully identify additional new product candidates to advance into clinical trials could have a material adverse effect on our business, operating results and prospects.

We may fail to select or capitalize on the most scientifically, clinically and commercially promising or profitable product candidates.

We have limited technical, managerial and financial resources to determine which of our product candidates should proceed to initial clinical trials, later-stage clinical development and potential commercialization. We may make incorrect determinations in allocating resources among these product candidates. Our decisions to allocate our R&D, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better opportunities. For example, our key pipeline programs in active development include product candidates in solid tumor oncology, and we are focusing most of our execution efforts and resources on these programs, intending to mainly advance them

in generation of proof-of-concept data internally. However, our focus on the solid tumor oncology therapeutic area may be unsuccessful and may never lead to the development of viable commercial products. Similarly, our decisions to delay or terminate drug development programs, such as our decision to suspend development activities related to multiple metabolic disease product candidates and for aldafermin in patients with F2/F3 NASH to concentrate our resources elsewhere, also may be incorrect and could cause us to miss valuable opportunities.

Under the terms of our Amended Collaboration Agreement with Merck, we have the right, exercisable during a specified period prior to the commencement of Phase 3 clinical testing of the applicable product candidate, to convert our economic participation from a milestones and net sales royalty arrangement into a cost and profit share arrangement. If we exercise the cost and profit share right, we have the ability to participate in a co-detailing relationship in the United States. Due to the limited exercise period, we may have to choose whether a product candidate will be subject to a cost and profit share arrangement before we have as much information as we would like, including whether and when such program may receive FDA approval of the applicable biologics license application, or BLA. As a result of such incomplete information or due to incorrect analysis by us, we may select a cost and profit share program that later proves to have less commercial potential than an alternative, or none at all, or may pass on a cost and profit share program that proves commercially successful.

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team, or to continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In April 2023, we announced a restructuring of our workforce, reducing our existing headcount by approximately 33%. At the same time, our founder, Dr. Jin-Long Chen, resigned from the Board and his position as Chief Scientific Officer. These significant changes may cause additional attrition and negatively affect employee morale. Additionally, as we are operating our business with fewer employees, including fewer members of senior management, the loss of a significant number of our remaining employees or of any of our current executive officers could result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and further commercialization of our product candidates.

There is intense competition for qualified personnel, including management, in the technical fields in which we operate, particularly in the oncology field, and we may not be able to attract and retain qualified personnel necessary for the successful research, development and future commercialization, if any, of our product candidates. We recruit for talent in the biotechnology and pharmaceutical industry in the San Francisco Bay Area, which is one of the most competitive and highest cost labor markets in the United States and periodically experiences higher turnover rates than other industries. For example, in 2022, we continued to experience a challenging recruiting environment with relatively high rates of employees leaving the company to pursue other opportunities, particularly in the first three quarters of the year.

Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. The labor market tightened significantly after the beginning of the ongoing COVID-19 pandemic. During the first couple of years of the COVID-19 pandemic, we experienced employee attrition at rates higher than we experienced historically, which may recur and could have a negative impact on our productivity. If we are unable to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

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

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. A number of pharmaceutical and biotechnology companies are pursuing the development or marketing of pharmaceuticals that seek to treat the same diseases that we are pursuing with our most advanced product candidates, particularly in the oncology field. Some of these pharmaceuticals in development are active, or seek to be active, against the same targets that our product candidates are engineered to effect, including the targets that are the focus of our immuno-oncology candidates,

ILT2, ILT3, ILT4 and LAIR1. It is probable that the number of companies seeking to develop products and therapies for the treatment of cancer, retinal diseases and liver and metabolic diseases will increase. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval and approval or marketing authorization from comparable health authorities such as the European Commission for superior products or for other products that would compete with our product candidates. Many of our competitors have established distribution channels and commercial infrastructure to support the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaboration or partnering relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaboration or partnering arrangements with large, established companies.

Our competitors may obtain regulatory approval of their products more rapidly than us or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidates or achieve a competitive position in the market. These companies also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Although we believe there are no FDA- or European Commission-approved therapies that specifically target the signaling pathways that our current product candidates are designed to modulate or inhibit, there are numerous currently approved therapies for treating the same diseases or indications (other than NASH or GA) for which our product candidates may be useful and many of these currently approved therapies act through mechanisms similar to our product candidates. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products, including branded generic products. This may make it difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development. For more information regarding the competition that our most advanced product candidates face, or may face, see the discussion of specific competition for each product candidate in “Business-Our Pipeline Programs” in our 2022 Annual Report on Form 10-K.

In February 2023, Apellis Pharmaceuticals, Inc., or Apellis, announced that the FDA approved SYFOVRE™ (pegcetacoplan injection) for the treatment of GA secondary to AMD. Apellis' regulatory approval for pegcetacoplan injection may affect future late-stage clinical trial designs, if any, and require added clinical development expense. Iveric bio, Inc.’s, or Iveric's, avacincaptad pegol, a PEGylated aptamer inhibitor of complement C5, completed a Phase 2/3 clinical trial that demonstrated statistically significant reductions in the rate of GA lesion area growth in the avacincaptad pegol arm versus the sham arm. In February 2023, Iveric announced that the FDA had accepted its NDA for avacincaptad pegol. Even if we are successful in securing a future BD Arrangement for the NGM621 program, which may not occur in a timely manner or at all, and our partner obtains regulatory approval of NGM621, which is substantially uncertain given the failure to meet the primary endpoint in the CATALINA trial, NGM621 may not be able to compete effectively against pegcetacoplan and avacincaptad pegol, which could adversely affect our future revenues and business prospects in the event we are able to successfully partner the program.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate, as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by physicians and patients;
- the actual and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the viewpoints of influential physicians with respect to the product candidate;
- the inclusion or exclusion of the product candidate from treatment guidelines established by various physician groups;
- the cost of treatment relative to alternative treatments;
- our pricing and the availability of coverage and adequate reimbursement by third parties and government authorities as described in the risk factor titled "*Even if we obtain approval to market our products, these products may become subject to unfavorable pricing regulations, reimbursement practices from third-party payors or healthcare reform initiatives in the United States and abroad, which could harm our business*";
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- any unfavorable publicity relating to the product candidate.

For example, aldafermin is currently administered via a once-daily subcutaneous injection, which may negatively impact market acceptance of an approved aldafermin product, if any. In addition, refer to the risk factor titled *"Our product candidates may cause undesirable side effects or adverse events or have other properties or safety risks, which could delay or prevent continued clinical development or their regulatory approval or limit the commercial profile of any approved label.*" If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Even if we obtain approval to market our products, these products may become subject to unfavorable pricing regulations, reimbursement practices from third-party payors or healthcare reform initiatives in the United States and abroad, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. In many regions, including the European Union, or EU, Japan and Canada, the pricing of prescription drugs is controlled by the government and some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after regulatory approval for the product is granted. Regulatory agencies in those countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market our products at a premium as new drugs. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, private health insurers, health maintenance organizations and other organizations, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Governments and private insurers closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drug products. We cannot be sure that coverage and reimbursement will be available for any product that we or our partners commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product

candidate for which we or our partners obtain regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our partners may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

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

The advancement of healthcare reform may negatively impact our ability to profitably sell our product candidates, if approved.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product for which we obtain marketing approval.

For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, (1) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive legislation repealing the ACA, such legislation may be reintroduced. Members of Congress have introduced legislation to modify or replace certain provisions of the ACA. It is unclear how these efforts to repeal and/or replace the ACA will impact the ACA and our business. For example, the Tax Cuts and Jobs Act, or the 2017 Tax Act, repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the “individual mandate.” On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Prior to the United States Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed

certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. The IRA also, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA and IRA may be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures may impact the ACA or IRA, increase the pressure on drug pricing or limit the availability of coverage and adequate reimbursement for our product candidates, which would adversely affect our business.

There has also been increasing executive, legislative and enforcement interest in the United States with respect to drug pricing practices. There have been U.S. congressional inquiries, presidential executive orders and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, reduce

the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, in an executive order, the administration of President Biden expressed its intent to pursue certain policy initiatives to reduce drug prices and, in response, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to lower drug prices. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

In many countries outside the United States, government-sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and/or difficulty in understanding the value of medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure and we expect that legislators, policy makers and healthcare insurance funds in the EU Member States will continue to propose and implement cost cutting measures. These measures include mandatory price controls, price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage, government-mandated price cuts, limitations on coverage of target population and introduction of volume caps.

Many countries implement health technology assessment, or HTA, procedures that use formal economic metrics such as cost effectiveness to determine prices, coverage and reimbursement of new therapies. These assessments are increasingly implemented in established and emerging markets. In the EU, the newly-adopted Regulation (EU) 2021/2282 on Health Technology Assessment, or HTA Regulation, which will become effective in January 2025, will allow EU member states to use common HTA tools, methodologies and procedures to conduct joint clinical assessments and joint scientific consultations whereby HTA authorities may provide advice to health technology developers. Each EU member state will, however, remain exclusively competent for assessing the relative effectiveness of health technologies and making pricing and reimbursement decisions. Given that the extent to which pricing and reimbursement decisions are influenced by the HTA process currently varies between EU member states, it is possible that our products may be subject to favorable pricing and reimbursement status only in certain EU countries. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, including following periodic review, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. Moreover, in order to obtain reimbursement for our products in some EU member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Efforts to generate additional data for the HTA process will involve additional expenses which may substantially increase the cost of commercializing and marketing our products in certain EU member states.

We expect that countries will continue taking aggressive actions to seek to reduce expenditures on drugs. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

We cannot predict the likelihood, nature or extent of healthcare reform initiatives that may arise from future legislation or administrative action. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and clinical trial sites are located outside of the United States. Furthermore, if we, Merck or any future partner succeeds in developing any of our product candidates, we intend to market them in the EU and other jurisdictions in addition to the United States. If approved, we, Merck or any future partner may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of challenges and risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy and data protection regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions in the supply of clinical trial material resulting from any events affecting raw material or component supply or manufacturing capabilities abroad, including those that may result from the ongoing COVID-19 pandemic;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits on our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of inflation and local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political, geopolitical and economic instability, including wars such as the conflict between Russia and Ukraine, terrorism and political unrest, disease outbreaks, epidemics and pandemics, including COVID-19 and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we or our partner commercializes any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and

- the inability to commercialize any products that we may develop.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician endorsement of our products or expand our business.

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

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we or our partner obtains marketing approval. Our arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products for which we or our partner obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program, such as Medicare and Medicaid;
- the federal False Claims Act, or FCA, imposes criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act, or HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, or HITECH, also imposes obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses, and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, processing and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, as amended, and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the HHS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance

guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and local laws requiring the registration of pharmaceutical sales representatives; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing; and state and foreign laws that govern the privacy and security and other processing of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, additional regulatory oversight, litigation, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of EU member states, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics, including the COVID-19 pandemic.

Disease outbreaks, epidemics and pandemics, such as the COVID-19 pandemic, in regions where we have concentrations of clinical trial sites or other business operations could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of third-party manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics have negative impacts on our ability to initiate new clinical trial sites, to enroll new patients and to maintain existing patients who are participating in our clinical trials, which may include increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of our product candidates, if at all. For example, our ability to attract additional clinical trial sites and principal investigators to conduct our clinical trials and to conduct the necessary clinical trial site initiation procedures was impacted by COVID-19 quarantines, shelter-in-place and similar restrictions imposed by federal, state and local governments. In addition, during the COVID-19 pandemic, we experienced, from time to time, a slower pace of clinical site initiation and clinical trial enrollment and a higher subject dropout rate than originally anticipated in certain of our clinical trials, which we believe may have been due to factors such as the vulnerability of our studied patient populations, site staff shortages, clinical trial site suspensions, reallocation of medical resources and the challenges of working remotely due to shelter-in-place and similar government orders and guidelines, among other factors

General supply chain issues may be exacerbated during disease outbreaks, epidemics and pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. For example, in 2022 we were made aware of a shortage of tubes required for taking blood samples, requiring the use of tubes of a different size from those specified in one of our protocols. In addition, our CMOs' facilities and operations have been adversely affected by labor, raw material and component shortages, high turnover of staff and difficulties in hiring trained and qualified replacement staff during the COVID-19 pandemic. These difficulties have resulted in some delays in early development timelines and we could experience more significant disruptions to our supply chain and operations as a result of disease outbreaks, epidemics or pandemics in the future. If our CMOs are required to obtain an alternative source of certain raw materials and components, for example, additional testing, validation activities and regulatory approvals may be required which can also have a negative impact on timelines. Any associated delays in the manufacturing and supply of drug substance and drug product for our clinical trials could adversely affect our ability to conduct ongoing and future clinical trials of our product candidates on our anticipated development timelines. Likewise, the operations of our third-party manufacturers may be requisitioned, diverted or allocated by U.S. or foreign government orders such as under emergency, disaster and civil defense declarations in connection with the COVID-19 pandemic or otherwise. For example, early in the COVID-19 pandemic, our aldafermin drug product CMO advised us that it could be required under orders of the U.S. government to allocate manufacturing capacity to the manufacture or distribution of

COVID-19 vaccines. If any of our CMOs or raw materials or components suppliers become subject to acts or orders of U.S. or foreign government entities to allocate or prioritize manufacturing capacity, raw materials or components to the manufacture or distribution of vaccines or medical supplies needed to test or treat patients in a disease outbreak, epidemic or pandemic, this could delay our clinical trials, perhaps substantially, which could materially and adversely affect our business.

Moreover, COVID-19 continues to evolve, and the extent to which COVID-19 may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the emergence, infectiousness and severity of new variants, travel restrictions, quarantines and social distancing in the United States and other countries, business closures or business disruptions, global supply challenges, and the effectiveness of actions in the United States and other countries to contain and treat the disease. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. To the extent the effects of the continuing COVID-19 pandemic, or any future disease outbreak, epidemic or pandemic, adversely affects our business and results of operations, it also may have the effect of heightening many of the other risks and uncertainties described elsewhere in this ‘‘Risk Factors’’ section.

Risks Related to Regulatory Approvals

The regulatory approval processes of the FDA and comparable foreign health authorities are lengthy and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.

Currently, none of our product candidates has received regulatory approval and we do not expect our product candidates to be commercially available for several years, if at all. The time required to obtain approval from the FDA and comparable foreign health authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the health authorities. In addition, approval policies, regulations or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate’s development and may vary among jurisdictions. It is possible that none of our existing or future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign health authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of results of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies;
- unfavorable quality review or audit/inspection findings; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign health authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and commercialization, or we may decide to abandon the development program for other reasons. If we obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant accelerated approval or conditional marketing authorization based on a surrogate endpoint and contingent on the successful outcome of costly post-marketing confirmatory clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet

medical needs for the disease or condition, and the FDA may grant accelerated approval based on a surrogate endpoint reasonably likely to predict clinical benefit. However, Fast Track designation does not guarantee, or in any way change the standards for, full product approval.

Many agents in development for NASH have, or are expected to, opt for an accelerated approval pathway and rely on surrogate endpoints for initial approval. If we or a future partner seek accelerated approval for one of our product candidates based on a surrogate endpoint, the FDA may not accept such endpoint, may require additional studies or analysis or may not approve our product candidate on an accelerated basis, or at all. For example, in June 2020, Intercept Pharmaceuticals, Inc., or Intercept, announced that it had received a complete response letter regarding its new drug application, or NDA, for obeticholic acid for the treatment of NASH, in which the FDA indicated that it had determined that the predicted benefit of obeticholic acid based on a surrogate histopathologic endpoint was uncertain and did not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommended that Intercept submit additional post-interim analysis efficacy and safety data from its ongoing Phase 3 study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue. In addition, if full approval is granted for another product in the same indication for which we are seeking accelerated approval for one of our product candidates, the accelerated approval pathway may no longer be available to us or a future partner for our product candidate.

In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the United States.

Sponsors that benefit from PRIME designation are potentially eligible for accelerated assessment of their marketing authorization applications, although this is not guaranteed. If a product for which PRIME designation was granted is the subject of an accelerated assessment, the product may be placed on the market in the EU before our product candidate with a similar therapeutic indication.

Our failure to obtain health authority approval in foreign jurisdictions would prevent us from marketing our product candidates outside the United States.

If we or our partners succeed in developing any products, we intend to market them in the EU and other foreign jurisdictions in addition to the United States. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product pricing and reimbursement approvals before health authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by health authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we fail to obtain approval of any of our product candidates by health authorities in another country, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign health authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and comparable foreign health authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign health authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy, or REMS, or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Failure to comply with any related obligations may result in the suspension or withdrawal of an obtained approval and in civil and/or criminal penalties. Receipt of approval for narrower indications than sought, restrictions on marketing through a

REMS or similar strategy imposed in an EU member state or other foreign country, or significant labeling restrictions or requirements in an approved label such as a boxed warning, could have a negative impact on our ability to recoup our R&D costs and to successfully commercialize that product, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects. In any event, if we are unable to comply with our post-marketing obligations imposed as part of the marketing approvals in the United States, the EU, or other countries, our approval may be varied, suspended or revoked, product supply may be delayed and our sales of our products could be materially adversely affected.

In addition, manufacturers of drug substance and drug products and their facilities are subject to continual review and periodic inspections by the FDA and comparable foreign health authorities for compliance with current Good Manufacturing Practices, or cGMP, regulations. If we or a regulatory agency discover 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 on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or if our product candidates are found to cause undesirable or unacceptable side effects, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require that we conduct and complete post-marketing studies;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or initiate a recall of such product;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or refuse to permit the import or export of products.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, Department of Justice, HHS, Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations and civil and criminal sanctions by the government. Additionally, comparable foreign health authorities, public prosecutors, industry associations, healthcare professionals and other members of the public will heavily scrutinize advertising and promotion of any product candidate outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal FCA, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these FCA lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member state laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Failure to comply with EU, EU member state, and other country laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of a marketing authorization, or with other applicable regulatory requirements, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties. In addition, legislation adopted at the EU level may be implemented differently by individual member states. These regulations, and their differing implementations in member states, increase our legal and financial compliance costs and may make some activities more time-consuming and expensive.

Even if we are able to obtain regulatory approvals for any of our product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted.

Even if we receive regulatory approval for any of our product candidates, we will have tested them in only a small number of patients during our clinical trials. If an application for marketing is approved for any of our product candidates and more patients begin to use our product, new risks and side effects associated with our products may be discovered. As a result, health authorities may revoke their approvals. Additionally, we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities for our product candidates. Equivalent obligations could be imposed by the foreign health authorities. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for such product are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

Risks Related to Our Intellectual Property

Our success depends in significant part upon our ability to obtain and maintain intellectual property protection for our products and technologies.

Our success depends in significant part on our ability and the ability of our current or future licensors, licensees, partners or collaborators to establish and maintain adequate intellectual property covering the product candidates that we plan to develop. In addition to taking other steps designed to protect our intellectual property, we have applied for, and intend to continue applying for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. However, the patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees, partners or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees, partners or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Pending and future patent applications filed by us or our current or future licensors', licensees', partners' or collaborators' may not result in patents being issued that protect

our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products.

We have filed numerous patent applications both in the United States and in certain foreign jurisdictions to obtain patent rights to our inventions, with claims directed to compositions-of-matter, methods of use, formulations, combination therapy and other technologies relating to our product candidates. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, whether the claims of the patents will exclude others from making, using or selling our product or product candidates, or products or product candidates that are substantially similar to ours. In countries where we have not and do not seek patent protection, third parties may be able to manufacture and sell products that are substantially similar or identical to our products or product candidates without our permission, and we may not be able to stop them from doing so.

Similar to other biotechnology companies, our patent position is generally highly uncertain and involves complex legal and factual questions. In this regard, we cannot be certain that we or our current or future licensors, licensees, partners or collaborators were the first to make an invention, or the first inventors to file a patent application claiming an invention in our owned or licensed patents or pending patent applications. In addition, even if patents are issued, given the amount of time required for the development, testing and regulatory review of our product candidates, any patents protecting such candidates might expire before or shortly after the resulting products are commercialized. Moreover, the laws and regulations governing patents could change in unpredictable ways that could weaken the ability of us and our current or future licensors, licensees, partners or collaborators to obtain new patents or to enforce existing patents and patents we may obtain in the future. In any event, the issuance, scope, validity, enforceability and commercial value of our patent rights and those of our current or future licensors, licensees, partners or collaborators are highly uncertain and may not effectively prevent others from commercializing competitive technologies and products.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees, partners or collaborators to perform these activities, which means that these patent applications may not be prosecuted, and these patents may not be enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees, partners or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees, partners or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as broad or effective as that in the United States and we may be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States, if at all. Accordingly, our efforts, and those of our licensors, licensees, partners or collaborators, to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We own one issued United States patent that covers our NGM621 product candidate, although the product and related compositions-of-matter and methods of use are disclosed and claimed in other pending U.S. non-provisional and/or national stage applications in particular foreign countries. We do not currently own or have a license to any issued patents that cover our NGM707, NGM831 and NGM438 product candidates, although these product candidates are disclosed and claimed in our pending U.S. non-provisional and international applications. The patent landscape surrounding all of our product candidates is crowded, and there can be no assurance that we will be able to secure patent protection that would adequately cover such product candidates, that we will obtain sufficiently broad claims to be able to prevent others from selling competing products or that we will be able to protect and maintain any patent protection that we initially secure.

Any changes we make to our product candidates to cause them to have what we view as more advantageous properties may not be covered by our existing patents and patent applications, and we may be required to file new patent applications and/or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidates is crowded, and there can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to any of our product candidates.

We may be unable to obtain intellectual property rights or technologies necessary to develop and commercialize our product candidates.

Several third parties are actively researching and seeking and obtaining patent protection in the fields of cancer, retinal diseases, CVM-related diseases, including heart failure, and liver and metabolic diseases, and there are issued third-party patents and published third-party patent applications in these fields. The patent landscape around our product candidates is complex, and we are aware of several third-party patents and patent applications containing claims directed to compositions-of-matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter that might be relevant to our product candidates. However, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates and technologies.

Depending on what patent claims ultimately issue and how courts construe the issued patent claims, as well as the ultimate formulation and method of use of our product candidates, we may need to obtain a license to practice the technology claimed in such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing rights to third-party intellectual property rights we have, we might be unable to develop and commercialize one or more of our product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We could lose the ability to continue the development and commercialization of our products or product candidates if we breach any license agreement related to those products or product candidates.

Our commercial success depends upon our ability, and the ability of our current and future licensors, licensees, partners and collaborators, to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. A third party may hold intellectual property rights, including patent rights that are important or necessary to the development of our products. As a result, we are a party to a number of technology and patent licenses that are important to our business, and we expect to enter into additional licenses in the future. If we fail to comply with the obligations under these agreements, including payment and diligence obligations, our licensors may have the right to terminate these agreements. In the event of a termination of these agreements, we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or to engage in any other activities necessary to our business that require the freedom-to-operate afforded by the agreements, or we may face other penalties under the agreements. For example, we are party to license agreements with multiple vendors, including our licenses with Horizon Discovery Ltd. and Lonza Sales AG, under which we license cell lines and other technology used to produce multiple product candidates, including some that are currently subject to our collaboration with Merck. We require prior consent from some of these vendors to grant sub-licenses under these agreements. Therefore, these vendors may be able to prevent us from granting sub-licenses to third parties, which could affect our ability or Merck's ability to use certain desired manufacturers in order to manufacture our product candidates. In the event of a termination of our license agreements, our ability or Merck's ability to manufacture or develop any product candidates covered by these agreements may be limited or halted unless we can develop or obtain the rights to technology necessary to produce these product candidates.

Any of the foregoing could materially adversely affect the value of the product or product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or amended agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe patents or misappropriate or otherwise violate intellectual property rights owned or controlled by us or our current or future licensors, licensees, partners or collaborators. In the future, it may be necessary to initiate legal proceedings to enforce or defend these intellectual property rights, to protect trade secrets or to determine the validity or scope of intellectual property rights that are owned or controlled by us or our current or future licensors, licensees, partners or collaborators. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results.

If we or our current or future licensors, licensees, partners or collaborators initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant 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 lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or USPTO, or made a misleading statement during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us or our current or future licensors, licensees, partners or collaborators is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent does not cover the technology in question. An adverse result in any litigation proceeding could put one or more of the patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third parties may initiate legal proceedings against us or our current or future licensors, licensees, partners or collaborators to challenge the validity or scope of intellectual property rights we own or control. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of patents owned or controlled by us or our current or future licensors, licensees, partners or collaborators. These proceedings can be expensive and time-consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us. Accordingly, despite our efforts, we or our current or future licensors, licensees, partners or collaborators may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the United States.

There is a risk that some of our confidential information could be compromised by disclosure during litigation because of the substantial amount of discovery required. Additionally, many foreign jurisdictions have rules of discovery that are different than those in the United States and that may make defending or enforcing our patents extremely difficult. There also could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Third-party pre-issuance submission of prior art to the USPTO, opposition, derivation, revocation, reexamination, *inter partes* review or interference proceedings, or other pre-issuance or post-grant proceedings, as well as other patent office proceedings or litigation in the United States or other jurisdictions brought by third parties against patents or patent applications owned or controlled by us or our current or future licensors, licensees, partners or collaborators, may be necessary to determine the inventorship, priority, patentability or validity of these patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection and allow third parties to commercialize our technology or product candidates without payment to us. Additionally, potential licensees, partners or collaborators could be dissuaded from collaborating with us to license, develop or commercialize current or future product candidates if the breadth or strength of protection provided by our patents and patent applications is threatened. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of the third-party intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Third parties may initiate legal proceedings against us or our current or future licensors, licensees, partners or collaborators alleging that we infringe their intellectual property rights. Alternatively, we may initiate legal proceedings to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. In this regard, we are aware of several third-party patents and patent applications containing claims directed to compositions-of-matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter that might be relevant to our product candidates. These proceedings can be expensive and time-consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us.

In addition, we may be subject to claims that we or our employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Likewise, we and our current or future licensors, licensees, partners or collaborators may be subject to claims that former employees, partners, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. Litigation may be necessary to defend against these claims.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. 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 in favor of the granted third-party patent. This is a high burden, requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim.

An unfavorable outcome in any such proceeding could require us and our current or future licensors, licensees, partners or collaborators to cease using the related technology or developing or commercializing the product or product candidate, or to attempt to license rights to it from the prevailing party, which may not be available on commercially reasonable terms, or at all. Additionally, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

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

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own competing products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. 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, and our business, financial condition, results of operations and prospects may be adversely affected.

In Europe, expected by the end of 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. It is our initial belief that the UPC, while offering a cheaper streamlined process, has potential disadvantages to patent holders, such as making a single European patent vulnerable in all jurisdictions when challenged in a single jurisdiction.

Risks Related to Ownership of Our Common Stock

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

The market price for our common stock has fluctuated significantly from time to time, for example, varying between a high of $32.12 on March 17, 2021 and a low of $2.92 on October 17, 2022. The trading price of our common stock has been and may continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. In addition to the factors discussed in this "Risk Factors" section, these factors include:

- interim or final results of clinical trials of our product candidates or those of our competitors;
- our ability to raise adequate capital through public or private equity or debt offerings or negotiate potential BD Arrangements in a timely manner or at all;
- the success of competitive products or technologies;
- regulatory actions with respect to our product candidates or our competitors' product candidates or products;
- timeline delays in our clinical trials, including delays resulting from the effects of the ongoing global COVID-19 pandemic or otherwise;
- the level of expenses related to any of our product candidates or clinical development programs;

- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors or partners of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- regulatory, legal or payor developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;

- the results of our efforts to in-license or acquire additional product candidates or products;
- 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;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- purchases or sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

In addition, the stock market in general, and The Nasdaq Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including in connection with the ongoing COVID-19 pandemic, the conflict between Russia and Ukraine and recent and potential future bank failures, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including worsening economic conditions and other adverse effects or developments relating to the effects of the ongoing COVID-19 pandemic and recent and potential future bank failures, macroeconomic factors including inflation and rising interest rates, and geopolitical instability, including instability resulting from the conflict between Russia and Ukraine and the related sanctions imposed against Russia, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described elsewhere in this “Risk Factors” section, could have a dramatic and material adverse impact on the market price of our common stock.

Because of volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation.

Holders of stock in companies that have a volatile stock price frequently bring securities class action litigation against the company that issued the stock. We may be the target of this type of litigation in the future. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit and the time and attention of our management could be diverted from other business concerns, either of which could seriously harm our business. Refer to the risk factor titled “*An active trading market for our common stock may not be sustained and sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.*”

Our principal stockholders, including entities affiliated with The Column Group, Merck and management, own a substantial percentage of our stock and collectively will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, significant stockholders, including entities affiliated with The Column Group and Merck, and their respective affiliates, beneficially own a substantial amount of our voting stock. These stockholders collectively may be able to determine all matters requiring stockholder approval. For example, these stockholders collectively may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders. In addition, if any of our significant stockholders decide to sell a meaningful amount of their ownership position and there is not sufficient demand in the market for our common stock, our stock price could fall.

An active trading market for our common stock may not be sustained and sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Our common stock is currently listed on The Nasdaq Global Select Market under the symbol “NGM” and trades on that market. We cannot ensure that an active trading market for our common stock will be sustained. Accordingly, we cannot ensure the liquidity of any trading market, your ability to sell your shares of our common stock when desired or the prices that you may obtain for your shares.

For the trading days during the three months ended March 31, 2023, the average daily trading volume for our common stock on The Nasdaq Global Select Market was only 338,500 shares. As a result, sales of a substantial number of shares of our common stock in the public market, including pursuant to the Sales Agreement or by any of our large stockholders, or even the perception in the market that we or the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. In addition, as a result of the low trading volume of our common stock, the trading of relatively small quantities of shares by our stockholders could disproportionately influence the market price of our common stock in either direction. The price for our shares could, for example, decline significantly in the event that a large number of shares of our common stock are sold on the market without commensurate demand, as compared to an issuer with a higher trading volume that could better absorb those sales without an adverse impact on its stock price. Moreover, certain holders of our common stock have rights, subject to certain 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 do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, if any.

Some provisions of our charter documents, Delaware law and our agreement with Merck may have anti-takeover effects or could otherwise discourage an acquisition of us by others, even if an acquisition would benefit our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

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 to remove our current management. These provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- authorizing the issuance of “blank check” preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, which is generally a person that together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Certain provisions in our agreement with Merck may also deter a change of control. For example, under the Amended Collaboration Agreement, a change of control gives Merck the right to terminate the research phase of the collaboration as well as additional rights if our acquirer is a qualifying large pharmaceutical company or has a research, development or commercialization program that competes with a program licensed by Merck, if any.

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders; any action asserting a claim against us or any director or officer or other employee arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; any action with respect to the validity of our amended and restated certificate of incorporation or amended and restated bylaws; any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; or any action asserting a claim against us or any director or officer or other employee that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Securities and Exchange Act of 1934, as amended, or the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act of 1933, as amended, or 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 certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

We, our CROs, our CMOs, our current and potential future partners and other third parties we rely on or partner with could experience a cybersecurity incident that could harm our business.

We collect, store and transmit proprietary, confidential and sensitive information, including personal information (such as health-related data), in the course of our business. Our technology systems and the information and data processed and stored in our technology systems or otherwise by us or on our behalf, and the technology systems of, and data accessed on our behalf by, our research collaborators, partners, CROs, CMOs, contractors, consultants and other third parties on which we depend to operate our business, may be vulnerable to security breaches, loss, damage, corruption, unauthorized access, use or disclosure or misappropriation. Such incidents may result from the actions of a wide variety of actors, including traditional hackers, our personnel or the personnel of the third parties we work with, sophisticated nation-states and nation-state-supported actors. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our

systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. Threats we and third parties on which we rely may face are constantly evolving and include (without limitation) malware, viruses, software vulnerabilities and bugs, software or hardware failure, hacking, denial of service attacks, social engineering (including phishing), ransomware, inside threats, credential stuffing or other cyberattacks, telecommunications failures, earthquakes, fires, floods and similar threats. Threats such as ransomware attacks, for example, are becoming increasingly prevalent and severe. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. Our ability to monitor third parties on whom we rely to operate our business is limited, and these third parties may be subject to, and may expose us to, cyberattacks and other security incidents.

We may, under certain data privacy and security obligations, be required to, or we may choose to, expend significant resources or modify our business activities (including our clinical trial activities) in an effort designed to protect against security incidents. While we have developed systems and processes designed to protect the integrity, confidentiality and security of the confidential and personal information under our control, we cannot assure you that any security measures that we or our third-party service providers implement will be effective in preventing cybersecurity incidents. There are many different cyber-crime and hacking techniques, and as such techniques continue to evolve, we may be unable to anticipate attempted security breaches, identify them before our information is exploited or react in a timely manner.

Certain functional areas of our workforce work remotely on a full- or part-time basis outside of our corporate network security protection boundaries or otherwise utilize network connections, computers and devices outside of our premises or network, which imposes additional risks to our business, including increased risk of industrial espionage, phishing and other cybersecurity attacks, and unauthorized dissemination of proprietary or confidential information, including personal information, any of which could have a material adverse effect on our business.

Despite our efforts to strengthen security and authentication measures, we have not always been able in the past, and may be unable in the future, to detect vulnerabilities in our information technology systems. We have experienced an overall increase in cybersecurity incidents since 2020, none of which, to date, have caused material disruption to our business, or to our knowledge, involved a material security breach. For example, in December 2020, we detected that an attacker had gained access to a single system on our network and unsuccessfully attempted to use that access to stage a broader attack against us. We or the third parties we rely on or partner with could experience a material system failure, security breach or other cybersecurity incident, including any related to or in connection with any of the aforementioned threats, in the future, which could interrupt our operations, disrupt our development programs and have a material adverse effect on our business, financial condition and results of operations. For example, the loss or corruption of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates, to analyze clinical trial samples and to conduct clinical trials, and cybersecurity incidents experienced by these third parties could have a material adverse effect on our business. Security breaches and other cybersecurity incidents affecting us or the third parties we rely on or partner with could also result in substantial remediation costs and expose us to litigation (including class claims), regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, fines, penalties, indemnification obligations, negative publicity, reputational harm, monetary fund diversions, interruptions in our operations (including availability of data), financial loss and other liabilities and harms. Additionally, such incidents may trigger data privacy and security obligations requiring us to notify relevant stakeholders. These disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition and results of operations.

The withdrawal of the United Kingdom from the EU, commonly referred to as Brexit, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator.

On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-U.K. Trade and Cooperation Agreement, or the TCA. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the TCA.

Among the changes that are now applied are that Great Britain (England, Scotland and Wales) are treated as a third country. Northern Ireland, with regard to EU regulations, continues to follow many aspects of EU regulatory rules. As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and accept official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The eventual adoption of the Retained EU Law (Revocation and Reform) Bill that is currently going through the UK adoption procedure may, however, result in substantial change to the extent to which EU laws influence these and other actions in the UK.

After running a public consultation which ended in December 2022, the UK government unilaterally agreed to permanently accept EU batch testing and batch release. However, it is not certain whether the UK will continue this approach, particularly following adoption of the current Retained EU Law (Revocation and Reform) Bill. If the UK were to adopt an approach whereby re-testing and/or re-release in the UK would be required, this could result in increased costs. Furthermore, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use. As regards marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a national marketing authorization. Northern Ireland, however, continues to be covered by the marketing authorizations granted by the European Commission.

The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation) and, as such, it falls within the scope of the Retained EU Law (Revocation and Reform) Bill as currently drafted. Adoption of the Retained EU Law (Revocation and Reform) Bill as currently drafted would result in the regulatory framework governing clinical trials in the UK being revoked unless Ministerial action were taken to retain or replace it. It is currently unclear to what extent the UK will seek to align its regulations with the EU following entry into application of the Clinical Trials Regulation in the EU which occurred on January 31, 2022.

Since January 1, 2021, an applicant for a marketing authorization granted by the European Commission in accordance with the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA can no longer be established in the UK. Since this date, companies established in the UK cannot use the centralized procedure and instead must follow one of the UK national authorization procedures to obtain a marketing authorization to market products in the UK. For an initial two-year period from January 1, 2021, MHRA could rely on a decision taken by the European Commission on the approval of a new centralized procedure marketing authorization when determining an application for a Great Britain marketing authorization, or use the MHRA's decentralized or mutual recognition procedures which enable marketing authorizations approved in EEA countries to be granted in Great Britain. Post Brexit, the MHRA has been updating various aspects of the regulatory regime for medicinal products in the UK. These include: introducing the Innovative Licensing and Access Procedure to accelerate the time to market and facilitate patient access for innovative medicinal products; updates to the UK national approval procedure, introducing a 150-day objective for assessing applications for marketing authorizations in the UK, Great Britain and Northern Ireland and a rolling review process for marketing authorization applications (rather than a consolidated full dossier submission). In September 2022, the MHRA extended the procedure whereby it may rely on a decision taken by the European Commission when determining an application for a Great Britain marketing authorization until December 31, 2023.

Orphan designation in Great Britain following Brexit is, unlike in the EU, not a pre-marketing authorization. Applications for orphan designation are made at the same time as an application for a marketing authorization. The

criteria to be granted an orphan drug designation are essentially identical to those in the EU but based on the prevalence of the condition in Great Britain. It is therefore possible that medical conditions that were or would have been designated as orphan conditions in Great Britain prior to the end of the Transition Period are or would no longer be and that conditions that were not or would not have been designated as orphan conditions in the EU will be designated as such in Great Britain.

Since a significant part of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU legislation, Brexit has the potential of materially impacting the regulatory framework with respect to the development, manufacture, approval, import and placement of our product candidates on the market in the UK and the EU. The changes effected by the TCA, as well as any future changes in the regulatory framework governing medicinal products, including the adoption of the Retain EU Law (Revocation and Reform) Bill, could increase the costs and complexity of doing business in or with the UK, which could adversely affect our business.

We are subject to rapidly changing and increasingly stringent foreign and domestic laws and regulations relating to privacy, data protection and information security. The restrictions imposed by these requirements or our actual or perceived failure to comply with them could harm our business.

We may collect, use, transfer or otherwise process proprietary, confidential and sensitive information, including personal information (including health-related data), which subjects us to numerous evolving and complex data privacy and security obligations, including various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations that govern the processing of such information by us and on our behalf. Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, impose strict requirements for processing personal information. For example, the EU GDPR, UK GDPR and other relevant laws that govern patient confidentiality and storage of personal health data may apply to our processing of personal information from clinical trials participants and other individuals located in the European Economic Area, or EEA, and/or the UK and, if any of our product candidates are approved, we may seek to commercialize those products in the EEA and/or the UK (as applicable). Companies that violate the EU GDPR can face private litigation, prohibitions on data processing, other administrative measures, reputational damage and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue. The EU GDPR requires us to, among other things: give detailed disclosures about how we collect, use and share personal information; contractually commit to data protection measures in our contracts with vendors; maintain adequate data security measures; notify regulators and affected individuals of certain data breaches; meet extensive privacy governance and documentation requirements; and honor individuals' data protection rights, including their rights to access, correct and delete their personal information. The UK has incorporated an amended version of the EU GDPR into UK law, commonly referred to as the UK GDPR, which is independent from, but at present materially aligned with, the EU GDPR, which together with the UK Data Protection Act of 2018, or UK DPA, covers the processing of personal information of UK residents. Non-compliance with UK GDPR may result in substantially similar adverse consequences to those in relation to the EU GDPR, including monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

On June 28, 2021, the European Commission adopted an adequacy decision permitting flows of personal data between the EU and the UK to continue without additional requirements. The UK Government also adopted a reciprocal adequacy decision in respect of EEA member states permitting flows of personal data from the UK to the EEA. However, the European Commission's UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision and remains under review by the European Commission during this period. The entry into force of the US-UK Data Access Agreement on October 3, 2022 may put at risk the European Commission's adequacy decision granted to the UK. If such adequacy decision were to be withdrawn, personal data could not flow freely between the UK and the EU and additional safeguards would need to be adopted, which could result in additional costs for us.

The relationship between the UK and the EU in relation to certain aspects of data protection laws remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. The UK's Data Protection and Digital Information Bill, or the Bill, was re-introduced before the UK Parliament in March 2023, introducing reforms intended to update and simplify the UK's data protection framework, deviating from the EU GDPR.

Certain jurisdictions have enacted data localization laws and laws restricting cross-border transfers of personal information. In particular, regulators and courts in the EEA and the UK have significantly restricted the transfer of personal information to the United States and other countries whose privacy laws it believes are

inadequate. 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 information from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses and the UK's international data transfer agreement, 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 information to the United States.

We continue to monitor changes in data protection laws related to the cross-border transfer of personal information; however, uncertainty remains regarding any future regulations, interpretations of existing law or guidance that may be issued, particularly by the EU authorities. If we are unable to implement a valid compliance solution for cross-border transfers of personal information, or if the requirements for a legally-compliant transfer are too onerous, we will face increased exposure to significant adverse consequences, including substantial fines, regulatory actions, as well as injunctions against the export and processing of personal information from the EEA. Our inability to import personal information from the EEA, UK or Switzerland or other countries may also restrict or prohibit our clinical trial activities in those countries; limit our ability to collaborate with CROs, service providers, contractors and other companies subject to laws restricting cross-border data transfers; require us to increase our data processing capabilities in other countries at significant expense and may otherwise negatively impact our business operations. We may also become subject to new laws in the EEA that regulate cybersecurity and non-personal data, such as data collected through the internet of things. Depending on how these laws are interpreted, we may have to make changes to our business practices and products to comply with such obligations.

Additionally, other countries have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

Privacy and data security laws in the United States at the federal, state and local level are increasingly complex and changing rapidly. For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, at the state level, the privacy and data protection landscape is changing rapidly. For example, the California Consumer Privacy Act of 2018, or CCPA, took effect on January 1, 2020. The CCPA gives California residents certain rights similar to the individual rights given under the EU GDPR, including the right to access and delete their personal information, opt-out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, including statutory fines for noncompliance and a limited private right of action in connection with certain data breaches. In addition, the California Privacy Rights Act of 2020, or CPRA, which became operative January 1, 2023, expands the CCPA's requirements, including in that it applies to personal information of business representatives and employees and establishes a new regulatory agency to implement and enforce the law. While the CCPA contains an exemption for certain personal information processed in connection with clinical trials, we may process other personal information that is subject to the CCPA and CPRA. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. The evolving patchwork of differing state and federal privacy and data security laws increases the cost and complexity of operating our business and increase our exposure to liability.

We may also be bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We may publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and 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.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal information on our behalf. In addition, these obligations may require us to change aspects of our business model. Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could impact whether or not we are in compliance.

If we (or third parties on which we rely) fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences, including (without limitation): government

enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal information 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 revision or restructuring of our operations.

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

Our facilities have experienced electrical blackouts as a result of a shortage of available electrical power. Future blackouts, which may be implemented by the local electricity provider in the face of high winds and dry conditions, could disrupt our operations. Our facility is located in a seismically active region. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a comprehensive recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. In addition, the sole supplier of clinical drug substances for NGM120, NGM707, NGM831, NGM438 and MK-3655 (NGM313) is located in Lithuania, a region that has experienced political unrest. Refer to the risk factor titled "*We rely completely on CMOs for the manufacture of our product candidates and are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates and any future products*." If our operations or the operations of third parties providing services to us are disrupted by any such occurrences, our business and future prospects may be negatively affected.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials, chemicals and radioactive and biological materials. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

Our ability to use net operating loss carryforwards and certain other tax attributes to offset taxable income could be limited.

We plan to use our current year operating losses to offset taxable income from any revenue generated from operations, including BD Arrangements. To the extent that our taxable income exceeds any current year operating losses, we plan to use our net operating loss carryforwards to offset income that would otherwise be taxable. Our federal net operating loss carryforwards generated in tax years beginning before January 1, 2018 are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the 2017 Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, our federal net operating losses generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the ability to deduct such federal net operating losses generated in tax years beginning after December 31, 2020 is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the 2017 Tax Act or the CARES Act.

In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if we experience an "ownership change," generally defined as a greater than 50% change, by value, in equity ownership over a three-year period, our ability to use our pre-change net operating loss carryforwards and certain other pre-change tax attributes (such as R&D tax credits) to offset our post-change income may be limited. Due to our initial public offering and other shifts in our stock ownership, we have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our use of federal net operating loss carryforwards and certain other tax attributes could be limited. State net operating loss carryforwards may be similarly limited. In addition, at the state level, there may be periods during which the use of

net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

New tax laws or regulations, changes to existing tax laws or regulations or changes in their application to us or our customers may have a material adverse effect on our business, cash flows, financial condition or results of operations.

New tax laws, statutes, rules, regulations, directives, decrees or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations, directives, decrees or ordinances could be interpreted, changed or modified. Any such enactment, interpretation, change or modification could adversely affect us, possibly with retroactive effect. For example, the recently enacted IRA imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. In addition, for certain research and experimental, or R&E, expenses incurred in tax years beginning after December 31, 2021, the 2017 Tax Act requires the capitalization and amortization of such expenses over five years if incurred in the United States and fifteen years if incurred outside the United States, rather than deducting such expenses currently. Although there have been legislative proposals to repeal or defer the capitalization requirement, there can be no assurance that such requirement will be repealed, deferred or otherwise modified. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings and the deductibility of expenses under the 2017 Tax Act, as amended by the CARES Act or any future tax reform legislation could have a material impact on the value of our deferred tax assets, result in significant one-time charges and increase our future U.S. tax expense.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred frequently in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

We continue to incur increased costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives. In addition, we are obligated to develop and maintain proper and effective internal control over financial reporting. In the future, we may not complete our analysis of our internal control over financial reporting in a timely manner, or our internal control over financial reporting may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

As a public company, we incur significant legal, accounting, insurance and other expenses, and these expenses further increased in connection with our loss of “emerging growth company” status as of December 31, 2021. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the Dodd-Frank Act, as well as rules adopted, and to be adopted, by the SEC and The Nasdaq Global Select Market. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and may make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur in the future to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Specifically, in order to comply with the requirements of being a public company, we need to undertake various actions, including maintaining effective internal controls and procedures. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded,

processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. In addition, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404(b) of the Sarbanes-Oxley Act, and to allow our independent registered public accounting firm to issue an attestation report on the effectiveness of our internal control over financial reporting. Our compliance with Section 404(b) of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit staff and outsource this function to a third party. We have hired and will need to retain our current accounting and financial staff who have the appropriate public company experience and technical accounting knowledge. If we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on The Nasdaq Global Select Market.

Our ability to successfully implement our business plan and comply with Section 404(b) of the Sarbanes-Oxley Act requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls may cause our operations to suffer, and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an attestation report from our independent registered public accounting firm as required under Section 404(b) of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on the price for our common stock and could adversely affect our ability to access the capital markets.

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

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 realities that judgments in decision-making can be faulty and 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.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

Our stock price and trading volume is heavily influenced by the way analysts and investors interpret our clinical trial results, any BD Arrangements we may enter into, our financial information and other disclosures. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about our business or publish negative reports about our business, regardless of accuracy, our stock price and trading volume could decline.

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

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Schedule Form	File Number	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	8-K	001-38853	3.1	4/8/19
3.2	Amended and Restated Bylaws	S-1	333-227608	3.4	9/28/18
10.1+*	Non-Employee Director Compensation Policy				
31.1+	Certification of Chief 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 Chief Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1+**	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

+ Filed or furnished herewith.

* Indicates management contract or compensatory plan or arrangement.

** The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q are not deemed filed with the SEC and are not to be incorporated by reference into any filing of NGM Biopharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

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.

NGM Biopharmaceuticals, Inc.

Date: May 4, 2023

By: /s/ David J. Woodhouse

David J. Woodhouse, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 4, 2023

By: /s/ Siobhan Nolan Mangini

Siobhan Nolan Mangini
President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1

NGM Biopharmaceuticals, Inc.
Non-Employee Director Compensation Policy

Approved by the Board of Directors: March 8, 2023

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of NGM Biopharmaceuticals, Inc. ("***NGM***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (the "***Director Compensation Policy***").

The Director Compensation Policy became effective on April 4, 2019 (the "***Effective Date***"). The Director Compensation Policy may be amended at any time in the sole discretion of the Board. Capitalized terms not explicitly defined in this Director Compensation Policy but defined in Company's 2018 Equity Incentive Plan, as amended and restated from time to time, or any successor equity incentive plan adopted by NGM (the "***Plan***"), will have the same definitions as in the Plan.

An Eligible Director may decline all or any portion of his or her compensation by giving notice to NGM prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

Philosophy

The Director Compensation Policy is designed to attract and retain experienced, talented individuals to serve on the Board. The Board anticipates that the Board (or a duly authorized committee thereof) will generally review Eligible Director compensation on an annual basis. The Director Compensation Policy, as amended from time to time, may take into account the time commitment expected of Eligible Directors, best practices and market rates in director compensation, the economic position of NGM, broader economic conditions, historical compensation structure, the advice of the compensation consultant that the Compensation Committee of the Board or the Board may retain from time to time, and the potential dilutive effect of equity awards on our stockholders.

Under the Director Compensation Policy, Eligible Directors receive cash compensation in the form of retainers to recognize their level of responsibility as well as the necessary time commitment involved in serving in a leadership role and/or on a committee of the Board (a "***Committee***"). Eligible Directors also receive equity compensation because we believe that stock ownership provides an incentive to act in ways that maximize long-term stockholder value. Further, we believe that stock-based awards are essential to attracting and retaining talented Board members. When stock options are granted, these stock options will have an exercise price at least equal to the Fair Market Value of Common Stock on the date of grant, so that stock options provide a return only if the Fair Market Value appreciates over the period in which the stock option vests and

remains exercisable. We believe that the vesting acceleration provided in the case of a Change in Control is consistent with market practices and is critical to attracting and retaining high quality directors.

To the extent this Director Compensation Policy would otherwise provide for compensation to any Eligible Director that would exceed any separate stockholder approved limit set forth in the Plan (including the limits set forth in Section 3(e) of the Plan), the benefits provided under this Director Compensation Policy will automatically be reduced to fall within such limits (or if previously paid, are subject to recoupment).

Annual Cash Compensation

Each Eligible Director shall receive the cash compensation described below. The annual cash compensation amount set forth below is payable in equal quarterly installments in arrears within 30 days following each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a Committee at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash retainer fees are vested upon payment.

1. Annual Board Service Retainer:
    a. Eligible Directors other than the Lead Independent Director or Non-Executive Chairperson, as applicable: $40,000
    b. Lead Independent Director: $65,000
    c. Non-Executive Chairperson: $75,000

2. Annual Committee Chair Service Retainer:
    a. Chairperson of the Audit Committee: $30,000
    b. Chairperson of the Compensation Committee: $15,000
    c. Chairperson of the Nominating & Corporate Governance Committee ("***NCGC***"): $10,000

3. Annual Committee Member Service Retainer (excludes Committee Chairs):
    a. Member of the Audit Committee: $10,000
    b. Member of the Compensation Committee: $6,000
    c. Member of the NCGC: $5,000

Equity Compensation

The equity compensation set forth below (including pursuant to an Annual Election, as defined below) will be granted under the Plan and will be documented on the applicable form of equity award agreement most recently approved for use by the Board (or a duly authorized committee thereof) for Eligible Directors. All stock options granted under the Director Compensation Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier

termination in connection with a termination of Continuous Service or a Corporate Transaction as provided in the Plan). Upon a termination of Continuous Service other than for death, Disability or Cause, the post-termination exercise period of a stock option will be 12 months from the date of termination.

1. Initial Option Grant. On the date of the Eligible Director's initial election to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director automatically, and without further action by the Board or Compensation Committee of the Board, will be granted a stock option to purchase shares of Common Stock having a Grant Date Value (as defined below) of $400,000 (the "***Initial Option Grant***"). One-third of the shares underlying the Initial Option Grant will vest after the first year, with the remaining shares vesting quarterly in years two and three following the grant date, such that the Initial Option Grant will be fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service on each applicable vesting date.

2. Annual Option Grant. On the date of each NGM annual stockholder meeting (an "***Annual Meeting***"), each Eligible Director automatically, and without further action by the Board or Compensation Committee of the Board, will be granted a stock option to purchase Common Stock having an Grant Date Value of $200,000 (the "***Annual Option Grant***"). The Annual Option Grant will vest in four approximately equal quarterly tranches, with the final tranche vesting on the earlier of (x) the first anniversary of the date of grant, and (y) the day prior to the next Annual Meeting, subject to the Eligible Director's Continuous Service on each applicable vesting date.

3. Calculation of Grant Date Value. The "***Grant Date Value***" of an equity award granted under this Director Compensation Policy will be determined using the same method the Company uses to calculate the grant date fair value of stock-based compensation for its financial statements (e.g., applying a Black-Scholes option pricing model in the case of stock options).

4. Treatment on a Change in Control. In the event of a Change in Control, any then-unvested equity award will fully vest (and become exercisable, in the case of an option) as of immediately prior to the effective time of such transaction, subject to the Eligible Director's Continuous Service on the effective date of such transaction. For clarity, such accelerated vesting will not accelerate the settlement of any equity award subject to a deferral election in accordance with Section 409A of the Internal Revenue Code.

5. Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust the number of shares underlying any Initial Option Grant and Annual Option Grant made after the date of such Capitalization Adjustment.

Election to Receive Annual Cash Compensation in the Form of Stock Options

Each Eligible Director may elect in writing (an "***Annual Election***") to receive his or her annual cash compensation in the form of a stock option (an "***Annual Election Option***"). Such Annual Election would apply to all annual cash compensation payable during the subsequent year of service, measured from the date of the Annual Meeting.

Except as provided below, any Annual Election must be submitted in January of each calendar year, or in the case of an individual who first becomes an Eligible Director in any calendar year, within 30 days following the date on which he or she first becomes an Eligible Director (and no later than 30 days prior to the date of the Annual Meeting). An Annual Election will be irrevocable once submitted. All Annual Elections must also be submitted during an "open window period" in accordance with the Company's then-effective Insider Trading and Trading Window Policy (or any other policy on trading in Company securities), and when the Eligible Director submitting the Annual Election is not otherwise aware of any material, nonpublic information with respect to the Company or any of its securities (collectively, an "***Open Window***"). If there were no Open Windows within the applicable timeframe above during which an Annual Election could be submitted, then the Annual Election for that calendar year will be due no later than the tenth business day following the commencement of the next Open Window.

An Annual Election Grant will be granted on the date of the next Annual Meeting, with a Grant Date Value equal to the aggregate amount of cash retainers that such Eligible Director would otherwise have been eligible to receive over the four fiscal quarters following such Annual Meeting, and will vest in quarterly tranches, with the final tranche vesting on the earlier of (x) the first anniversary of the date of grant, and (y) the day prior to the next Annual Meeting.

Expenses

The Company will reimburse Eligible Directors for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and/or Committee meetings; *provided*, that Eligible Directors timely submit to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

Exhibit 31.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David J. Woodhouse, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 4, 2023

By: /s/ David J. Woodhouse
David J. Woodhouse, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Siobhan Nolan Mangini, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 4, 2023

By: /s/ Siobhan Nolan Mangini
Siobhan Nolan Mangini
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

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), David Woodhouse, Chief Executive Officer and Director of NGM Biopharmaceuticals, Inc. (the "Company"), and Siobhan Nolan Mangini, President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: May 4, 2023

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 4th day of May, 2023.

/s/ David J. Woodhouse
David J. Woodhouse, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Siobhan Nolan Mangini
Siobhan Nolan Mangini
President and Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Quarterly Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NGM Biopharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.