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, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38853

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 2, 2022, the registrant had 79,257,148 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, 2022	December 31, 2021*
Assets		
Current assets:		
Cash and cash equivalents	$ 109,872	$ 151,795
Short-term marketable securities	219,960	214,458
Related party receivable from collaboration	103	4,945
Prepaid expenses and other current assets	7,687	8,082
Total current assets	337,622	379,280
Property and equipment, net	9,436	10,071
Operating lease right-of-use asset	3,570	4,045
Restricted cash	1,499	1,499
Other non-current assets	7,646	7,492
Total assets	$ 359,773	$ 402,387
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,815	$ 5,246
Accrued liabilities	29,478	33,258
Operating lease liability, current	5,153	5,077
Contract liabilities	5,117	17,774
Total current liabilities	44,563	61,355
Operating lease liability, non-current	4,073	5,385
Total liabilities	48,636	66,740
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, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.001 par value; 400,000 shares authorized; 78,087 and 77,962 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	78	78
Additional paid-in capital	763,152	754,664
Accumulated other comprehensive loss	(677)	(129)
Accumulated deficit	(451,416)	(418,966)
Total stockholders' equity	311,137	335,647
Total liabilities and stockholders' equity	$ 359,773	$ 402,387

See accompanying notes to these unaudited condensed consolidated financial statements.

*The condensed consolidated balance sheet as of December 31, 2021 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,	
	2022	**2021**
Related party revenue	$ 20,948	$ 21,575
Operating expenses:		
Research and development	42,806	40,699
General and administrative	10,723	8,721
Total operating expenses	53,529	49,420
Loss from operations	(32,581)	(27,845)
Interest income, net	176	114
Other (expense) income, net	(45)	187
Net loss	$ (32,450)	$ (27,544)
Net loss per share, basic and diluted	$ (0.42)	$ (0.36)
Weighted average shares used to compute net loss per share, basic and diluted	78,023	76,034

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,	
	2022	**2021**
Net loss	$ (32,450)	$ (27,544)
Other comprehensive loss, net of tax:		
Net unrealized loss on available-for-sale marketable securities	(548)	(22)
Total comprehensive loss	$ (32,998)	$ (27,566)

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 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

	Common Stock		Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	70,583	$ 71	$ 578,599	$ 4	$ (298,631)	$ 280,043
Issuance of common stock under offering, net of issuance costs	5,324	5	134,565			134,570
Issuance of common stock upon exercise of stock options	1,001	1	5,906	—	—	5,907
Vesting of common stock from early exercises	5	—	41	—	—	41
Stock-based compensation expense	—	—	6,582	—	—	6,582
Comprehensive loss	—	—	—	(22)	—	(22)
Net loss	—	—	—	—	(27,544)	(27,544)
Balance at March 31, 2021	76,913	$ 77	$ 725,693	$ (18)	$ (326,175)	$ 399,577

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,	
	2022	**2021**
Operating activities		
Net loss	$ (32,450)	$ (27,544)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,820	6,582
Depreciation	1,427	1,554
Amortization of premium on marketable securities	518	570
Non-cash lease expense	475	441
Other non-cash expenses	460	(315)
Changes in operating assets and liabilities:		
Related party receivable from collaboration	4,842	8
Related party contract asset	—	1,500
Prepaid expenses and other assets	241	(1,299)
Accounts payable	(431)	(2,128)
Accrued and other liabilities	(4,747)	(427)
Operating lease liability	(1,236)	(1,167)
Contract liabilities	(12,657)	—
Net cash used in operating activities	(35,738)	(22,225)
Investing activities		
Purchase of marketable securities	(86,904)	(144,996)
Proceeds from maturities of marketable securities	80,336	28,000
Purchases of property and equipment	(285)	(160)
Net cash used in investing activities	(6,853)	(117,156)
Financing activities		
Proceeds from follow on offering, net	—	134,570
Proceeds from exercise of stock options	668	5,907
Net cash provided by financing activities	668	140,477
Net (decrease) increase in cash and cash equivalents	(41,923)	1,096
Cash, cash equivalents and restricted cash, at beginning of period	153,294	148,516
Cash, cash equivalents and restricted cash, at end of period	$ 111,371	$ 149,612
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment purchases accrued and not yet paid	$ 436	$ 637
Right of use asset acquired under operating lease on the adoption of ASC 842	$ —	$ 5,855
Vesting of common stock from early exercises	$ —	$ 41

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., collectively referred to as the Company, is focused on discovering and developing novel, potentially life-changing medicines based on scientific understanding of key biological pathways underlying cancer, retinal diseases and liver and metabolic diseases. The Company's robust portfolio of product candidates range from early discovery to Phase 2b development and include NGM707, NGM831, NGM438, NGM120, NGM621, aldafermin and MK-3655 in active 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, 2021 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed with the United States Securities and Exchange Commission, or SEC, on March 1, 2022. 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, 2022 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 in Australia, NGM Biopharmaceuticals Australia Pty Ltd. 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, the valuation of common stock and the associated 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. Net losses were $32.5 million and $27.5 million during the three months ended March 31, 2022 and 2021, respectively. As of March 31, 2022, the Company had an accumulated deficit of $451.4 million. The Company expects its accumulated deficit will increase significantly over time and does not expect to experience positive cash flows from operations in the near future.

As of March 31, 2022, the Company had $329.8 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, 2022, $127.2 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 date of filing of this Quarterly Report on Form 10-Q.

To fully implement the Company's business plan and fund its operations, the Company will need 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), product collaborations, strategic alliances and licensing arrangements or a combination of the foregoing.

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 a bank it believes is highly creditworthy in amounts that may at times exceed federally insured limits. As of March 31, 2022 and December 31, 2021, 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, 2022, 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 balance represents collateral required under the Company's facility lease agreement and is classified as a non-current asset on the condensed consolidated balance sheets, as the collateral will not be returned to the Company within twelve months from the date of these condensed consolidated financial statements.

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.,

and Australian 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.

Related party receivables from collaborations 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 (formerly Merck Sharp & Dohme Corp.), or Merck, and any future collaboration agreements with other collaboration 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 agreements with other collaboration 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, 2022 and 2021.

Property and Equipment, Net

Property and equipment is 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 December 31, 2021, the Company was no longer an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended, and as a result, the Company was required to adopt Accounting Standards Update, or ASU, 2016-02, Leases (Topic 842), referred to as ASC 842, for the fiscal year beginning January 1, 2021 using a modified-retrospective approach under which the Company recognized and measured leases existing at, or entered into after, January 1, 2021. Accordingly, the Company's condensed consolidated financial statements and information for the periods ended March 31, 2021 have been restated to conform to the new standard.

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 noncancellable 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 laboratory and office facilities is classified as an operating lease.

The following table summarizes the effects of adopting ASC 842 on the Company's condensed consolidated statement of cash flows for the three months ended March 31, 2021 (in thousands):

	Three Months Ended March 31, 2021		
	Previously Reported	ASC 842 Adjustment	As Adjusted
Operating activities			
Noncash lease expense	$ —	$ 441	$ 441
Changes in operating assets and liabilities:			
Deferred rent	(726)	726	—
Operating lease liability	—	(1,167)	(1,167)
Net cash used in operating activities	$ (22,225)	$ —	$ (22,225)

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, 2022 and December 31, 2021, 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 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 research and development 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 research and development 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 research and development 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 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 research and development 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 research and development 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

Research and development costs are expensed as incurred. Research and development 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 research and development 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 research and development 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 grants, as well as shares issued under its 2019 Employee Stock Purchase Plan, or ESPP. Grants are awarded to employees, directors and nonemployees. The Company measures employee and director stock-based compensation expense for all stock-based awards at the grant date based on the fair value measurement of the award. Subsequent to the adoption of ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting on January 1, 2019, stock-based compensation expense for nonemployee awards is measured based on the fair value on the date of adoption. 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.

Foreign Currency Transactions

The functional currency of NGM Biopharmaceuticals Australia Pty Ltd., the Company's wholly-owned subsidiary, is the U.S. dollar. Accordingly, all monetary assets and liabilities of the subsidiary are remeasured into U.S. dollars at the current period-end exchange rates and non-monetary assets are remeasured using historical exchange rates. Income and expense elements are remeasured to U.S. dollars using the average exchange rates in effect during the period. Remeasurement gains and losses are recorded as other income (expense), net on the condensed consolidated statements of operations.

The Company is subject to foreign currency risk with respect to its clinical and manufacturing contracts denominated in currencies other than the U.S. dollar, primarily British Pounds, Swiss Francs, Australian dollars and the Euro. Payments on contracts denominated in foreign currencies are made at the spot rate on the day of payment. Changes in the exchange rate between billing dates and payment dates are recorded within other income (expense), net on the condensed consolidated statements of operations.

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. 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,	
	2022	2021
Numerator:		
Net loss	$ (32,450)	$ (27,544)
Denominator:		
Weighted average number of shares used in calculating net loss per share—basic and diluted	78,023	76,034
Net loss per share—basic and diluted	$ (0.42)	$ (0.36)

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,	
	2022	2021
Options to purchase common stock	13,240	11,301
Shares committed under ESPP	390	292
Total	13,630	11,593

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, 2022 and 2021, 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, 2022				
U.S. treasury securities	$ 168,668	$ 3	$ (662)	$ 168,009
Money market funds	105,292	—	—	105,292
Commercial paper	44,373	—	—	44,373
Corporate and agency bonds	7,596	—	(18)	7,578
Totals	$ 325,929	$ 3	$ (680)	$ 325,252
Classified as:				
Cash and cash equivalents				$ 105,292
Short-term marketable securities (amortized cost of $220,637)				219,960
Total				$ 325,252

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
As of December 31, 2021				
U.S. treasury securities	$ 141,093	$ —	$ (116)	$ 140,977
Money market funds	129,763	—	—	129,763
Corporate and agency bonds	64,997	7	(20)	64,984
Commercial paper	8,497	—	—	$ 8,497
Totals	$ 344,350	$ 7	$ (136)	$ 344,221
Classified as:				
Cash and cash equivalents				$ 129,763
Short-term marketable securities (amortized cost of $214,587)				214,458
Total				$ 344,221

Cash and cash equivalents in the table above excludes cash on deposit with banks of $4.6 million and $22.0 million as of March 31, 2022 and December 31, 2021, 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, 2022 and December 31, 2021, all of the Company's marketable securities had remaining contractual maturities of less than one year. As of March 31, 2022, the Company had 14 marketable securities in an unrealized loss position compared to 21 marketable securities in an unrealized loss position as of December 31, 2021. Marketable securities that had been in unrealized loss positions as of March 31, 2022 and December 31, 2021 had been in an unrealized loss position for less than twelve months. The Company does not 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, our 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, 2022	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
U.S. treasury securities	$ 168,009	$ —	$ —	$ 168,009
Money market funds	105,292	—	—	105,292
Commercial paper	—	44,373	—	44,373
Corporate and agency bonds	—	7,578	—	7,578
Totals	$ 273,301	$ 51,951	$ —	$ 325,252

	Fair Value Measurements			
As of December 31, 2021	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
U.S. treasury securities	$ 140,977	$ —	$ —	$ 140,977
Money market funds	129,763	—	—	129,763
Corporate and agency bonds	—	64,984	—	64,984
Commercial paper	—	8,497	—	8,497
Totals	$ 270,740	$ 73,481	$ —	$ 344,221

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

The Company estimates the fair values of investments in commercial paper and corporate and agency bond 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, 2022 and year ended December 31, 2021.

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, 2022	March 31, 2021
Cash and cash equivalents	$ 109,872	$ 148,113
Restricted cash	1,499	1,499
Total cash, cash equivalents and restricted cash	$ 111,371	$ 149,612

Property and Equipment

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

	March 31, 2022	December 31, 2021
Leasehold improvements	$ 25,880	$ 25,880
Laboratory equipment and office furniture	22,227	21,916
Computer equipment	1,253	1,225
Construction-in-progress	399	18
Total property and equipment, gross	49,759	49,039
Less: accumulated depreciation and amortization	(40,323)	(38,968)
Total property and equipment, net	$ 9,436	$ 10,071

Depreciation expense was $1.4 million and $1.6 million for the three months ended March 31, 2022 and 2021, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Clinical trials and research and development costs	$ 13,671	$ 12,070
Personnel-related costs	5,768	10,298
Manufacturing costs	4,667	7,773
Accrued expenses	5,372	3,117
Total accrued liabilities	$ 29,478	$ 33,258

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 for an additional two years by Merck through March 2022. As part of that extension, Merck agreed to continue to fund up to $75.0 million of our 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 our 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, as described in more detail below.

Merck owned approximately 16.6% of the Company's outstanding shares as of March 31, 2022.

The Amended Collaboration Agreement

Pursuant to the Amended Collaboration Agreement, the prior two-year extension of the research phase under the Original Agreement was deemed to end on March 31, 2021, while a new three-year research phase commenced on April 1, 2021. Under the Original Collaboration Agreement, all of the Company’s research and development programs, both those existing at the time the Company entered into the Original Collaboration Agreement and those the Company worked on during the research phase of the collaboration, other than aldafermin, were included within the scope of the collaboration. Under the terms of the Original Collaboration Agreement, upon completion of a human proof-of-concept trial for a particular collaboration compound, regardless of the results of such trial, Merck had the one-time option to obtain an exclusive, worldwide license, on specified terms, to that collaboration compound, as well as to all other compounds that were directed against the same target and that result in the same effect on such target, or the related compounds, referred to as the Merck license option. Under the Amended Collaboration Agreement, the scope of the collaboration and the resulting programs for which Merck has the Merck license option was narrowed. The collaboration as conducted under the Amended Collaboration Agreement, or the continuing collaboration, is focused primarily on the identification and 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, as well as 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, referred to as the Lab Programs. The ophthalmology compounds in the continuing collaboration include NGM621, which is being tested in a Phase 2 clinical trial, and its related compounds, and compounds directed against two other undisclosed ophthalmology targets and their related compounds. Collaboration compounds that remain within the scope of the continuing collaboration under the Amended Collaboration Agreement are referred to as continuing collaboration compounds. Given the narrowed research scope under the Amended Collaboration Agreement, the Company has 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 are not included within the research and development 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 continues 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. Merck has a one-time right to exercise its Merck license option, during the research phase or a tail period following such research phase, as applicable, for any continuing collaboration compound on a continuing program-by-continuing program basis when the Company or Merck achieves the specified Merck license option exercise point. The Merck license option exercise point for collaboration compounds under the Original Collaboration Agreement was the completion of a human proof-of-concept trial, exercisable within 60 days of Merck's receipt of an agreed-upon data package for the relevant program. This generally continues to be the Merck license option exercise point under the Amended Collaboration Agreement for continuing collaboration compounds that are directed to ophthalmology targets, including NGM621 and its related compounds and all of the continuing collaboration compounds from two other ophthalmology programs directed against undisclosed ophthalmology targets and their related compounds (including NGM621 and its related compounds, collectively referred to as the continuing ophthalmology collaboration compounds). Upon the completion of the ongoing Phase 2 NGM621 CATALINA clinical trial, Merck will have an additional one-time option to obtain an exclusive, worldwide license to all of the continuing ophthalmology collaboration compounds together, referred to as the ophthalmology bundle option. If Merck does not exercise this one-time ophthalmology bundle option for all continuing ophthalmology collaboration compounds, it may nevertheless exercise its regular Merck license option with respect to NGM621 and its related compounds at such time, and it may also exercise its regular Merck license option for the continuing ophthalmology collaboration compounds from each of the other two programs if a continuing ophthalmology collaboration compound from such continuing program completes a human proof-of-concept trial. Unlike the Original Collaboration Agreement, 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.

As was the case under the Original Collaboration Agreement, under the Amended Collaboration Agreement, if Merck exercises a Merck license option and obtains the relevant exclusive, worldwide license for a continuing collaboration compound and its related compounds, Merck will pay an option exercise fee to the Company and will be responsible, at its own cost, for any further development and commercialization activities for continuing collaboration compounds within that licensed continuing program. In such case, the Company will have the option to receive milestones and royalty payments or, in certain cases, to co-fund development and participate in a global cost and profit share arrangement of up to 50%, with an additional option to co-detail any such licensed continuing collaboration compound in the United States under the same terms as set forth in the Original Collaboration Agreement. If the Company elects to exercise its cost and profit share option for a particular continuing collaboration compound and its related compounds Merck has agreed to advance to the Company and/or assume up to 25% of the Company’s share of the global development costs for such licensed compound, subject to an aggregate cap over the course of the collaboration. All such amounts advanced or assumed by Merck would accrue interest and be recouped by Merck in full out of the Company’s share of any profits resulting from sales of the licensed compound for which the Company elected to exercise its cost and profit share option before the Company was entitled to receive any of those profits.

Except for the ophthalmology bundle option, the amount of the option exercise fees for continuing ophthalmology collaboration compounds upon completion of a human proof-of-concept trial remains the same under the Amended Collaboration Agreement as under the Original Collaboration Agreement. If Merck exercises the ophthalmology bundle option, it will pay the Company either $40.0 million or $45.0 million as the Merck license option exercise fee, depending upon the stage of development of one of the two earlier stage ophthalmology programs that is included in the ophthalmology bundle option. 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.

Under the Amended Collaboration Agreement, the parties’ rights and obligations with respect to MK-3655 and related FGFR1c/KLB agonists for which Merck exercised its Merck license option in November 2018 did not change.

On March 30, 2022, the Company and Merck entered into a letter agreement, or the Letter Agreement, regarding NGM621 manufacturing activities that the Company is undertaking during the Phase 2 NGM621 CATALINA clinical trial to avoid a significant delay between the completion of that trial and the start of a Phase 3

clinical trial for NGM621. The Company will be responsible for all payments owed to the third party manufacturer for such activities before Merck decides whether to exercise the ophthalmology bundle option or the NGM621 option following completion of the Phase 2 NGM621 CATALINA clinical trial. If Merck exercises either option, then in addition to paying the one-time option exercise fee to the Company, Merck will also reimburse the Company for certain amounts it paid to the third party manufacturer, according to the terms of the Letter Agreement and subject to certain limitations. Under the Amended Collaboration Agreement, Merck agreed to provide up to $86.0 million in research funding for the four calendar quarters ending March 31, 2022, which included the remaining $16.0 million of the up to $20.0 million in additional payments Merck agreed to pay as part of exercising its first option to extend the research phase of the collaboration under the Original Collaboration Agreement for two years through March 16, 2022. The Company was obligated to use commercially reasonable efforts to expend, and did spend, at least $35.0 million of such $86.0 million in funding during the same time frame on the ophthalmology and CVM-related programs and Lab Programs as required under the Amended Collaboration Agreement. The Company was permitted to use the remainder of the $86.0 million in research funding provided by Merck during such time frame to advance the released NGM compounds. During the remaining two years of the research phase after March 2022, Merck will provide up to a total of $20.0 million in research funding for the ophthalmology and CVM-related programs and the Lab Programs. Pursuant to the Letter Agreement, the Company may use part of this research funding to cover the costs of its personnel who provide support for the manufacturing activities conducted in preparation for a Phase 3 clinical trial for NGM621. Merck will also fund certain research and development costs related to NGM621, subject to certain limitations, until the earlier of the remaining two years of the research phase after March 2022 or until Merck exercises, or decides not to exercise, its license option with respect to NGM621 alone or bundled with the other continuing ophthalmology compounds. After March 2022, the Company, using its own funding, is required to use commercially reasonable efforts to research and develop a specific product candidate directed to a specific ophthalmology target to be ready for starting investigational new drug application-, or IND-, enabling studies by March 31, 2023. If Merck exercises its regular Merck license option with respect to NGM621 or the ophthalmology bundle option for all of the continuing ophthalmology collaboration compounds upon completion of the ongoing Phase 2 CATALINA clinical trial of NGM621 within 60 days of Merck's receipt of an agreed-upon data package and pays the applicable option exercise fee to the Company, then the Company will be obligated to reinvest $5.0 million or up to $15.0 million, respectively, of such option fee to fund research on the ophthalmology and CVM-related continuing programs.

Under the Amended Collaboration Agreement, the research phase for the ophthalmology continuing programs will end no later than March 31, 2024. The research phase for the CVM-related continuing programs will also continue until March 31, 2024, unless the parties mutually agree to extend the research phase to March 31, 2026, in which case Merck will provide up to a total of $20.0 million in research funding during those additional two years. The research phase for the Lab Programs will end no later than December 31, 2022.

As under the Original Collaboration Agreement, Merck has the right under the Amended Collaboration Agreement to review the then-ongoing continuing programs in the three-month period before the end of applicable research phase and to elect to designate one or more continuing programs for which research and development would continue to be conducted, until the applicable Merck license option exercise point is reached, for up to three years after the end of such research phase, with the possibility of extension if the Company is conducting ongoing ophthalmology clinical trials, if Merck is using commercially reasonable efforts to progress one or more ophthalmology continuing programs or if Merck determines to continue progressing a CVM-related continuing program or Lab Program toward the nomination of a research program development candidate, and any such extension is referred to as an Amended Collaboration Agreement tail period. Under the Amended Collaboration Agreement, the Amended Collaboration Agreement tail period, if any, for the ophthalmology continuing programs would be separate from the Amended Collaboration Agreement tail period, if any, for the CVM-related continuing programs or the Lab Program, and Merck would be primarily responsible for performing all research and development activities, itself or through third-party contractors, during the Amended Collaboration Agreement tail period, if any, for the CVM-related continuing programs or the Lab Program.

The Company concluded that the Amended Collaboration Agreement is a separate arrangement containing a three-year performance obligation to provide distinct research and development services in accordance with ASC 606. The total transaction price under the Amended Collaboration Agreement is $125.5 million and represents the sum of potential funding amounts, including $86.0 million in research funding for the four calendar quarters ending March 31, 2022, $20.0 million in research funding for the ophthalmology and CVM-related continuing programs during the remaining two years of the research phase after March 2022 and $19.5 million in estimated NGM621 reimbursable expenses during the remaining two years of the research phase after March 2022. 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 a series of research and development 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.

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

If Merck exercises its regular Merck license option for NGM621 or the ophthalmology bundle option for all of the continuing ophthalmology collaboration compounds upon completion of the Phase 2 CATALINA clinical trial within 60 days of Merck's receipt of an agreed-upon data package, pays the applicable Merck license option exercise fee to the Company and reimburses the Company for third party manufacturing payments in accordance with the Letter Agreement this would not result in a modification of the contract as total contract consideration and the Company's performance obligation under the Amended Collaboration Agreement will not change.

A breakout of the milestone payments in connection with the potential achievement of certain clinical development events for each of the first three indications is as follows (in thousands):

	First Indication	Second Indication	Third Indication
Upon administration of an applicable product to the first patient in the first Phase 3 clinical trial for such product for the given indication	$ 35,000	$ 25,250	$ 17,500
Upon first completion of a proof-of-concept trial for a CVM-related research program development candidate	$ 10,000	$ —	$ —
Upon first completion of a proof-of-concept trial for a certain research development candidate for a lab program	$ 10,000	$ —	$ —

A breakout of the aggregate milestone payments in connection with the potential achievement of both acceptance of an application for and receipt of regulatory approval for each of the first three indications, for each of the three geographic areas, is as follows (in thousands):

	First Indication	Second Indication	Third Indication	Total
United States	$ 75,000	$ 56,250	$ 37,500	$ 168,750
European Union	60,000	45,000	30,000	135,000
Japan	30,000	22,500	15,000	67,500
	$ 165,000	$ 123,750	$ 82,500	$ 371,250

Summary of Related Party Revenue

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

	Three Months Ended March 31,	
	2022	2021
Related party revenue	$ 20,948	$ 21,575

For the three months ended March 31, 2022, the Company recognized collaboration and license revenue of $20.9 million primarily related to reimbursable research and development activities associated with the performance obligation under the Amended Collaboration Agreement. For the three months ended March 31, 2021, the Company recognized collaboration and license revenue for the two-year extension period through March 31, 2021 under the Original Agreement. Revenue recognized related to the reimbursable research and development activities was recognized using the cost-based input model related to research and development 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, 2022 and December 31, 2021, 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. As of March 31, 2022 and December 31, 2021, the Company recorded contract liabilities of $5.1 million and $17.8 million, respectively.

6. Commitments and Contingencies

Operating Lease 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 laboratory facility 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. The 333 Oyster Point lease agreement required a letter of credit in the amount of $2.3 million as a security deposit to the lease, which the Company has recorded as non-current restricted cash on the condensed consolidated balance sheets. In accordance with the agreement, the Company reduced the letter of credit amount by $0.4 million on each of the third and fourth anniversaries of the rent commencement date and reclassified each $0.4 million amount from restricted cash to cash and cash equivalents on the condensed consolidated balance sheets.

As of March 31, 2022, the weighted-average remaining lease term for the 333 Oyster Point lease agreement was 1.75 years 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 were $1.3 million in both the three-month periods ended March 31, 2022 and 2021.

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

	Three Months Ended March 31,	
	2022	2021
Operating lease costs	$ 541	$ 541
Variable lease costs (1)	324	309
Total lease cost	$ 865	$ 850

(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, 2022, the maturities of the Company's operating lease liabilities and future minimum lease payments were as follows (in thousands):

Year Ending December 31,	
2022 (remaining)	$ 3,991
2023	5,455
Total undiscounted lease payments	9,446
Less: present value adjustment	(220)
Present value of lease liabilities	$ 9,226

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. Stockholders' Equity

Preferred Stock

The Company has 10,000,000 shares of preferred stock authorized, which may be issued at the discretion of the Company's board of directors. The board of directors may issue shares of preferred stock in one or more series and may fix the number, rights, preferences, privileges and restrictions on such shares. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and sinking fund terms. As of March 31, 2022, the Company does not have any shares of preferred stock issued or outstanding.

Common Stock

As of March 31, 2022 and December 31, 2021, the Company had reserved shares of common stock for issuance as follows (in thousands):

	March 31, 2022	December 31, 2021
Reserve balance for Sales Agreement	14,183	14,183
Common stock options outstanding	13,240	10,485
Common stock options available for grant	6,937	6,698
ESPP shares available for purchase	507	507
401(k) Matching Plan (1)	200	18
Total	35,067	31,891

(1) The Company sponsors a 401(k) defined contribution plan for its employees. Employee contributions are voluntary. In December 2011, the Company adopted the 401(k) Matching Plan, under which the Company made matching contributions in the form of common stock at a rate of $1.00 for each $2.00 of employee contributions up to a maximum $750 of common stock per employee per year. Effective January 1, 2022, the Company increased its matching contributions to a rate of $1.00 for each $2.00 of employee contributions up to a maximum $3,500 of common stock per employee per year. Effective January 1, 2022, the Company increased shares of common stock reserved pursuant to the 401(k) Matching Plan to 200,000 shares from 17,813 shares of common stock as of December 31, 2021.

Open Market Sale Agreement

In June 2020, the Company entered into the Sales Agreement with Jefferies relating to the sale of shares of its common stock. In accordance with the terms of the Sales Agreement, the Company may offer and sell shares of its common stock having an aggregate offering price of up to $150.0 million from time to time through Jefferies, acting as its sales agent. As of March 31, 2022, $127.2 million of the Company's common stock remained available to be sold under the Sales Agreement, subject to conditions specified in the Sales Agreement.

Equity Incentive Plan

In 2018, the Company adopted the 2018 Equity Incentive Plan, or the 2018 Plan, for eligible employees, officers, directors, advisors and consultants, which provides for the grant of incentive and non-statutory stock

options, restricted stock awards and stock appreciation rights. The terms of the stock option agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2018 Plan. Options granted by the Company generally vest within four years and are exercisable from the grant date until ten years after the date of grant. Vesting of certain employee options may be accelerated in the event of a change in control of the Company.

Early Exercise of Stock Options

The 2018 Plan allows for the granting of options that may be exercised before the options have vested. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment or services, at the price paid by the purchaser, and are not deemed to be issued for accounting purposes until those related shares vest. The amounts received in exchange for these shares have been recorded as a liability on the condensed consolidated balance sheets and are reclassified into Company common stock and additional paid-in-capital as the shares vest. The Company's right to repurchase these shares generally lapses in equal installments over four years beginning from the original vesting commencement date. Since the beginning of March 2021, the Company has not granted any options under the 2018 Plan that can be early exercised prior to vesting.

Stock Option Activity

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

	Outstanding Options			
	Number of Options (In Thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In Thousands)
Balances at December 31, 2021	10,485	$ 15.79	6.68	$ 52,349
Options granted	3,007	15.26		
Options exercised	(125)	5.36		
Options cancelled	(127)	21.57		
Balances at March 31, 2022	13,240	$ 15.71	7.22	$ 35,840
Vested and expected to vest at March 31, 2022	12,727	$ 15.56	7.14	$ 35,799
Exercisable at March 31, 2022	8,603	$ 13.13	6.00	$ 35,691

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, 2022 and 2021 was $10.19 per share and $19.83 per share, respectively. The intrinsic value of stock options exercised during the three months ended March 31, 2022 and 2021 was $1.3 million and $22.3 million, respectively. Due to the Company's net operating losses, the Company did not realize any tax benefits from stock-based payment arrangements for the three months ended March 31, 2022 and 2021.

Employee Stock-Based Compensation Expense

Employee and director stock-based compensation expense for the three months ended March 31, 2022 and 2021 was calculated based on awards previously granted to employees and directors that are ultimately expected to vest and has been reduced for estimated forfeitures.

Employee and director stock-based compensation expense was allocated as follows (in thousands):

	Three Months Ended March 31,	
	2022	2021
Research and development	$ 4,138	$ 3,504
General and administrative	3,609	3,011
Total stock-based compensation expense	$ 7,747	$ 6,515

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. As of March 31, 2022, 493,022 shares of common stock had been purchased under the ESPP.

8. Income Taxes

Since inception, the Company has incurred net losses and expects to record a net loss for the year ending December 31, 2022. 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, 2022 and 2021.

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, 2021 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 1, 2022, or the 2021 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 retinal diseases, cancer and liver and metabolic diseases. 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 robust portfolio of product candidates ranging from early discovery to Phase 2b development. Currently, we have seven programs in active development, including four in Phase 2 or 2b studies, across three therapeutic areas: cancer, retinal diseases and liver and metabolic diseases. Our biology-centric drug discovery approach 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 therapeutic area-agnostic discovery engine, led by biology and motivated by unmet patient need.

Pipeline Programs and Operational Updates

Pipeline Programs

We currently have six product candidates in the clinic, four wholly-owned by us (NGM707, NGM831, NGM120 and aldafermin), one being progressed by our collaborator, Merck Sharp & Dohme LLC, or Merck (MK-3655), and one optionable by Merck (NGM621). In addition, we have one wholly-owned product candidate, NGM438, expected to enter the clinic in the second quarter of 2022.

- **Oncology**. Our 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 may also reverse inhibition of ILT2-expressing lymphoid cells to further stimulate anti-tumor immune responses.

- We are conducting an open-label, Phase 1 portion of a Phase 1/2 clinical trial evaluating NGM707 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with advanced solid tumors. We expect to enroll approximately 180 patients in this trial. The Phase 1a cohort of the trial evaluating NGM707 as a monotherapy is ongoing.
- In December 2021, we entered into a clinical trial collaboration and supply agreement with Merck to evaluate the potential of NGM707 co-administered with pembrolizumab in the ongoing Phase 1/2 trial of NGM707.
- ***Looking forward****:* We anticipate a readout of initial data from the Phase 1a cohort in the second half of 2022. In addition, we will be enrolling a Phase 1b cohort that will evaluate NGM707 in combination with pembrolizumab in patients with advanced solid tumors. The Phase 1a/1b portions of the trial are expected to be followed by a Phase 2 dose-expansion in cohorts of specific tumor types.

- **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 antitumor activity.
  - In March 2022, we initiated an open-label, Phase 1 portion of a Phase 1/1b clinical trial to evaluate NGM831 as a monotherapy and in combination with pembrolizumab for the treatment of patients with advanced solid tumors. We expect to enroll up to approximately 80 patients in this trial. The ongoing Phase 1a cohort of the trial is a dose-ranging study of NGM831 as a monotherapy. The Phase 1b cohort is a dose-ranging study of NGM831 in combination with pembrolizumab in patients with advanced solid tumors.
- **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 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.
  - ***Looking forward:*** We expect to initiate first-in-human testing of NGM438 in patients with advanced solid tumors in the second quarter of 2022.
- **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.
  - 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 and metastatic pancreatic cancer. The Phase 1 component of the trial included a Phase 1a cohort evaluating NGM120 as a monotherapy in patients with select advanced solid tumors and a Phase 1b cohort evaluating NGM120 in combination with gemcitabine and Nab-paclitaxel in patients with metastatic pancreatic cancer. We are currently enrolling patients into a Phase 2 component of the trial (referred to as the PINNACLES trial) testing NGM120 in combination with gemcitabine and Nab-paclitaxel as first-line treatment in patients with metastatic pancreatic cancer.

        - ***Looking forward***: We plan to report additional data from the Phase 1a and Phase 1b cohorts of the Phase 1/2 NGM120 trial in the second half of 2022.

- **Retinal diseases**.
    - **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 disease progression in patients with geographic atrophy, or GA, secondary to age-related macular degeneration. We have completed a Phase 1 trial demonstrating that NGM621 was well tolerated with no patients experiencing serious adverse events or drug-related adverse events. Ocular adverse events observed were mild in severity and representative of those commonly associated with IVT injections. We also completed enrollment of the ongoing Phase 2 CATALINA clinical trial, which was designed to be a Phase 3-supportive or -enabling clinical trial. The CATALINA trial is evaluating the efficacy and safety of NGM621 when given to patients with GA every four weeks or every eight weeks via IVT injections compared to sham control.
        - In February 2022, NGM621 received Fast Track designation from the United States Food and Drug Administration, or FDA, for GA secondary to age-related macular degeneration.
        - ***Looking forward***: We expect to report topline data from the Phase 2 CATALINA trial in the fourth quarter of 2022. If supported by the results of the CATALINA trial, we plan to use such trial results and guidance from the FDA to inform Phase 3 planning and design for NGM621. Merck has a one-time option to license NGM621 and its related compounds upon completion of the ongoing Phase 2 CATALINA clinical trial (either alone or bundled with all of the other ophthalmology compounds and their respective related compounds included within the scope of the current collaboration with Merck) within 60 days of Merck's receipt of an agreed-upon data package for each of the programs.

- **Liver and metabolic diseases.**
    - **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. Aldafermin is in Phase 2b development in the ALPINE 4 trial for the treatment of 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 ALPINE 4 clinical trial is designed to evaluate the treatment effect of aldafermin over 48 weeks.
        - In January 2022, we completed enrollment of 160 patients in the United States, Europe, Hong Kong and Australia in our Phase 2b ALPINE 4 clinical trial of aldafermin.
        - ***Looking forward:*** We expect to report topline data from the Phase 2b ALPINE 4 trial in the first half of 2023.
    - **MK-3655** (formerly NGM313). MK-3655 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, in Phase 2b development for the treatment of NASH, was licensed by Merck in November 2018.
        - Merck is continuing enrollment in the worldwide 52-week randomized, double-blind Phase 2b trial of MK-3655 in patients with NASH and liver fibrosis stage 2 or 3, or F2 or F3, by the NASH Clinical Research Network classification.

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, collaboration 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.

Operational Updates

Partnering has been and is expected to continue to be a key component of our strategy. For example, our collaboration with Merck, described in " — Our Merck Collaboration" below, 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. Given the breadth of opportunities produced by our prolific discovery engine, and the current narrower scope of our Merck collaboration, we may decide to pursue additional strategic partners to progress, in whole or in part, some of our wholly-owned product candidates and/or commercialize any resulting approved product.

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, while we initiated the Phase 1/1b clinical trial of NGM831 in March 2022 and expect to commence first-in-human testing of NGM438 in the second quarter of 2022, our planned individual new drug application, or IND, submissions for NGM438 and NGM831 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 aldafermin and MK-3655 are currently manufactured 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 invasion of 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.

We seek to allocate our capital efficiently and strategically and fund our 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 reasons to concentrate our resources on what we consider our most promising product candidates. However, given the substantial decrease in research funding we will now receive from Merck as compared to historical periods commensurate with the decreased collaboration scope described below, going forward we will need to devote a substantial amount of our own financial resources to 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 will need to enter into additional collaborations in order to proceed with such development through to regulatory approval.

Our Merck Collaboration

In 2015, we 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 financially supported by Merck, but scientifically directed by us with input from Merck. The original research phase of the collaboration was for five years and was extended for an additional two years by Merck through March 2022. As part of that extension, Merck agreed to continue to fund up to $75.0 million of our 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 us, Merck agreed to make additional payments totaling up to $20.0 million in support of our R&D activities during 2021 through the first quarter of 2022.

On June 30, 2021, we 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, but with a narrower scope than in the Original Collaboration Agreement. Under the Amended Collaboration Agreement, the collaboration is focused primarily on the identification, R&D 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 ophthalmology compounds in the collaboration include NGM621 (and its related compounds) and compounds directed against two other undisclosed ophthalmology targets (and their related compounds). The collaboration scope also includes 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. The research phase will now continue generally through March 31, 2024, with possible extensions for each of the various programs to allow us or Merck to complete ongoing development.

Under the Amended Collaboration Agreement, Merck committed to provide up to $86.0 million in R&D funding for the four calendar quarters ending March 31, 2022. Going forward, Merck is providing significantly more limited annual R&D funding. In this regard, for the period that started on April 1, 2022 and ending on March 31, 2024, Merck will provide up to $20.0 million of R&D funding for the ophthalmology programs (other than NGM621), the CVM-related programs and the Lab Programs. Pursuant to the letter agreement that we entered into with Merck on March 30, 2022, or the Letter Agreement, we may use part of this R&D funding to cover our personnel costs for supporting manufacture of NGM621 for use in a possible Phase 3 clinical trial. If the parties mutually agree to extend the research phase for the CVM-related programs from March 31, 2024 to March 31, 2026, then Merck will provide up to a total of $20.0 million in R&D funding during the additional two years of the CVM program research phase. Merck will also fund certain R&D costs related to NGM621 in an amount expected to be up to approximately $20.0 million, until the earlier of Merck's decision to exercise, or not to exercise, its License Option with respect to NGM621 alone or bundled with the other continuing ophthalmology compounds (as described below) or, March 31, 2024. During the period before Merck’s decision, we are responsible under the Letter Agreement for paying all amounts owed to third parties for NGM621 manufacturing activities performed in anticipation of a Phase 3 clinical trial. If Merck decides to exercise its License Option, Merck will reimburse us for certain amounts we paid to such third parties, according to the terms of the Letter Agreement and subject to certain limitations, in addition to paying us the one-time option exercise fee described below.

In addition, we have certain obligations to conduct R&D related to collaboration compounds that will not be reimbursed by Merck. We are required to use commercially reasonable efforts to research and develop a specific product candidate directed to an ophthalmology target to be ready by March 31, 2023 for starting IND-enabling studies and we are responsible for the cost of such work after March 2022. We will have additional R&D funding obligations under the collaboration of up to $5.0 million or $15.0 million in the event that Merck, as described in greater detail below, exercises its License Option to NGM621 alone or bundled with the other continuing ophthalmology compounds, respectively, and pays us the applicable option exercise fee. We also may spend more than the amounts we will be reimbursed by Merck for activities related to collaboration compounds.

Under the Original Collaboration Agreement, upon the completion of each proof-of-concept clinical trial under the program, Merck had a one-time option to obtain a worldwide, exclusive license to the product candidate tested in the trial and compounds related to it, referred to as a License Option, within 60 days of Merck's receipt of an agreed-upon data package for such program. Under the Amended Collaboration Agreement, Merck retains a License Option to each collaboration compound and its related compounds upon completion of a human proof-of-

concept trial for a particular collaboration compound, regardless of the results of such trial, or at earlier points as specified in the Amended Collaboration Agreement, including the option to license NGM621 and its related compounds (either alone or bundled with all of the other ophthalmology collaboration compounds and their respective related compounds included within the scope of the Amended Collaboration Agreement) upon completion of the CATALINA clinical trial within 60 days of Merck's receipt of an agreed-upon data package. For each program for which Merck exercises its License Option and pays the applicable option exercise fee, Merck is responsible for any further development and commercialization activities for the licensed compounds and we have the option, when a licensed compound has advanced to Phase 3 clinical trials, to receive milestones and royalty payments or, in certain cases, to co-fund development and participate in a global cost and profit share arrangement of up to 50%, with an additional option to co-detail any such licensed compounds in the United States. If we elect to exercise our cost and profit share option for a particular licensed compound and its related compounds, Merck has agreed to advance to us and/or assume up to 25% of our share of the global development costs for such licensed compound, subject to an aggregate cap over the course of the collaboration. All such amounts advanced or assumed by Merck would accrue interest and be recouped by Merck in full out of our share of any profits resulting from sales of the licensed compound for which we elected to exercise our cost and profit share option before we would be entitled to receive any of those profits.

If Merck does not exercise a License Option within the specified time period, then we would be free to develop and commercialize the product candidate tested in the proof-of-concept trial and its related compounds independently or with third-party partners, subject to an obligation to make low single-digit royalty payments to Merck. Merck exercised its License Option for MK-3655 and its related FGFR1c/KLB agonists in November 2018 under the Original Collaboration Agreement.

As a result of entering into the Amended Collaboration Agreement, we have the right to independently research, develop and commercialize all of the clinical, preclinical and research assets that we researched or developed under the Original Collaboration Agreement that are now outside the narrower scope of the collaboration, including NGM707, NGM831, NGM438 and NGM120, subject to an obligation to make low single-digit royalty payments to Merck. The parties' rights and obligations remain the same with respect to MK-3655 and its related FGFR1c/KLB agonists. We also have full rights to all future programs we pursue that fall outside of the scope of the specific therapeutic areas and programs included in Amended Collaboration Agreement.

Similar to the Original Collaboration Agreement, during the applicable research phase (including any applicable tail period for each program) for the ophthalmology programs, CVM-related programs and Lab Programs, we may not directly or indirectly research, develop, manufacture or commercialize, outside of the collaboration, any product with specified activity against any target that is being researched or developed under the applicable programs and, if Merck exercises its License Option for a program, we may not directly or indirectly research, develop, manufacture or commercialize any product with specified activity against the target that is the subject of that program for so long as Merck's license to it remains in effect. 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 CVM-related programs.

Because, under the Amended Collaboration Agreement, the level of R&D funding from Merck going forward will be substantially lower on an annual and overall basis than the R&D funding previously provided by Merck, 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, and, to a lesser extent, with respect to programs that are within the scope of the collaboration under the Amended Collaboration Agreement that we are required to fund. In addition, our funding requirements would increase for any programs that are within the scope of the current 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, which could include NGM621. Accordingly, we will need to raise significant additional capital and/or we will need to enter into additional collaborations in order to proceed with development through regulatory approval and commercialization of our current and potential future product candidates. Neither may be possible and, as a result, if adequate funds are not available when we need them, we may need to significantly delay, scale back or discontinue development of some or all of such product candidates or scale back or discontinue discovery efforts, which could have a material adverse effect on our business, operating results and prospects, or we may be required to cease operations altogether. In particular, if Merck elects to license NGM621 and its related compounds after completion of the CATALINA trial, we would need to raise substantial additional capital if we opt to co-develop the program and are therefore required to contribute to the costs of Phase 3 development as described above. Similarly, if Merck does not elect to license NGM621 and its related compounds after completion of the

CATALINA trial, we would need to raise substantial additional capital and/or partner the program in order to proceed to Phase 3 development of NGM621 if supported by the results from the CATALINA trial.

For more information on the terms of the Amended Collaboration Agreement, see Note 5, “Research Collaboration and License Agreements,” of the notes to audited consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Financial Highlights

Since inception, we have funded our operations primarily through:

- fees received from collaboration partners, which since inception through March 31, 2022 includes reimbursement of R&D expenses of $510.9 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 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 $22.1 million through December 31, 2021 from sales of 817,100 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; and
- 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.

At March 31, 2022, we had $329.8 million in cash, cash equivalents and short-term marketable securities.

We have incurred net losses each year since our inception. As of March 31, 2022, we had an accumulated deficit of $451.4 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 Merck or future collaboration partners, if any. For further discussion of our financial position and future sources of funding, see “Liquidity and Capital Resources” below.

COVID-19 Business Update

We are continuing to closely monitor the impact of the global COVID-19 pandemic on our business and have taken and continue to take proactive efforts designed to protect the health and safety of our patients, employees, clinical trial investigators and site staff, while maintaining business continuity. We are currently operating under a hybrid work model where some employees work on site, others work remotely and others work a combination of on site and remote. There have been relatively minor impacts on overall productivity in our prior primarily remote and our current hybrid work model. However, the labor market has tightened significantly since the beginning of the COVID-19 pandemic, and we have experienced employee attrition at rates higher than we experienced historically, together with an increased rate of hiring new employees. We cannot predict whether these trends will continue or be exacerbated, the impact of COVID-19 on future productivity or whether or when we may be required to return to a more restrictive work model as the pandemic continues to evolve.

During the COVID-19 pandemic, we have experienced, from time to time, a slower pace of clinical trial site initiation and clinical trial enrollment and/or a higher subject drop-out rate than originally anticipated in certain of our clinical trials. We believe this may have been due to factors such as the vulnerability of our studied patient populations, clinical trial site suspensions, reallocation of medical resources, site staff shortages and the challenges of working remotely due to shelter-in-place and similar government orders and guidelines, among other factors. We have been proactively working to mitigate these and other effects of the COVID-19 pandemic by monitoring site initiations, patient enrollment and patient study adherence to provide support to patients and trial staff, often on a case-by-case and/or patient-by-patient basis. While the COVID-19 pandemic has not yet resulted in a significant impact to our disclosed clinical development timelines, as the COVID-19 pandemic continues to evolve, there may continue to be negative impacts on our ability to initiate new clinical trial sites, to enroll new patients and to retain existing patients participating in our clinical trials. These negative impacts may include increased clinical trial costs,

longer timelines and delay in our ability to obtain regulatory approvals of our product candidates, if at all. Moreover, we rely on CROs and other third parties to assist us with clinical development activities, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic.

In addition, while we have not yet experienced significant disruption to drug or related component supply for our ongoing clinical trials due to the COVID-19 pandemic, our contract manufacturers' 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. 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 the evolving effects of the continuing COVID-19 pandemic. If our contract manufacturers 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. If any of our contract manufacturers or raw materials or components suppliers become subject to acts or orders of U.S. or foreign government entities requiring them to allocate or prioritize manufacturing capacity, raw materials and components to the manufacture or distribution of COVID-19 vaccines or medical supplies needed to treat COVID-19 patients, this could delay our clinical trials, perhaps substantially, which could materially and adversely affect our business.

While the potential future economic impact caused by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the COVID-19 pandemic (as well as the invasion of Ukraine by Russia and the related sanctions imposed against Russia) could result in significant and prolonged disruption of global financial markets, and our ability to raise additional capital through public or private equity or debt offerings may be adversely impacted by disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, and in the biotechnology industry specifically, which could negatively affect the financial resources available to us. In addition, economic recession or additional market corrections resulting from, among other things, the spread of COVID-19 could materially affect our business and the value of our common stock. Finally, we also cannot predict how the evolving effects of the COVID-19 pandemic may influence the future decisions of Merck to license any programs available to it under the Amended Collaboration Agreement, such as NGM621 and its related compounds. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and results of operations, see the section titled “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

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, 2022, Merck paid us $586.0 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 fluctuate in future periods given the substantial decrease in the level of funding we will receive from Merck under with the Amended Collaboration Agreement commensurate with the decreased collaboration scope. 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,	
	2022	2021
Related party revenue	$ 20,948	$ 21,575

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.

As a result of the substantial decrease in the level of funding we are now receiving from Merck under the Amended Collaboration Agreement commensurate with the decreased collaboration scope as described above, we need to devote a substantial amount of our own financial resources to our development programs, particularly with respect to our wholly-owned programs and, to a lesser extent, with respect to programs that are within the scope of the Amended Collaboration Agreement that we are required to fund, as described above. In addition, our funding requirements would increase for any programs that are 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. In particular, if Merck elects to license NGM621 and its related compounds after completion of the CATALINA trial, we would need to raise substantial additional capital if we opt to co-develop the program and are therefore required to contribute to the costs of Phase 3 development as described above. Similarly, if Merck does not elect to license NGM621 and its related compounds after completion of the CATALINA trial, we would need to raise substantial additional capital and/or partner the program in order to proceed to Phase 3 development of NGM621 if supported by the results from the CATALINA trial. 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 advance initiate and advance clinical trials of our oncology programs, to prepare for the manufacture of NGM621 in anticipation of a potential Phase 3 trial and to complete the Phase 2b ALPINE 4 clinical trial of aldafermin.

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. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainty of:

- 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 evolving effects of the 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;
- whether Merck will elect to license, or to terminate its license, to any of our programs within the scope of the collaboration and the timing of such election or termination, particularly with respect to NGM621;
- the amount of our financial resources that we need to devote to our development programs and our obligations under the Amended Collaboration Agreement, and our ability to raise adequate additional capital or enter into collaborations to meet our funding requirements;
- the effect of products that may compete with our product candidates or other market developments;
- our ability to expand and enforce our intellectual property portfolio;
- the scope, rate of progress, results and expense of our ongoing, as well as any future, clinical trials and other R&D-related activities; and
- the impact and timing of any interactions with regulatory authorities, including timing and receipt of regulatory approvals.

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 will increase in the future to support our continued and increasing R&D activities. These increases will likely include increased costs related to the hiring of additional personnel, as well as fees paid to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate continued increased costs associated with being a public company, including expenses related to services associated with maintaining compliance with Nasdaq listing rules and related Securities and Exchange Commission, or 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 incur expenses associated with negotiating and entering into agreements with collaboration partners and with building a commercial organization in connection with, and prior to, potential future regulatory approval of our product candidates.

Results of Operations

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

	Three Months Ended March 31,		
	2022	2021	Change
Related party revenue	$ 20,948	$ 21,575	$ (627)
Operating expenses:			
Research and development	42,806	40,699	2,107
General and administrative	10,723	8,721	2,002
Total operating expenses	53,529	49,420	4,109
Loss from operations	(32,581)	(27,845)	(4,736)
Interest income, net	176	114	62
Other (expense) income, net	(45)	187	(232)
Net loss	$ (32,450)	$ (27,544)	$ (4,906)

Related Party Revenue from Merck

Revenue decreased $0.6 million in the three months ended March 31, 2022 compared to the same period in 2021 primarily due to a decrease in R&D revenue under the Amended Collaboration Agreement with Merck.

Under the Amended Collaboration Agreement, from April 1, 2022 until March 31, 2024, Merck will provide up to $20.0 million of R&D funding for the ophthalmology programs (other than NGM621), the CVM-related programs and the Lab Programs. If the parties mutually agree to extend the research phase for the CVM-related programs from March 31, 2024 to March 31, 2026, then Merck will provide up to a total of $20.0 million in R&D funding during the additional two years of the CVM program research phase. Merck will also fund certain R&D costs related to NGM621 in an amount expected to be up to approximately $20.0 million, until the earlier of Merck's decision to exercise, or not to exercise, its License Option with respect to NGM621 alone or bundled with the other continuing ophthalmology compounds or, March 31, 2024. In this regard, our related party revenue from Merck will decrease substantially in 2022 compared to 2021 and continue to remain at a significantly lower level during the remainder of the 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 fluctuate during the remainder of the collaboration.

Research and Development Expenses

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

	Three Months Ended March 31,	
	2022	2021
External R&D expenses:		
Aldafermin (FGF19 analog)	$ 4,362	$ 9,598
NGM621 (C3 inhibitor)	5,486	3,686
NGM120 (GFRAL antagonist)	1,479	1,361
NGM707 (Anti-ILT2/ILT4 dual antagonist)	3,678	1,165
NGM438 (LAIR1 antagonist)	2,022	1,515
NGM831 (ILT3 antagonist)	1,739	668
Other external R&D expenses	120	310
Total external R&D expenses	18,886	18,303
Personnel-related expenses	15,895	14,269
Internal and unallocated R&D expenses (1)	8,025	8,127
Total R&D expenses	$ 42,806	$ 40,699

(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 increased $2.1 million in the three months ended March 31, 2022 compared to the same period in 2021 primarily due to increases in external expenses, driven by our ongoing clinical trials of NGM707, NGM621, NGM831 and NGM120, our preclinical study of NGM438 and personnel-related expenses, partially offset by a decrease in expenses for our manufacturing activities and our clinical trials of aldafermin.

We expect our R&D expenses will increase in 2022 compared to 2021 primarily due to the continued advancement of our wholly-owned oncology programs. In 2022, we have substantial activities ongoing in all of our programs, and are targeting achievement of multiple milestones, including:

- NGM621: continuing treatment of patients in the fully enrolled Phase 2 CATALINA clinical trial, preparing to report topline data from that trial in the fourth quarter of 2022 and preparing for a potential Phase 3 trial;
- NGM707: continuing enrollment in the Phase 1 portion of the ongoing Phase 1/2 clinical trial and preparing for a readout of initial data from the Phase 1a cohort in the second half of 2022;
- NGM120: continuing enrollment in the Phase 2 PINNACLES portion of the Phase 1/2 clinical trial and preparing to report additional data from the Phase 1a and Phase 1b cohorts of the trial in the second half of 2022;
- NGM831: continuing enrollment in the Phase 1a portion of the ongoing Phase 1/1b clinical trial;
- NGM438: conducting a first-in-human clinical trial expected to be initiated in the second quarter of 2022; and
- Aldafermin: continuing treatment of patients in the fully enrolled Phase 2b ALPINE 4 clinical trial and preparing to report topline data from that trial in the first half of 2023.

General and Administrative Expenses

G&A expenses increased $2.0 million in the three months ended March 31, 2022 compared to the same period in 2021 primarily due to an increase in headcount, an increase in share-based compensation expense of $0.6 million and an increase in fees paid to outside consultants, lawyers and accountants of $0.9 million.

We anticipate that our G&A expenses in 2022 will increase compared to 2021 due to an increase in compensation-related expenses driven by higher headcount and other expenses related to the expansion and support of our business, in particular as needed to support our continued and increasing R&D activities, and to a lesser extent due to expenses associated with being a public company and with negotiating and entering into agreements with collaboration partners.

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 and increasing operating losses in 2022 and over the next several years. As of March 31, 2022, we had an accumulated deficit of $451.4 million, and we expect our accumulated deficit will increase significantly over time.

We have an active discovery research group and multiple pipeline programs in development. We have spent, and expect to continue to spend, significant resources to fund R&D of, and seek regulatory approvals for, our product candidates for the foreseeable future as our research, development, manufacturing, preclinical studies, clinical trial and related activities increase.

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 going forward will be substantially lower on an annual and overall basis than the R&D funding previously provided by Merck and we can no longer use R&D funding from Merck to support the development of any of our wholly-owned oncology programs, including NGM707, NGM831, NGM438 and NGM120. As a result, we need to fund not only our currently wholly-owned programs going forward, but also certain activities that remain within the scope of the ongoing collaboration with Merck that we are required to fund ourselves (and our failure to allocate funding to meet such requirements may be deemed a breach of the Amended Collaboration Agreement). In addition, we need to fund any programs

that are within the scope of the current collaboration with Merck in the event Merck does not elect to license these programs and we decide to continue to develop them, in the event Merck elects to terminate its license to any program it licenses and we decide to continue to develop it or in the event we opt to co-develop any program Merck elects to license. In particular, if Merck elects to license NGM621 and its related compounds after completion of the CATALINA trial, we would need to raise substantial additional capital if we opt to co-develop the program and are therefore required to contribute to the costs of Phase 3 development as described above. Similarly, if Merck does not elect to license NGM621 and its related compounds after completion of the CATALINA trial, we would need to raise substantial additional capital and/or partner the program in order to proceed to Phase 3 development of NGM621 if supported by the results from the CATALINA trial.

Our cash requirements for fiscal year 2022 will continue to be driven by our R&D and G&A expenses. In 2021 and 2020, our R&D expenses were $161.7 million and $164.0 million, respectively. In 2022 and over the next several years, we expect our R&D expenses to increase substantially unless we partner one or more of our wholly-owned programs, particularly as we advance our oncology product candidates into and through clinical development and, if supported by the results from the CATALINA trial, fund later-stage clinical development of NGM621. In 2021 and 2020, our G&A expenses were $36.9 million and $27.2 million, respectively. Beginning in 2022 and over the next several years, we expect our G&A expenses to increase moderately as we continue to hire additional personnel to support our growing R&D activities and as we continue to incur the increased costs associated with being a public company.

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. We have based this estimate on assumptions that may prove to be inaccurate and we could utilize our available capital resources sooner than we currently expect. 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 will need to raise significant additional capital or we will need to partner one or more of our wholly-owned programs and obtain funding or other resources through such arrangements. Neither may be possible and, as a result, we may be required to delay, scale back or discontinue development of such product candidates, which could have a material adverse effect on our business, operating results and prospects.

Sources of Liquidity

Cash and Investments

As of March 31, 2022, we had cash and cash equivalents of $109.9 million and short-term marketable securities of $220.0 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, 2022 and ends on March 31, 2024, Merck is committed to fund up to $20.0 million of R&D funding for the ophthalmology programs (other than NGM621), the CVM-related programs and the Lab Programs. Merck is also obligated to fund certain R&D costs related to NGM621 in an amount expected to be up to approximately $20.0 million, until the earlier of Merck's decision to exercise, or not to exercise, its license option with respect to NGM621 alone or bundled with the other continuing ophthalmology compounds or, March 31, 2024. See “Overview – Our Merck Collaboration” 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 March 31, 2022, $127.2 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, product collaborations, strategic alliances, licensing 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, resulting from, among other things, the continuing effects of the COVID-19 pandemic, macroeconomic factors including inflation and geopolitical instability, including instability resulting from the invasion of Ukraine by Russia and the related sanctions imposed against Russia. 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.

We may seek other third-party collaborators for the development and commercialization of any product candidates that are not within the scope of the collaboration with Merck. If we decide to enter into any such arrangements with any third parties, and are successful in doing so, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from any such arrangement will depend on the specific terms we reach with any collaborator, as well as each of our collaborators' abilities to successfully perform the functions assigned to them in such arrangement towards developing, seeking regulatory approval for and commercializing our product candidates.

If we are unable to raise adequate additional capital through public or private equity or debt offerings, collaborations 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.

Cash Flow Activity

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

	Three Months Ended March 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	$ (35,738)	$ (22,225)
Investing activities	(6,853)	(117,156)
Financing activities	668	140,477
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (41,923)	$ 1,096

Operating Activities

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.

In the three months ended March 31, 2021, cash used in operating activities was $22.2 million, which consisted of a net loss of $27.5 million, adjusted for non-cash charges of $8.4 million and net cash used in operating assets and liabilities of $3.1 million. The non-cash charges consisted primarily of stock-based compensation expense of $6.6 million and depreciation expense of $1.6 million. The change in operating assets and liabilities was mainly driven by decreases in accounts payable of $2.1 million, related party contract assets of $1.5 million and deferred rent of $0.7 million, partially offset by an increase in prepaid expenses and other current assets of $1.3 million.

Investing Activities

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.

In the three months ended March 31, 2021, cash used in investing activities was $117.2 million, which consisted primarily of purchases of marketable securities of $145.0 million with net proceeds from our follow-on offering, partially offset by $28.0 million in net proceeds on maturity of marketable securities.

Financing Activities

In the three months ended March 31, 2022, net cash provided by financing activities consisted of proceeds from employee equity incentive plans of $0.7 million. In the three months ended March 31, 2021, net cash provided by financing activities was $140.5 million, and consisted of net proceeds from the follow-on offering of $134.6 million and proceeds from employee equity incentive plans of $5.9 million.

Contractual Obligations

We have contractual obligations related to our lease liabilities. See Note 6 to our condensed consolidated financial statements included in Part I, Item 1, “Financial Statements and Supplementary Data,” of this Quarterly Report on Form 10-Q for information regarding our lease commitments.

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, 2022, we had not accrued for any termination or cancellation charges 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. We expect our R&D expenses to increase substantially beginning in 2022 and over the next several years unless we partner one or more of our wholly-owned programs, particularly as we advance our oncology product candidates into and through clinical development and support our later-stage clinical development of NGM621. See "Funding Requirements" above for additional 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 consolidated balance sheets and are not considered to be contractual obligations. See "Business - Licensing Arrangements" in Part I, Item 1 of the 2021 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 2021 Annual Report on Form 10-K.

Newly Issued Accounting Pronouncements

There have been no new accounting pronouncements or changes to accounting pronouncements during the three months ended March 31, 2022 that are of significance or potential significance to us.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the three months ended March 31, 2022, 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 2021 Annual Report on Form 10-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of March 31, 2022, 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, 2022, 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, 2022, 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.

Summary Risk Factors

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 have incurred net losses every year since our inception, we have no source of product revenue, we expect to continue to incur significant and increasing 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 (formerly Merck Sharp & Dohme Corp.), or Merck, and that revenue will be substantially lower going forward as compared to historical periods.
- In order to complete the development and commercialization of our current and potential future product candidates and to finance our other operations, we will require substantial additional capital that may not be available to us on acceptable terms, or at all, and as a result, we may be required to delay, scale back or discontinue development of our product candidates.
    - In particular, if Merck elects to license NGM621 and its related compounds after completion of the Phase 2 CATALINA trial, we would need to raise substantial additional capital if we opt to co-develop the program and are therefore required to contribute to the costs of Phase 3 development.
    - Similarly, if Merck does not elect to license NGM621 and its related compounds after completion of the CATALINA trial, we would need to raise substantial additional capital and/or partner the program in order to proceed to Phase 3 development of NGM621 if supported by the results from the CATALINA trial.
- 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 most advanced product candidates, NGM621, NGM120, aldafermin and MK-3655, are only in Phase 2 development, 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.

- Similarly, clinical trials of our other product candidates, including the ongoing trials of NGM707 and NGM831, may fail to produce positive results or to demonstrate safety and efficacy to the satisfaction of health authorities.

- Aldafermin and MK-3655 are being developed for the treatment of nonalcoholic steatohepatitis, or NASH, an indication for which there are no approved products, which makes it difficult to predict the timing, cost and potential success of their clinical development and regulatory approval for the treatment of NASH, as evidenced by the fact that our previously completed Phase 2b ALPINE 2/3 trial of aldafermin in patients with NASH and liver fibrosis stage 2 or 3, or F2 or F3, by the NASH Clinical Research Network classification did not meet its primary endpoint and, as a result, we decided to suspend further development of aldafermin in patients with F2/F3 NASH.
- We may not be able to obtain and maintain the relationships with our current collaborator, Merck, potential future collaborators and other third parties that are necessary to develop, manufacture and commercialize some or all of our product candidates.
    - We depend on our collaboration with Merck for revenue and for the development and commercialization of our product candidates that remain within the scope of the collaboration.
    - In the future we may depend on collaborations with other third parties for revenue and for the development and commercialization of our product candidates and such collaborations involve numerous risks, any of which could materially and adversely affect our business and financial condition.
    - 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, including our current reliance on single source manufacturers and suppliers, difficulties in supply chain, including procuring raw materials and components and the availability of manufacturing slots, and difficulties in production, including scaling up and validating initial production, contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, turnover of qualified staff or improper storage conditions, or difficulties with quality control, product stability or quality assurance testing, 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.
- The COVID-19 pandemic continues to adversely impact our business and operations, as well as the businesses or operations of our contract manufacturers, clinical research organizations, clinical trial sites or other third parties with whom we conduct business.
- Our future success depends in part on our ability to attract and retain highly skilled employees, including members of our current senior management team, especially our Chief Scientific Officer, Dr. Jin-Long Chen, and during the ongoing COVID-19 pandemic we have experienced employee attrition at rates higher than we have experienced historically, which may continue or be exacerbated and could have a negative impact on our productivity.
- Our product candidates other than aldafermin and MK-3655 are currently manufactured at a facility in Lithuania. The invasion of Ukraine by Russia 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.
- We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, us.
- Our success depends in significant part upon our ability to obtain and maintain intellectual property protection for our products and technologies.
- We may not successfully identify new product candidates to expand our development pipeline.
- 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. We are obligated to develop and maintain proper and effective internal control over financial reporting, and, beginning with our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 1, 2022, or the 2021 Annual Report on Form 10-K, we were required to comply with the requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. If we are not able to comply with the requirements of Section 404(b) of the Sarbanes-Oxley Act in a timely manner, or 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.

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 and increasing 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 $120.3 million, $102.5 million and $42.8 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of March 31, 2022, we had an accumulated deficit of $451.4 million.

We expect to continue to incur significant and increasing 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 further expect to incur substantial and increasing operating losses in 2022 and over the next several years as our research, development, manufacturing, preclinical studies, clinical trial and related activities and related expenses increase and we expect our accumulated deficit will also increase significantly in future periods. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue outside of our collaboration with Merck. 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 or our current collaborator's and potential future collaborators' ability 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 we obtain marketing approval, if any, and, if launched independently by us without a collaborator, 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. For example, 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, and, as a result, we decided to suspend further development of aldafermin in patients with F2/F3 NASH. Even if we successfully complete development and regulatory processes for other product candidates or of aldafermin in other indications, 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 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 ongoing 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 - Our Merck Collaboration” in Part I, Item 2 of this Quarterly Report on Form 10-Q, the R&D funding we receive from Merck under the collaboration going forward will be substantially lower on an annual and overall basis than the research funding previously provided by Merck due to the narrower scope of 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, which amended and restated our then-existing collaboration agreement with Merck, originally entered into in 2015, which, together with amendments made prior to June 30, 2021, we refer to as the Original Collaboration Agreement.

In this regard, for the period that started on April 1, 2022 and ends on March 31, 2024, Merck is committed to fund up to $20.0 million in R&D funding for the ongoing ophthalmology programs (other than NGM621), the cardiovascular or metabolic -, or CVM-, related programs and other smaller laboratory programs subject to the collaboration. Merck is also obligated to fund certain R&D costs related to NGM621 in an amount expected to be up to approximately $20.0 million, until the earlier of Merck's decision to exercise, or not to exercise, its license option with respect to NGM621 and its related compounds (either alone or bundled with all of the other continuing ophthalmology compounds and their respective related compounds) or, March 31, 2024. As a result, 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 and, to a lesser extent, with respect to programs that are within the scope of the current collaboration under the Amended Collaboration Agreement that we are required to fund (and our failure to allocate funding to meet such requirements may be deemed a breach of the Amended Collaboration Agreement). In addition, our funding requirements would increase for any programs that are within the scope of the current 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. In particular, if Merck elects to license NGM621 and its related compounds after completion of the CATALINA trial, we would need to raise substantial additional capital if we opt to co-develop the program and are therefore required to contribute to the costs of Phase 3 development. Similarly, if Merck does not elect to license NGM621 and its related compounds after completion of the CATALINA trial, we would need to raise substantial additional capital and/or partner the program in order to proceed to Phase 3 development of NGM621 if supported by the results from the CATALINA trial.

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, we will need to raise significant additional capital and/or we will need to enter into additional collaborations in order to proceed with development through regulatory approval and commercialization of our current and potential future product candidates. Neither may be possible and, as a result, if adequate funds are not available when we need them, we may need to significantly delay, scale back or discontinue development of some or all of our product candidates or scale back or discontinue discovery efforts, which could have a material adverse effect on our business, operating results and prospects, or we may be required to cease operations altogether.

We will 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 be required to delay, scale back or discontinue development of such product candidates.

As an R&D company, our operations have consumed substantial amounts of cash since inception, and we will require 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;
- whether Merck exercises its option to license product candidates upon completion of human proof-of-concept studies, such as its license option for NGM621 upon completion of the Phase 2 CATALINA trial, or at the earlier 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;
- the amount of our financial resources that we will need to devote to our obligations under the Amended Collaboration Agreement;
- 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;
- 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 the twelve months from the date of filing of this Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. 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, product collaborations, strategic alliances, licensing 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 the biotechnology industry specifically, resulting from, among other things, the continuing effects of the COVID-19 pandemic, macroeconomic factors including inflation and geopolitical instability, including instability resulting from the invasion of Ukraine by Russia and the related sanctions imposed against Russia.

If adequate funds are not available from public or private equity or debt offerings on acceptable terms when needed, 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 product collaborations 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.

Even if we decide we want to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of such product candidates, we may not be able to enter into agreements on acceptable terms, if at all. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon the potential collaborator's evaluation of the subject product candidate and its market opportunity, our assessment of the collaborator's resources and expertise and the terms and conditions of the potential collaboration.

We are also restricted under our existing Amended Collaboration Agreement with Merck, and may be restricted under future collaboration agreements, from entering into additional agreements on certain terms with potential collaborators. 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, including, if Merck exercises its option to license a program, we may not directly or indirectly research, develop, manufacture or commercialize any product with specified activity against the target that is the subject of that program for so long as Merck's license to that program remains in effect. The human hormone fibroblast growth factor 19, or FGF19 program, including aldafermin, is excluded from this provision, notwithstanding that both aldafermin and MK-3655 signal, in part, through the fibroblast growth factor receptor 1c, or FGFR1c, pathway. 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 CVM-related programs.

We may not be able to raise adequate additional capital or negotiate potential future collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to delay, scale back or discontinue our research, the development of any product candidate for which we are seeking a collaboration or one or more of our other development programs, delay a product candidate's potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense, or we may be prevented from pursuing research, development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

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. 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

We depend on our collaboration with Merck for the development and commercialization of our product candidates within the scope of the collaboration. Our collaboration with Merck involves numerous risks, any of which could materially and adversely affect our business and financial condition.

As described in more detail under "Management's Discussion and Analysis of Financial Condition and Results of Operations - Overview of Our Business - Our Merck Collaboration" 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 R&D funding and, for products 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. Under the Amended Collaboration Agreement, the research phase of the collaboration continues generally through March 2024, with possible extensions for each of the various programs to allow us or Merck to complete ongoing development during designated tail periods. The level of R&D funding we expect to receive from Merck going forward will be substantially lower on an annual and overall basis than the R&D funding previously provided by Merck. In addition, we do not know whether Merck will exercise its option to license additional product candidates, such as its license option for NGM621 upon completion of the Phase 2 CATALINA trial within 60 days of Merck's receipt of an agreed-upon data package, or whether Merck will terminate its license to a licensed program under the terms of the Amended Collaboration Agreement or otherwise.

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 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 MK-3655 or any future licensed program, as it did in 2019 when it terminated its license to our growth differentiation factor 15, or GDF15, agonist program, which included currently suspended product candidates NGM395 and NGM386. 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 complete certain of our research and development programs, which would materially and adversely affect our business and our stock price would likely decline. In addition, in the event that Merck decides to take over any product candidates included in the scope of the collaboration for development during any tail period, or exercises it license option for any such product 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 collaborations with third parties other than Merck for the development and commercialization of our product candidates and for revenue. If those collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.

We may seek other third-party collaborators for the development and commercialization of any product candidates that are not within the scope of the collaboration with Merck or if Merck elects not to proceed with development of any product candidates that are within the scope of the current collaboration. For example, if Merck does not elect to license NGM621 and its related compounds after completion of the CATALINA trial, we would need to raise substantial additional capital and/or partner the program in order to proceed to Phase 3 development of NGM621 if supported by the results from the CATALINA trial. If we decide to enter into any such arrangements with any third parties, and are successful in doing so, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from any such arrangement will depend on the specific financial terms we reach with any collaborator, as well as each of our collaborators' abilities to successfully perform the functions assigned to them in such arrangement towards developing, seeking regulatory approval for and commercializing our product candidates.

Collaborations involving our product candidates, including our collaboration with Merck, pose risks to us, including the following:

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations. For example, under the terms of the collaboration with Merck, if Merck exercises its

option to acquire an exclusive license for a product candidate that is within the scope of the collaboration, our ability to influence the resources Merck devotes to such product 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.

- Collaborators 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 collaborator'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. In addition, under the terms of the Amended Collaboration Agreement, it is possible for Merck to unilaterally terminate the MK-3655 program and any other program (whether or not we have exercised our cost and profit share option) upon prior written notice, such as it did for NGM386 and NGM395, without triggering a termination of the remainder of the Amended Collaboration Agreement. Moreover, Merck might also opt not to designate any collaboration product 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.
- Collaborators 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.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- A collaborator with marketing and distribution rights might not commit sufficient resources to the marketing and distribution of our product candidates.
- Collaborators 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 collaborators 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 collaborations, including, in the case of our collaboration with Merck, if we undergo a change in control.
- Collaborations 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.

Collaboration agreements might not lead to development or commercialization of product candidates in the most efficient manner, or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration 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 our collaboration with Merck and any potential future collaborators, 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 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 collaborators 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 collaborators 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 collaborators 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 collaborators 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 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 intended to manufacture our product candidates; and
- our CMOs' 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 evolving effects of the 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. For MK-3655 and any other product candidates licensed by Merck, we will rely on Merck's internal manufacturing capacity or a third-party manufacturer engaged by Merck. 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, such as our ongoing activities with a CMO to transfer the process for the manufacture of NGM621 in anticipation of a potential Phase 3 trial, 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 planned individual new drug application 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.

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 recently 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 *"The COVID-19 pandemic continues to adversely impact our business and operations, as well as the businesses or operations of our manufacturers, CROs or other third parties with whom we conduct business. Our business could be materially and adversely affected in the future by the effects of other disease outbreaks, epidemics and pandemics, including by the evolving effects of 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 aldafermin and MK-3655 are currently 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 invasion of 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 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

The COVID-19 pandemic continues to adversely impact our business and operations, as well as the businesses or operations of our manufacturers, CROs or other third parties with whom we conduct business. Our business could be materially and adversely affected in the future by the effects of other disease outbreaks, epidemics and pandemics, including by the evolving effects of the COVID-19 pandemic.

Disease outbreaks and epidemics in regions where we have concentrations of clinical trial sites or other business operations or pandemics, such as the COVID-19 pandemic, 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. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as the United States and international economy and financial markets. In this regard, the COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as significant reductions in business-related activities have occurred, supply chains have been disrupted and manufacturing and clinical development activities have been curtailed or suspended.

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic could materially and adversely affect our operations. After reopening our offices to a hybrid work model in October 2021, with the increased rate of transmission experienced with the Omicron SARS-CoV-2 variant in early 2022, we returned to a more restrictive model, temporarily discouraging in-person meetings and presence on site unless necessary to perform one’s job responsibilities. Although we are operating under a hybrid work model, we may be forced to, or determine that we should, resume a more restrictive remote work model. In connection with these measures, we may be subject to

claims based upon, arising out of or related to COVID-19 and our actions and responses thereto, including any determinations that we have made and may make in the future with respect to our onsite operations.

Further, the effects of current and future governmental shelter-in-place orders and our remote work policies may materially and adversely impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. For example, since the beginning of the COVID-19 pandemic, the labor market has tightened significantly and we have experienced employee attrition at rates higher than we have experienced historically, together with an increased rate of hiring new employees. Over the last year, the competition to attract, retain and replace employees in the industry has intensified. We cannot predict whether these trends will continue or be exacerbated, the impact of COVID-19 on future productivity or whether or when we may be required to return to a more restrictive work model as the COVID-19 pandemic continues to evolve. Future similar, and perhaps more severe, disruptions in our operations could materially and adversely impact our business, financial condition, results of operations and growth prospects.

As the COVID-19 pandemic continues to evolve, there may be additional negative impacts in the future 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. 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 has been and may continue to be impacted by quarantines, shelter-in-place and similar restrictions imposed by federal, state and local governments. These restrictions may also continue to prohibit or discourage patients from enrolling in, or continuing to participate in, our clinical trials. Principal investigators and clinical trial site staff, as healthcare providers, may have heightened exposure to COVID-19 and if their health is impacted by COVID-19, it could adversely impact the conduct of our clinical trials at their sites. Similarly, potential participants in our clinical trials, many of whom are particularly vulnerable, may be unwilling to enroll in, and enrolled patients may be unwilling to continue to participate in, our clinical trials due to concerns about traveling to sites for required screening and clinical trial visits and procedures. In this regard, during the COVID-19 pandemic, we have experienced, from time to time, a slower pace of clinical site initiation and clinical trial enrollment and a higher subject drop out rate than originally anticipated in certain of our clinical trials. We believe this 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.

Enrolled patients may also be unable to comply with clinical trial protocols if quarantines, shelter-in-place and similar restrictions continue to impede patient movement or interrupt healthcare services. Accordingly, we have developed and implemented additional clinical study policies and procedures designed to help protect trial participants from exposure to COVID-19 as a result of their trial participation, which include the use of telemedicine visits with trial participants, remote monitoring of clinical trial sites and other measures, as appropriate, designed to ensure that data from our clinical trials that may be temporarily disrupted as a result of safety measures during the COVID-19 pandemic are collected pursuant to the study protocol and consistent with current Good Clinical Practices, or cGCPs, with any material protocol deviation reviewed and approved by the clinical trial sites' institutional review boards, or IRBs, or ethics committees. We may be required to develop and implement additional clinical study policies and procedures to mitigate the evolving effects of the COVID-19 pandemic, which could significantly increase our R&D expenses. General supply chain issues exacerbated during the COVID-19 pandemic 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, recently 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. If any of the foregoing or any future efforts to mitigate the impact of the COVID-19 pandemic on our clinical trials are not successful, or if the effects of the COVID-19 pandemic persist or become more severe, it could materially and adversely affect our clinical development timelines and our ability to obtain regulatory approvals of our product candidates and could significantly increase our costs.

We also could see an adverse impact on our ability to report clinical trial results, or interact with regulators, IRBs and ethics committees or other important agencies due to limitations in health authority employee resources or otherwise. Moreover, we rely on CROs and other third parties to assist us with clinical development activities, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic.

Quarantines, shelter-in-place and similar government orders and guidelines could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which

would disrupt our supply chain and delay our clinical development efforts. 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. 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 the evolving effects of the continuing COVID-19 pandemic. 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. As an example, in 2020, the Defense Production Act was invoked pursuant to which the U.S. government may, among other things, require domestic industries to provide essential goods and services needed for the national defense, such as drug material or other supplies needed to treat COVID-19 patients or to produce or distribute vaccines, which could require our third-party manufacturers to allocate manufacturing capacity or raw materials or components in a way that delays or interrupts our supply of clinical trial material. For example, early in the 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 COVID-19 vaccines or medical supplies needed to treat COVID-19 patients, this could delay our clinical trials, perhaps substantially, which could materially and adversely affect our business.

In any event, if the effects of the COVID-19 pandemic persist or become more severe or more acutely impact geographies with particular relevance to our business, we could experience significant disruptions to our current and potential future clinical development timelines, impacts on our ability to obtain regulatory approvals of our product candidates and increases in our costs, all or any of which would adversely affect our business, financial condition, results of operations and growth prospects.

While the potential future economic impact caused by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the COVID-19 pandemic (as well as the invasion of Ukraine by Russia and the related sanctions imposed against Russia) could result in significant and prolonged disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect the financial resources available to us. In addition, economic recession or additional market corrections resulting from, among other things, the spread of COVID-19 could materially affect our business and the value of our common stock. We also cannot predict how the evolving effects of the COVID-19 pandemic may influence the future decisions of Merck to license any programs available to it under the Amended Collaboration Agreement, such as NGM621 and its related compounds.

While we expect the COVID-19 pandemic to continue to affect our business operations, the extent of the impact on our clinical development and regulatory efforts, our ability to raise sufficient additional capital on acceptable terms, if at all, the decisions of Merck and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. Such developments include the emergence and spread of SARS-CoV-2 variants in the United States and other countries, including the potential emergence of variants that may prove especially contagious or virulent, the ultimate duration and severity of the COVID-19 pandemic, government actions, such as travel restrictions, quarantines and social distancing requirements in the United States and in other countries, business closures or business disruptions, and the effectiveness of vaccination programs and other actions taken globally to contain and treat COVID-19. To the extent the evolving effects of the COVID-19 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.

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 evolving effects of the 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 research and development personnel; or
- the placement of a clinical hold on a trial by the FDA or comparable foreign health authorities.

For example, in the third quarter of 2021, the manufacturer of Abraxane® (paclitaxel protein bound), or Abraxane, reported a shortage of Abraxane to the FDA due to manufacturing delays. Abraxane, also referred to as Nab-paclitaxel, is required for treatment of patients in our ongoing Phase 1/2 NGM120 clinical trial. The Phase 2 portion of the trial (referred to as the PINNACLES trial) is studying NGM120 in combination with gemcitabine and Nab-paclitaxel as first-line treatment in patients with metastatic pancreatic cancer to assess NGM120's effect on both cancer and cancer-related cachexia. It is possible that if our clinical trial sites are unable to obtain Nab-paclitaxel in a timely fashion, or at all, that enrollment in the Phase 1/2 NGM120 trial could substantially be delayed or precluded altogether.

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 collaborators' 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, 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 collaborators 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, 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. While we continued, and have completed, enrollment in our Phase 2b ALPINE 4 clinical trial of aldafermin in patients with compensated cirrhosis due to NASH (liver fibrosis stage 4, or F4, by the NASH Clinical Research Network classification), we updated the design of the ALPINE 4 trial, elevating the Enhanced Liver Fibrosis, or ELF, test, a reproducible, quantitative non-invasive liver prognostic test that evaluates liver fibrosis and correlates to liver-related outcomes, to be the primary endpoint for the trial. The ELF test is a composite blood test measuring the presence of three biomarkers associated with liver matrix metabolism. Liver biopsy data will also be measured and reported as a secondary endpoint upon completion of the trial. For more information, see the risk factor titled "*Aldafermin, which is wholly-owned by us, as well as MK-3655, which is being developed by our collaborator, Merck, are 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 clinical development and regulatory approval for the treatment of NASH.*" We may determine to discontinue any further development of aldafermin in the future, in which case, we will not receive any return on our investment in aldafermin.

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.

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 collaborators 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, despite the results reported in our Phase 1 and 2 clinical trials for aldafermin, in Phase 1 clinical trials for MK-3655, NGM621 and NGM120 and in preclinical studies for our other product candidates, including three of our oncology product candidates, NGM707, NGM831 and NGM438, 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, 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.

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.

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 have experienced, and we have reported, serious adverse events, or SAEs, in the treatment arms of our completed trials of MK-3655, NGM621 and aldafermin. Ocular SAEs reported in our ongoing Phase 2 CATALINA trial of NGM621, which remains masked to treatment assignment, include retinal detachment in the non-study eye, development of choroidal neovascularization in the study eye, visual worsening due to arterial occlusive disease in the study eye and decreases of vision, or visual acuity loss, due to worsening geographic atrophy, or GA, in the study and non-study eye. 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 and NGM831, 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 or 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 trial. If we or Merck, as appropriate, are required to undertake substantial additional testing as a result of the detection of ADAs in subjects using aldafermin, MK-3655 or any other product candidate, the costs of our clinical trials may increase. If we or Merck determine that ADAs are causing safety or efficacy concerns when using any of our product candidates, we or Merck 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.

In clinical trials to date, NGM621 has been delivered to clinical sites in vials and then administered to patients using commercially available single-use syringes. The manufacturer of a commercially available single-use syringe widely used by ophthalmologists for intravitreal, or IVT, injections, including investigators in the Phase 2 CATALINA trial, issued a notice that such single-use syringes should not be used for ocular medications due to an increased potential for adverse eye conditions. We have not experienced any safety concerns in our ongoing or completed NGM621 clinical trials relating to syringe use; however, we communicated with the FDA and our study investigators regarding this issue and are evaluating alternative syringes that may be suitable for intraocular use. However, if any patient in our clinical trials experiences a safety event due to the use of these commercially available single-use syringes, we could be required to delay or halt our clinical trials or may be subject to product liability claims.

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, which is wholly-owned by us, as well as MK-3655, which is being developed by our collaborator, Merck, are 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 clinical development and regulatory approval for the treatment of NASH.

We are developing aldafermin, and Merck is developing MK-3655, 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 recently 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 in particular. If the clinical trials for aldafermin and MK-3655 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.

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 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. 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, especially our Chief Scientific Officer, Dr. Jin-Long Chen, 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. An important element of our strategy is to take advantage of the R&D and other expertise of our current management. The loss of any one of our executive officers, including, in particular, Dr. Jin-Long Chen, our Chief Scientific Officer, 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. In particular, the hiring environment in the San Francisco Bay Area, where we are headquartered, is extremely competitive. 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 has tightened significantly since the beginning of the ongoing COVID-19 pandemic, and we have experienced employee attrition at rates higher than we experienced historically, which may continue and could have a negative impact on our productivity. If we are unable to continue 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 collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative 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 EMA-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-Key Therapeutic Areas and Pipeline Programs” in our 2021 Annual Report on Form 10-K.

In addition, in the third quarter of 2021, Apellis Pharmaceuticals, Inc., or Apellis, presented top-line results from two Phase 3 clinical trials of its product candidate, pegcetacoplan (an anti-complement C3), in patients with GA secondary to age-related macular degeneration. One trial met the primary endpoint of significantly reducing GA progression at a one-year time point in the pegcetacoplan arm versus the sham arm, while the other trial did not meet its primary endpoint. In the first quarter of 2022, Apellis also reported additional data on the safety and efficacy of pegcetacoplan from an un-prespecified 18-month analysis of the two Phase 2 trials and that it plans to submit a new drug application for pegcetacoplan for GA to the FDA in the second quarter of 2022. If Apellis obtains regulatory approval of pegcetacoplan, it may affect our future late-stage clinical trial designs and require added clinical development expense. Additionally, if we obtain regulatory approval of NGM621, we may not be able to compete effectively against pegcetacoplan, which may adversely affect our future revenues and business prospects.

We may encounter difficulties in managing our growth, which could adversely affect our operations.

Over the past few years, we have significantly increased our headcount and advanced our pipeline and the complexity of our operations, which has placed a strain on our administrative and operational infrastructure. We expect this strain to continue as we seek to maintain our growth and seek to obtain and manage relationships with third parties. Our ability to manage our operations and growth effectively depends upon the continual improvement of our procedures, hybrid and remote work policies, reporting systems and operational, financial and management controls, particularly in light of the evolving effects of the COVID-19 pandemic. We also may not be able to expand or identify and access sufficient facilities to accommodate our growth, particularly given our location in South San Francisco, California and the current high demand for, and restricted supply of, R&D facilities in this market. The current lease for our facilities in South San Francisco is scheduled to expire in December 2023. While we believe we will be able to extend our lease or obtain new and/or additional space, as needed, on commercially reasonable terms, based on current market conditions our lease obligations will likely be higher in the future. We may not be able to implement administrative and operational improvements in an efficient or timely manner and may discover deficiencies in existing systems and controls. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures, which in turn may slow our growth or give rise to inefficiencies that would increase our losses.

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. While we are undertaking efforts to develop formulations and presentations of aldafermin that allow for more convenient or less frequent dosing, there is no assurance that these efforts will be successful, which may negatively impact market acceptance of an approved aldafermin product, if any. In addition, see 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 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 collaborators obtain regulatory approval. If coverage and reimbursement are not

available or reimbursement is available only to limited levels, we and our collaborators 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, 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.” In December 2019, a U.S. District Court upheld a ruling that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA remains in effect in its current form, although it may be subject to judicial or Congressional challenges in the future. Any such challenges to the ACA and the healthcare reform measures of the administration of President Biden may 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, the United States Department of Health and Human Services, or 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. 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. These measures include: mandatory price controls; price referencing; therapeutic-reference pricing; increases in mandates; incentives for generic substitution and biosimilar usage and government-mandated price cuts. Many countries have health technology assessment agencies that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies. These agencies are expanding in both established and emerging markets and are expected to become law in EU member states in the near future with the adoption of the Health Technology Assessment Regulation. Many countries also limit coverage to populations narrower than those specified on product labels or impose volume caps to limit utilization. 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 collaborator succeeds in developing any of our product candidates, we intend to market them in the European Union, or the EU, and other jurisdictions in addition to the United States. If approved, we, Merck or any future collaborator 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 local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars such as the current military conflict between Russia and Ukraine, terrorism and political unrest, outbreak of disease, 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 collaborator 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 collaborator 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 collaborator 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.

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 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 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.

In some jurisdictions such as the United States and the EU, initiating Phase 3 clinical trials and clinical trials in the pediatric population is subject to a requirement to obtain approval or a waiver from the FDA, the competent authorities of the EU member states and/or the EMA. If we do not obtain such waivers or approval, our ability to conduct clinical trials and obtain marketing authorizations or approvals may be severely impaired, and our business may be adversely impacted.

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. Accordingly, although NGM621 has received Fast Track designation from the FDA for GA secondary to age-related macular degeneration and aldafermin has received Fast Track designation from the FDA for NASH, we may not necessarily experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures.

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 Merck 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 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 Merck 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. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. It permits increased interaction and early dialogue between regulatory authorities and companies developing promising medicinal products, to optimize their product development plans and speed up their evaluation to help the product potentially reach patients sooner than under the normal review timelines. Product developers that benefit from PRIME designation are potentially eligible for accelerated assessment of their marketing authorization applications, or MAA, although this is not guaranteed. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

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

If we or our collaborators 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 research and development 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, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, 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.

Failure to comply with EU and EU member state 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.

Many EU member states periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. In addition, we expect that legislators, policymakers and healthcare insurance funds in the EU member states will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. 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. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states, including those representing the larger markets. The HTA process, which is currently governed by national laws in each EU member state, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU member states. In June 2021, the European Parliament and Council reached a provisional agreement on a draft HTA regulation that aims to harmonize the clinical benefit assessment of HTA across the EU. Entry into application of the Regulation could impose stricter and more detailed procedures to be followed by marketing authorization holders concerning conduct of HTA in relation to their products that may influence related pricing and reimbursement decisions. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the EU may continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems of the EU member states. These measures could include limitations on the prices we will be able to charge for our products or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

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. If aldafermin is approved by the FDA based on a surrogate endpoint pursuant to accelerated approval regulations (Subpart E regulations), we will be required to conduct additional clinical trials establishing clinical benefit on the ultimate outcome of NASH. 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. 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 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 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 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' 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 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 or collaborators may be subject to claims that former employees, 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 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.

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 $8.81 on October 7, 2019. 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 elsewhere in this "Risk Factors" section, these factors include:

- developments associated with our collaboration with Merck or any termination of the collaboration;
- the success of competitive products or technologies, including disclosure of interim data by our competitors;
- regulatory actions with respect to our product candidates or our competitors' product candidates or products;
- results of clinical trials of our product candidates or those of our competitors;
- timeline delays in our clinical trials, including delays resulting from the evolving effects of the global COVID-19 pandemic or otherwise;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors or collaborators of significant acquisitions, strategic collaborations, joint ventures, collaborations 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 level of expenses related to any of our product candidates or clinical development programs;
- 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;
- 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 and the Russian invasion of Ukraine, 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 evolving effects of the COVID-19 pandemic, macroeconomic factors including inflation or geopolitical instability, including instability resulting from the invasion of Ukraine by Russia 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 potential 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 also 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 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 may be able to determine all matters requiring stockholder approval. For example, these stockholders 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, 2022, the average daily trading volume for our common stock on The Nasdaq Global Select Market was only 237,697 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, or DGCL, 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 DGCL 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 current terms of our agreement with Merck, 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.

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; any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us 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, 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, 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. 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.

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 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, 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, none of which, to date, have caused material disruption to our business, or to our knowledge, involved a material security breach. Most recently, 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.

Brexit will continue to create significant uncertainty concerning the future relationship between the United Kingdom, or UK, and the EU, following the UK withdrawal from the EU in January 2020. Since a significant portion of the regulatory framework in the UK is derived from EU laws, Brexit materially impacts the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will

be treated as a “third country,” a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement.

In this regard, in December 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-UK Trade and Cooperation Agreement, or TCA. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. As part of the TCA, the EU and the UK will recognize cGMP inspections carried out by the other party and the acceptance of official cGMP 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 UK has unilaterally agreed to accept EU batch testing and batch release for a period of at least 2 years until January 1, 2023. However, 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 it relates to marketing authorizations, Great Britain will have a separate regulatory submission process, approval process and national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission. For example, the scope of a marketing authorization for a medicinal product granted by the European Commission or by the competent authorities of EU member states will no longer encompass Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the UK competent authorities will be required to place medicinal products on the market in Great Britain. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the European Commission. These changes, as well as future changes, 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. For example, we process personal information from clinical trials participants and other individuals located in the European Economic Area, or EEA, and, if any of our product candidates are approved, we may seek to commercialize those products in the EEA. The collection, use and other processing of personal information, including health data, in the EEA or regarding residents of the EEA are governed by the EU’s General Data Protection Regulation ((EU) 2016/679), or EU GDPR, and other relevant laws that govern patient confidentiality and storage of personal health data. 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 aligned with, the EU GDPR, which together with the UK Data Protection Act of 2018, or UK DPA, covers the processing of personal data of UK residents. Non-compliance with UK data protection laws may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

The EU GDPR and accompanying laws are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. Because of the remote work policies we implemented due to the COVID-19 pandemic, information that is normally protected, including company confidential information, may be less secure. Cybersecurity and data security threats continue to evolve and raise the risk of an incident that could affect our operations or compromise our business information or sensitive personal data, including health data. We may also need to collect more extensive health-related information from our employees to manage our workforce.

Certain jurisdictions, including the EEA, UK and Switzerland, have enacted data localization laws and laws restricting cross-border transfers of personal information. For example, the EU GDPR generally restricts the transfer of personal information from the EEA to countries outside of the EEA, such as the United States, which the

European Commission does not consider is providing an adequate level of data privacy and security. One of the primary mechanisms designed to allow United States companies to continue to import personal information from the EA has been the European Commission's Standard Contractual Clauses, or SCCs. SCCs are standard contractual obligations that may be entered between a party exporting personal information from the EU and a party receiving the personal information in a third country that has not been deemed by the European Commission to provide an adequate level of data privacy and security. In addition to implementing and complying with such contractual obligations, the European Commission's most recent version of the SCCs, released on June 4, 2021, requires parties to meet additional obligations, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the data at issue. If adequate data protection cannot be guaranteed, EEA residents may complain to the data protection authorities, which may require data transfers under the contract to be suspended. The European Commission's updated SCCs may further increase the legal risks and liabilities under European privacy, data protection and information security laws. Additionally, due to potential legal challenges, there exists some uncertainty regarding whether the SCCs will remain a valid mechanism for transfers of personal information out of the EEA. Laws in the UK and Switzerland similarly restrict transfers of personal information outside of those jurisdictions to countries such as the United States that are deemed not to provide an adequate level of personal information protection.

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 or guidance that may be issued, particularly by the EU authorities. At present, we primarily rely on individuals' explicit consent, which can be revoked at any time, to transfer their personal information from the EU to the United States and other countries, but in certain cases we have relied or may rely on the SCCs. If we are unable to rely on explicit consent to transfer individuals' personal information from the EU, or if we are otherwise unable to implement a valid compliance solution for cross-border transfers of personal information, we will face increased exposure to substantial fines, regulatory actions, as well as injunctions against the export and processing of personal information from Europe. Our inability to import personal information from the EEA, UK or Switzerland or other countries may also restrict 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.

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, just over a month after the EU GDPR took effect, the California legislature passed the California Consumer Privacy Act of 2018, or CCPA, which 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. Since the enactment of the CCPA, new privacy and data security laws have been proposed in more than half of the states and in United States Congress, reflecting a trend toward more stringent privacy legislation in the United States. 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. The CCPA itself will expand substantially as a result of California voters approving a November 2020 ballot measure that adopted the California Privacy Rights Act of 2020, or CPRA, which becomes fully effective on January 1, 2023, and will, among other things, create a new administrative agency to implement and enforce California's privacy laws. While certain clinical trials activities are exempt from the CCPA's requirements, other personal information that we handle may be subject to the CCPA, forthcoming CPRA and similar laws, including laws that have been or may be adopted in states other than California, which may increase our compliance costs, exposure to regulatory enforcement action and other liabilities.

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 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.

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 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, NGM621, NGM707, NGM831 and NGM438 is located in Lithuania, a region that has experienced political unrest. See "*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.

Our ability to use net operating loss carryforwards 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 corporate collaborations. 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 net operating loss carryforwards generated in tax years ended on or prior to December 31, 2017 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 Section 382 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 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 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. For example, California has imposed limits on the usability of California net operating loss carryforwards and certain tax credits to offset California taxable income or California tax liabilities in tax years beginning after 2019 and before 2023. Any such limitations may result in greater tax liabilities than we would incur in the absence of such limitations and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows.

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 income, sales, use or other tax laws, statutes, rules, regulations, directives, decrees or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the 2017 Tax Act sanctioned many significant changes to the U.S. tax laws. Future guidance from the U.S. Internal Revenue Service, or IRS, and other tax authorities with respect to the 2017 Tax Act may affect us, and certain aspects of the 2017 Tax Act may be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the 2017 Tax Act. 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 or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges and could 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 we have hired and will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404(b) of the Sarbanes-Oxley Act in a timely manner, or 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 that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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 collaborations 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	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+*	Letter Agreement, by and between NGM Biopharmaceuticals, Inc. and Merck Sharp & Dohme Corp., dated as of March 30, 2022.				
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 herewith.

* Certain confidential information contained in this exhibit has been omitted because it is both not material and is of the type that the Registrant treats as private or confidential.

** 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 5, 2022 By: /s/ David J. Woodhouse
David J. Woodhouse, Ph.D.
Chief Executive Officer and Director

Date: May 5, 2022 By: /s/ Siobhan Nolan Mangini
Siobhan Nolan Mangini
Chief Financial Officer
(Principal Financial Officer)

Exhibit 10.1
EXECUTION VERSION

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS OF THE TYPE THAT THE COMPANY TREATS AS PRIVATE OR CONFIDENTIAL

March 30, 2022
Merck Sharp & Dohme Corp.
[***]
Attention: Office of Secretary
Merck Sharp & Dohme Corp.
[***]
Attention: VP, Transactions, Business Development & Licensing, MRL
Re: NGM621 Pre-Phase 3 Clinical Trial CMC Expenses
[***]

This letter agreement ("**Letter Agreement**") concerns the Amended and Restated Research Collaboration, Product Development and License Agreement (the "**Agreement**") dated June 30, 2021 by and between NGM Biopharmaceuticals, Inc. ("**NGM**") and Merck Sharp & Dohme Corp. ("**Merck**"). Capitalized terms not defined in this Letter Agreement have the meanings ascribed to them in the Agreement.

NGM, in parallel with its performance of the CATALINA Clinical Study, is continuing to progress planning for the manufacture of NGM621 with the goal of facilitating the commencement of a Phase 3 Clinical Trial for NGM621 promptly after the completion of the CATALINA Clinical Study. The purpose of this Letter Agreement is for Merck and NGM to agree to the following matters with respect to such manufacture:

1) *CMC Activities under the Lonza Agreement.*
    a. Pursuant to that certain Master Services Agreement entered into on or about March 30, 2022 by and among NGM, Lonza Sales AG (also known as Lonza Sales Ltd), and Lonza AG (also known as Lonza Ltd), NGM will be responsible for payment of certain amounts for the performance by Lonza Sales AG, Lonza AG, and certain Lonza Affiliates (collectively, "**Lonza**"), including Lonza Biologics Tuas Pte Ltd, a Singapore corporation ("**Lonza Singapore**"), of pre-Phase 3 Clinical Trial CMC activities for NGM621, including but not limited to

[***] (such agreement, including the Letter of Intent between NGM and Lonza Singapore effective as of October 4, 2021, as amended December 3, 2021, January 2, 2022, and February 1, 2022, and any work orders or change orders entered into under such agreements, collectively, the "**Lonza Agreement,**" and such activities performed by or on behalf of Lonza as contemplated in the Lonza Agreement, together with activities performed by third parties (the "**Supporting Parties**") that are not Subcontractors or External Laboratories (each, as defined in the Lonza Agreement) to perform activities [***], collectively, the "**CMC Activities**"). The performance of such CMC Activities commenced on or about [***] (the "**Lonza Cost Commencement Date**"). Subject to and in accordance with the terms of this Letter Agreement, (a) in the case of [***] then Merck will reimburse NGM for certain costs actually incurred and paid to Lonza and Supporting Parties for such CMC Activities from and after the Lonza Cost Commencement Date [***] or (b) in the case of [***] then Merck will [***]. NGM will document all amounts it pays to Lonza and Supporting Parties with respect to the CMC Activities performed during the period of time from the Lonza Cost Commencement Date until [***]. The costs that NGM expects to incur for the CMC Activities will be [***] during the [***] (such amounts actually paid by NGM to Lonza or the Supporting Parties, the "[***] **Lonza Costs**"), which amount assumes that [***]. NGM will provide Merck with [***] reports of the [***] Lonza Costs paid during [***] together with reasonable detail.

b. To facilitate [***] NGM agrees to share certain information and processes from and under the Lonza Agreement and any agreement with a Supporting Party with Merck as described below. [***], upon Merck's reasonable request, and to enable Merck's comments to be timely incorporated into any final documentation, NGM will provide Merck with the opportunity to provide feedback on, and conduct functional area review of, [***]. During [***] upon Merck's reasonable request, NGM will [***]. After Lonza and NGM [***], NGM will provide Merck with [***]. In addition to the above, at all times during the Lonza Agreement, NGM will (i) keep Merck reasonably informed of the progress under the Lonza Agreement or the progress with any Supporting Parties, (ii) solicit Merck's consent [***] prior to [***], (iii) solicit Merck's consent prior to [***], and (iv) use Commercially Reasonable Efforts to meet its obligations pursuant to the Lonza Agreement.

c. NGM hereby represents, warrants and covenants that (i) it has provided Merck with true and complete copies of the Lonza Agreement (including any statement of work entered into thereunder) as in effect as of the date of this Letter Agreement, (ii) it will provide Merck with true and complete copies of any proposed or executed amendments to the Lonza Agreement and any proposed or amended statements of work entered into thereunder, (iii) it will consult reasonably with Merck in the spirit of the Agreement, including but not limited to

[***], (iv) except for any changes to the [***] Lonza Costs, which will be handled pursuant to clause (v) hereunder, it will consult reasonably with Merck and consider Merck's reasonable comments prior to [***], and (v) it will seek Merck's prior written consent for any [***] Lonza Costs [***]; provided, however, that the consultation obligation in clause (iv) above will end if [***]. For clarity, following the date of this Letter Agreement, if the [***] Lonza Costs [***], then Merck's prior written consent would be required before [***].

d. Merck acknowledges and agrees [***]. For the purposes of this Section 1 of this Letter Agreement, "**Lonza Affiliate**" means any company, partnership or other entity that directly or indirectly Controls, is Controlled by, or is under Common control with Lonza Sales AG, Lonza AG, or Lonza Singapore, where "Control" means the direct or indirect ownership of more than fifty percent (50%) of the issued share capital, the right to vote or the legal power to direct or cause the direction of the general management and policies of such company or business entity.

2) *CMC Activity FTE Costs*. NGM will provide qualified personnel to support the CMC Activities during the [***] (starting on the Lonza Cost Commencement Date) ("[***] **FTE Support**"). NGM will keep true, accurate and complete records of the FTE costs it incurs (at the applicable FTE Rate in accordance with the Agreement) for the provision of such support (the "**CMC Activity FTE Costs**"), and NGM will provide Merck with [***] reports of any CMC Activity FTE Costs. Subject to the other terms of this Letter Agreement, including Sections 3, 4 and 5, Merck shall reimburse NGM for CMC Activity FTE Costs in accordance with this Section 2 of this Letter Agreement. The CMC Activity FTE Costs shall count towards the Research Funding Cap as set forth in Section 3 of the Letter Agreement and NGM shall invoice Merck during [***] for all CMC Activity FTE Costs incurred by NGM during [***], and Merck shall pay such invoice within [***] of receipt. NGM shall invoice Merck for any CMC Activity FTE Costs that it incurs during [***], if applicable, within [***] after the end of the [***] in which such CMC Activity FTE Costs are incurred and Merck shall pay such invoice within [***] of receipt. Merck shall be entitled to audit NGM's records regarding the CMC Activity FTE Costs as described in Section 4.2.2(b) of the Agreement.

3) *Interplay of CMC Activity FTE Costs with Research Funding Cap.* All payments made by Merck pursuant to Section 2 of this Letter Agreement to reimburse NGM for CMC Activity FTE Costs from the Lonza Cost Commencement Date until the end of New Research Program Year 3 shall count towards the Research Funding Cap for New Research Program Years 2 and 3 combined, even though such payments are not Research Funding and are not for NGM's performance of the Ophthalmology Research Program. Merck shall not be obligated to pay any CMC Activity FTE Costs during Research Program Years 2 and 3, to the extent that such CMC Activity FTE Costs, together with (a) all amounts previously paid by Merck pursuant to Section 2 of this Letter Agreement

to reimburse NGM for CMC Activity FTE Costs from the Lonza Cost Commencement Date until the end of New Research Program Year 3 and (b) all Research Funding paid by Merck with respect to (i) the Ophthalmology Research Program (other than research, development and manufacture of NGM621), (ii) the CVM Research Program and (iii) the [***], in each case of (i)-(iii) for New Research Program Years 2 and 3, exceeds, alone or in the aggregate, the Research Funding Cap for New Research Program Years 2 and 3 combined.

4) *CMC Activity Cost Reimbursement and Payments Following Exercise of the NGM621 Option*.
   a. If Merck exercises the NGM621 Option, [***] of such exercise; provided that (i) unless Merck otherwise consents to such costs in writing (pursuant to Section 1 of this Letter Agreement), in no event shall Merck be obligated to reimburse NGM for [***] and (ii) Merck will in no event be obligated to reimburse NGM for [***].
   b. In addition, if Merck exercises the NGM621 Option, NGM shall promptly thereafter, at Merck's election: [***]. If Merck exercises the NGM621 Option and [***], in addition to NGM's and Merck's obligations under this Letter Agreement and the Agreement, including without limitation Sections 2.2(e) and 5.5.5 of the Agreement, Merck and NGM will [***].
   c. In the event that Merck exercises the NGM621 Option and [***].
5) *Cost Reimbursement and Payments if Merck Does Not Exercise the NGM621 Option*.
   a. If Merck does not exercise the NGM621 Option and [***], Merck will not be responsible for (i) reimbursing NGM for the [***] Lonza Costs, (ii) reimbursing NGM for or paying any amounts owed to Lonza by NGM during the [***], (iii) reimbursing NGM for any CMC Activity FTE Costs incurred [***], or (iv) any [***] set forth in Section 4 of this Letter Agreement.
   b. If Merck does not exercise the NGM621 Option and [***], NGM shall promptly notify Merck of such election and [***] and Merck will not be responsible for (i) reimbursing NGM for the [***] Lonza Costs, (ii) reimbursing NGM for or paying any amounts owed to Lonza by NGM during the [***], or (iii) paying the [***] set forth in Section 4 of this Letter Agreement; other than, in the event that [***] within [***]. For clarity, excluding any CMC Activity FTE Costs payable by Merck to NGM pursuant to Section 2 of this Letter Agreement, if Merck [***], Merck will in no event be required to pay NGM [***] under this Letter Agreement.

6) *Miscellaneous*. Notwithstanding the role of the JEDDC or Alliance Managers in communicating updates about the subject of this Letter Agreement, this Letter Agreement may only be amended consistent with the amendment and waiver provisions set forth in Section 16.8 of the Agreement. Any written communication pursuant to this Letter Agreement, notably any written consents required hereunder, shall also be addressed to the Alliance Manager of NGM and Merck, as applicable. If NGM intends to [***] NGM will obtain written consent from Merck's Alliance Manager or his or her designee. This Letter Agreement shall govern the obligations of Merck and NGM only to the extent expressly set forth herein (it being the intent of the parties that all of the terms and provisions of the Agreement that do not relate to the manufacture of NGM621 shall be unaltered and shall remain in full force and effect and that the execution, delivery and performance of this Letter Agreement shall not operate as a waiver of or consent to any past, present or future breach of any provision of the Agreement).

The Parties acknowledge and agree that this Letter Agreement is an agreement in writing by Merck as contemplated by Section 4.2.7(b) of the Agreement. [***].

[Remainder of page intentionally left blank]

Please confirm Merck's agreement with the foregoing by arranging for an authorized representative of Merck to sign a copy of this letter. This Letter Agreement shall be effective as of March 30, 2022.

Best regards,

/s/ David Woodhouse

NGM Biopharmaceuticals, Inc.

Acknowledged and Agreed:

Merck Sharp & Dohme Corp.

[***]

[***]

[***]

[***]

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 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 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 5, 2022

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 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 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 5, 2022

By: /s/ Siobhan Nolan Mangini

Siobhan Nolan Mangini
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 J. Woodhouse, Chief Executive Officer of NGM Biopharmaceuticals, Inc. (the "Company"), and Siobhan Nolan Mangini, 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, 2022, to which this Certification is attached as Exhibit 32.1 (the "Periodic 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 Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 5, 2022

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 5th day of May, 2022.

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

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

This certification accompanies the Quarterly Report on Form 10-Q 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 on Form 10-Q), irrespective of any general incorporation language contained in such filing.