

**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, 2021

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**

(State or other jurisdiction of  
incorporation or organization)

**333 Oyster Point Boulevard  
South San Francisco, CA**

(Address of principal executive offices)

**26-1679911**

(I.R.S. Employer  
Identification No.)

**94080**

(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 of Securities Registered	Trading Symbol	Name of Each Exchange on which Securities are 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 3, 2021, the registrant had 77,018,206 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 share amounts)*  
*(Unaudited)*

	March 31, 2021	December 31, 2020*
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 148,113	\$ 147,017
Short-term marketable securities	264,543	148,139
Related party receivable from collaboration	325	333
Related party contract asset	4,600	6,100
Prepaid expenses and other current assets	8,268	6,837
Total current assets	425,849	308,426
Property and equipment, net	13,733	14,526
Restricted cash	1,499	1,499
Other non-current assets	4,460	4,592
Total assets	<u>\$ 445,541</u>	<u>\$ 329,043</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 7,535	\$ 9,663
Accrued liabilities	29,763	29,945
Deferred rent, current	3,011	2,975
Total current liabilities	40,309	42,583
Deferred rent, non-current	5,655	6,417
Total liabilities	45,964	49,000
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; no shares issued or outstanding as of March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.001 par value; 400,000,000 shares authorized; 76,913,578 and 70,585,364 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	77	71
Additional paid-in capital	725,693	578,599
Accumulated other comprehensive income (loss)	(18)	4
Accumulated deficit	(326,175)	(298,631)
Total stockholders' equity	399,577	280,043
Total liabilities and stockholders' equity	<u>\$ 445,541</u>	<u>\$ 329,043</u>

See accompanying notes to unaudited condensed consolidated financial statements.

\*The condensed consolidated balance sheet as of December 31, 2020 has been derived from the audited financial statements as of that date.

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

	Three Months Ended March 31,	
	2021	2020
Related party revenue	\$ 21,575	\$ 24,364
Operating expenses:		
Research and development	40,699	38,439
General and administrative	8,721	6,595
Total operating expenses	49,420	45,034
Loss from operations	(27,845)	(20,670)
Interest income, net	114	1,175
Other income, net	187	380
Net loss	\$ (27,544)	\$ (19,115)
Net loss per share, basic and diluted	\$ (0.36)	\$ (0.28)
Weighted average shares used to compute net loss per share, basic and diluted	76,034,145	67,396,229

*See accompanying notes to unaudited condensed consolidated financial statements.*

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

	<b>Three Months Ended March 31,</b>	
	<b>2021</b>	<b>2020</b>
Net loss	\$ (27,544)	\$ (19,115)
Other comprehensive loss, net of tax:		
Net unrealized loss on available-for-sale marketable securities	(22)	(80)
Total comprehensive loss	<u>\$ (27,566)</u>	<u>\$ (19,195)</u>

*See accompanying notes to unaudited condensed consolidated financial statements.*

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

	Common Stock		Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 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
Changes in unrealized loss on available-for-sale securities	—	—	—	(22)	—	(22)
Net loss	—	—	—	—	(27,544)	(27,544)
Balance at March 31, 2021	76,913	\$ 77	\$ 725,693	\$ (18)	\$ (326,175)	\$ 399,577

	Common Stock		Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	66,886	\$ 67	\$ 526,771	\$ 25	\$ (196,144)	\$ 330,719
Issuance of common stock upon exercise of stock options	984	1	3,590	—	—	3,591
Vesting of common stock from early exercises	21	—	162	—	—	162
Stock-based compensation expense	—	—	3,695	—	—	3,695
Changes in unrealized loss on available-for-sale securities	—	—	—	(80)	—	(80)
Net loss	—	—	—	—	(19,115)	(19,115)
Balance at March 31, 2020	67,891	\$ 68	\$ 534,218	\$ (55)	\$ (215,259)	\$ 318,972

*See accompanying notes to unaudited condensed consolidated financial statements.*

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

	Three Months Ended March 31,	
	2021	2020
<b>Cash flows from operating activities</b>		
Net loss	\$ (27,544)	\$ (19,115)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,554	1,731
Amortization of premium (discount) on marketable securities	570	(122)
Stock-based compensation expense	6,582	3,695
Other non-cash (income) expenses, net	(315)	120
Changes in operating assets and liabilities:		
Related party receivable from collaboration	8	4,464
Related party contract asset	1,500	—
Prepaid expenses and other assets	(1,299)	(2,005)
Accounts payable	(2,128)	(5,343)
Accrued liabilities	(427)	3,026
Deferred rent	(726)	(689)
Deferred revenue	—	(4,872)
Net cash used in operating activities	(22,225)	(19,110)
<b>Cash flows from investing activities</b>		
Purchase of marketable securities	(144,996)	(29,399)
Proceeds from sales and maturities of marketable securities	28,000	56,837
Purchase of property and equipment	(160)	(565)
Net cash provided by (used in) investing activities	(117,156)	26,873
<b>Cash flows from financing activities</b>		
Net proceeds from follow on offering	134,570	—
Proceeds from issuance of common stock upon exercise of stock options	5,907	3,591
Net cash provided by financing activities	140,477	3,591
Net increase in cash and cash equivalents	1,096	11,354
Cash, cash equivalents and restricted cash at beginning of period	148,516	247,472
Cash, cash equivalents and restricted cash at end of period	\$ 149,612	\$ 258,826
<b>Non-cash investing and financing activities:</b>		
Vesting of common stock from early exercises	41	162
Property and equipment purchases accrued and not yet paid	637	270

*See accompanying notes to unaudited condensed consolidated financial statements.*

**NGM BIOPHARMACEUTICALS, INC.**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Description of Business**

NGM Biopharmaceuticals, Inc. and its wholly-owned subsidiary, collectively referred to as the Company, is focused on discovering and developing novel therapeutics based on scientific understanding of key biological pathways underlying liver and metabolic diseases, retinal diseases and cancer. The Company's robust portfolio of product candidates range from early discovery to late-stage development and include aldafermin, MK-3655, NGM621, NGM120, NGM707 and NGM438. The Company has additional undisclosed 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. Its 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, 2020 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020 filed with the United States Securities and Exchange Commission, or SEC, on March 15, 2021. 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 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. 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 Codification 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.

***Uses and Sources of Liquidity***

Since inception, the Company has incurred net losses and negative cash flow from operations. During the three months ended March 31, 2021, the Company incurred a net loss of \$27.5 million compared to \$19.1 million for the three months ended March 31, 2020. As of March 31, 2021, the Company had an accumulated deficit of \$326.2 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, 2021, the Company had \$412.7 million of cash, cash equivalents and short-term marketable securities. In January 2021, the Company sold 5,324,074 shares of its common stock through an underwritten public offering at a price to the public of \$27.00 per share for aggregate net proceeds to the Company of \$134.6 million after deducting underwriting discounts and commissions and other offering expenses paid by the Company. In June 2020, the Company entered into an Open Market Sale Agreement<sup>SM</sup>, or the Sales Agreement, with Jefferies LLC. During the three months ended March 31, 2021, no shares of the Company's common stock

were sold pursuant to the Sales Agreement. As of March 31, 2021, \$127.4 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 these unaudited condensed consolidated financial statements.

To fully implement the Company's business plan and fund its operations, the Company will need to raise additional capital through public or private equity offerings (which may include potential net proceeds from future sales, if any, under the Sales Agreement), debt financings, government or other third-party funding, 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 placing its investments with a bank it believes is highly creditworthy and with highly rated money market funds. As of March 31, 2021 and December 31, 2020, 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 gain as a separate component of stockholders' equity. Other income (expense), 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, 2021, 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 12 months from the date of these condensed consolidated financial statements.

#### ***Concentration of Credit and Other Risks***

Cash and cash equivalents and marketable securities from the Company's available-for-sale and marketable security 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 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 collaboration agreement with 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, 2021 and 2020.

### **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**

The Company's lease agreements for its laboratory and office facilities are classified as operating leases. Rent expense is recognized on a straight-line basis over the term of the lease. Incentives granted under the Company's facilities leases, including allowances to fund leasehold improvements and rent holidays, are capitalized and are recognized as reductions to rental expense on a straight-line basis over the term of the lease.

### **Impairment of Long-Lived Assets**

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized as the amount by which the carrying amount of the asset exceeds the estimated fair value of the asset. As of March 31, 2021 and December 31, 2020, 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.

### **Revenue Recognition**

Accounting Standards Update, or ASU, 2014-09, Revenue from Contracts with Customers (Topic 606) requires an entity to recognize revenue upon the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. 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.

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 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.

### ***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 expenses costs for its clinical trial activities performed by third parties, including clinical research organizations, or CROs, and other service providers, as they are incurred, based upon estimates of the work completed over the life of the individual

study in accordance with associated agreements. The Company uses assessments by internal personnel and information it receives from outside service providers to estimate the clinical trial costs incurred.

### **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, Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting on January 1, 2019, stock-based compensation expense for non-employee 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 ordinary 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 ordinary 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 share and per share amounts):

	Three Months Ended March 31,	
	2021	2020
<b>Numerator:</b>		
Net loss	\$ (27,544)	\$ (19,115)
<b>Denominator:</b>		
Weighted average number of shares used in calculating net loss per share—basic and diluted	76,034,145	67,396,229
Net loss per share—basic and diluted	\$ (0.36)	\$ (0.28)

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

	Three Months Ended March 31,	
	2021	2020
Options to purchase common stock	11,300,905	10,824,034
Shares committed under ESPP	291,992	396,360
<b>Total</b>	<b>11,592,897</b>	<b>11,220,394</b>

### ***Segment and Geographical Information***

The Company operates in one business segment. Substantially all of the Company's long-lived assets, comprised of property and equipment, are based in the United States. For the three months ended March 31, 2021 and 2020, 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. Under the Jumpstart Our Business Startups Act of 2012, as amended, the JOBS Act, the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act.

### ***Recently Adopted Accounting Pronouncements***

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (ASC 808): Clarifying the Interaction between ASC 808 and ASC 606, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer. In addition, ASC 808 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the participant is not a customer for that transaction. The Company adopted ASU 2018-18 effective January 1, 2021, noting no material impact on the Company's results of operations and financial position.

In December 2019, the FASB issued ASU 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. The new guidance modifies ASC 740 to simplify several aspects of accounting for income taxes, including eliminating certain exceptions to the guidance in ASC 740 related to the approach for intraperiod tax allocation. The Company adopted ASU 2019-12 effective January 1, 2021, noting no material impact on the Company's results of operations and financial position.

### ***Recent Accounting Pronouncements Not Yet Adopted***

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which increases lease transparency and comparability among organizations. Under the new standard, lessees will be required to recognize right-of-use, or ROU, assets and lease liabilities arising from lease arrangements on the balance sheet, with the exception of leases with a term of twelve months or less, which permits a lessee to make an accounting policy election by class of underlying asset not to recognize the ROU assets and lease liabilities. In March 2018, the FASB approved an alternative transition method to the modified retrospective approach, which eliminates the requirement to restate prior period financial statements and allows the cumulative effect of the retrospective allocation to be recorded as an adjustment to the opening balance of retained earnings at the date of adoption. In November 2019, the FASB issued ASU 2019-10, which deferred the effective date for certain ASUs including ASU 2016-02. In June 2020, due to the evolving impacts of the COVID-19 pandemic, the FASB issued ASU 2020-05, which further defers the effective date of ASU 2016-02, which is now effective for the Company's fiscal year beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022.

The Company plans to adopt the new lease standard in the fiscal year beginning January 1, 2022, using the optional transition method, which allows the Company to recognize a cumulative-effect adjustment to the opening balance of accumulated deficit at the date of adoption and apply the new disclosure requirements beginning in the

period of adoption. The Company also plans to elect the package of practical expedients permitted under the transition guidance within the new standard, which, among other things, allows the Company to carryforward the historical lease classification and make an accounting policy election whereby ROU assets and lease liabilities associated with lease arrangements with terms less than one year will not be recognized. The Company continues to evaluate the impact of this new lease standard to its results of operations and financial position.

### 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
<b>As of March 31, 2021</b>				
Money market funds	\$ 124,089	\$ —	\$ —	\$ 124,089
U.S. government agencies securities	113,153	26	—	113,179
Corporate and agency bonds	76,474	1	(45)	76,430
Commercial paper	74,934	—	—	74,934
Totals	<u>\$ 388,650</u>	<u>\$ 27</u>	<u>\$ (45)</u>	<u>\$ 388,632</u>
Classified as:				
Cash and cash equivalents				\$ 124,089
Short-term marketable securities (amortized cost of \$264,561)				264,543
Total				<u>\$ 388,632</u>

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
<b>As of December 31, 2020</b>				
Money market funds	\$ 137,658	\$ —	\$ —	\$ 137,658
U.S. government agencies securities	98,647	9	(3)	98,653
Commercial paper	41,945	—	—	41,945
Corporate and agency bonds	7,543	—	(2)	\$ 7,541
Totals	<u>\$ 285,793</u>	<u>\$ 9</u>	<u>\$ (5)</u>	<u>\$ 285,797</u>
Classified as:				
Cash and cash equivalents				\$ 137,658
Short-term marketable securities (amortized cost of \$148,135)				148,139
Total				<u>\$ 285,797</u>

Cash and cash equivalents in the table above excludes cash on deposit with banks of \$24.0 million and \$9.4 million as of March 31, 2021 and December 31, 2020, 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, 2021 and December 31, 2020, the Company's marketable securities had remaining contractual maturities less than one year. As of March 31, 2021, there were eleven marketable securities in an unrealized loss position compared to one marketable security in an unrealized loss position as of December 31, 2020. Marketable securities that had been in unrealized loss positions as of March 31, 2021 and December 31, 2020 had been in an unrealized loss position for less than 12 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):

<b>As of March 31, 2021</b>	<b>Fair Value Measurements</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets:</b>				
Money market funds	\$ 124,089	\$ —	\$ —	\$ 124,089
U.S. government agencies securities	—	113,179	—	113,179
Commercial paper	—	74,934	—	74,934
Corporate and agency bonds	—	76,430	—	76,430
<b>Totals</b>	<b>\$ 124,089</b>	<b>\$ 264,543</b>	<b>\$ —</b>	<b>\$ 388,632</b>

  

<b>As of December 31, 2020</b>	<b>Fair Value Measurements</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Total</b>
<b>Assets:</b>				
Money market funds	\$ 137,658	\$ —	\$ —	\$ 137,658
U.S. government agencies securities	—	98,653	—	98,653
Commercial paper	—	41,945	—	41,945
Corporate and agency bonds	—	7,541	—	7,541
<b>Totals</b>	<b>\$ 137,658</b>	<b>\$ 148,139</b>	<b>\$ —</b>	<b>\$ 285,797</b>

The carrying amounts of cash and cash equivalents, the related party receivable and contract asset from collaboration 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 corporate agency bond securities, commercial paper and government agencies 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, 2021 and year ended December 31, 2020.

#### **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):

	<b>March 31, 2021</b>	<b>December 31, 2020</b>
Cash and cash equivalents	\$ 148,113	\$ 147,017
Restricted cash	1,499	1,499
<b>Total cash, cash equivalents and restricted cash</b>	<b>\$ 149,612</b>	<b>\$ 148,516</b>

## Property and Equipment

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

	March 31, 2021	December 31, 2020
Leasehold improvements	\$ 25,880	\$ 25,880
Laboratory equipment and office furniture	23,585	23,638
Computer equipment	1,271	1,271
Construction in process	521	48
Total property and equipment, gross	51,257	50,837
Less: accumulated depreciation and amortization	(37,524)	(36,311)
Total property and equipment, net	\$ 13,733	\$ 14,526

Depreciation expense was \$1.6 million and \$1.7 million for the three months ended March 31, 2021 and 2020, respectively.

## Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	March 31, 2021	December 31, 2020
Clinical trials and research and development costs	\$ 9,758	\$ 9,316
Manufacturing costs	8,644	8,297
Personnel-related costs	5,962	8,921
Accrued expenses	5,399	3,411
Total accrued liabilities	\$ 29,763	\$ 29,945

## 5. Research Collaboration and License Agreements

### Merck

In 2015, the Company entered into a collaboration agreement with Merck, or the 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 the Company with input from Merck. In exchange for certain rights and access to the Company's drug discovery approach, in April 2015, Merck paid the Company an upfront cash licensing fee of \$94.0 million and purchased approximately \$106.0 million of the Company's Series E convertible preferred stock. The Company considered the ASC 606 criteria for combining contracts and determined that the Collaboration Agreement and stock purchase agreement should be combined into a single contract. The Company accounted for the combined agreement based on the fair values of the assets and services exchanged, resulting in \$106.0 million allocated to the equity component and \$94.0 million allocated to the revenue components.

The Collaboration Agreement contemplated an initial five-year research term, and Merck was granted the unilateral right to extend the research phase of the collaboration for two additional two-year terms. Each extension is considered to be and is accounted for as a separate arrangement, if and when the option is exercised by Merck. Under the current terms of the Collaboration Agreement, Merck is required to pay a \$20.0 million extension fee each time it elects to exercise its unilateral right to extend the research phase of the collaboration for an additional two-year term. In March 2019, Merck exercised its first option to extend the research phase of the collaboration for two additional years through March 16, 2022.

Under the current terms of the Collaboration Agreement, if and when Merck elects to extend the research phase for an additional two years, the level of funding that Merck will provide to the Company during such extension will be negotiated at the time of the extension, subject to certain minimum and maximum funding limits based on a percentage of the then-existing funding. As part of the two-year extension through March 16, 2022, Merck agreed to continue to fund the Company's research and development efforts up to \$75.0 million each year consistent with the

initial five-year term and, in lieu of a \$20.0 million extension fee that would have otherwise been payable to the Company, Merck agreed to make additional payments totaling up to \$20.0 million in support of the Company's research and development program activities during 2021 and in the first quarter of 2022.

Under the current terms of the Collaboration Agreement, Merck was required to notify the Company no later than March 17, 2021 of its unilateral decision whether to exercise its option to extend the research phase of the collaboration for an additional two-year term through March 16, 2024. In March 2021, Merck initiated discussions with the Company with respect to elements of the ongoing collaboration that might be optimized to better address the evolving interests and priorities of both the Company and Merck during the remainder of the current research phase through March 16, 2022 and during any extension of the current research phase and any tail period after the end of the research phase (which tail period is discussed below). In this regard, the parties continue to negotiate potential modifications to the terms of the collaboration. In order to allow negotiations to proceed, the parties agreed to extend the March 17, 2021 deadline for Merck to deliver its extension notification decision until June 30, 2021.

The Company has determined the scientific direction and areas of therapeutic interest, with input from Merck, and is primarily responsible for the conduct of all research, preclinical and early clinical development activities, through human proof-of-concept trials. The Company has made the final determinations as to which compounds to advance into and through initial clinical trials and which to progress into a human proof-of-concept trial and the design of any such trials, with input from Merck through various governance committees.

Under the current terms of the Collaboration Agreement, upon completion of a human proof-of-concept study for a particular product candidate, regardless of the results of such study, Merck has the one-time option to obtain an exclusive, worldwide license, on specified terms, to that product candidate, as well as to all other molecules that are directed against the same target and that result in the same effect on such target, collectively referred to as a Merck Licensed Program. For each program that Merck licenses, Merck must pay the Company a one-time fee of \$20.0 million. If Merck exercises its license option, Merck is responsible, at its own cost, for any further development and any commercialization activities for compounds within the applicable Merck Licensed Program, subject to the Company's options to cost and profit share worldwide, and to co-detail those compounds in the United States. Where the Company exercises such an option, the compound is referred to as an NGM Optioned Product. If the Company elects to enter into a cost and profit share on an NGM Optioned Product, Merck has agreed to advance to the Company and/or assume up to 25% of the Company's share of the global development costs, subject to an aggregate cap over the course of the collaboration. All amounts advanced or assumed accrue interest and would be recouped by Merck in full out of the Company's share of any profits resulting from sales of the NGM Optioned Product before the Company is entitled to receive any of those profits. If the Company does not elect to enter into a cost and profit-sharing arrangement for a compound it has licensed to Merck, the Company is eligible to receive an aggregate of up to \$449.0 million in pre-commercial milestone payments upon the achievement of specific clinical development and regulatory events with respect to the licensed compound for the first three indications in the United States, European Union, or EU, and Japan. The Company is also eligible to receive commercial milestone payments of up to \$125.0 million and to receive royalties at ascending low-double digit to mid-teen percentage rates, depending on the level of net sales Merck achieves worldwide for each licensed compound.

Under the current terms of the Collaboration Agreement, the Company also granted Merck a worldwide, exclusive right to conduct research and development on, and to manufacture, use and commercialize, small molecule compounds identified or developed by Merck that have specified activity against any target that the Company is researching or developing under the research phase of the collaboration and that, but for use of the Company's confidential and proprietary information, Merck would not have discovered. If Merck ultimately does not exercise its license option to a collaboration compound the Company has taken through a human proof-of-concept study that is directed to any such target, Merck's research license for its own small molecule program with respect to such target will become non-exclusive, but it will retain an exclusive license to any small molecule compounds that it has, as of that time, identified and developed. Merck has sole responsibility for research and development of any of these small molecule compounds, at its own cost. The Company is eligible to receive milestone and royalty payments on small molecule compounds that are developed by Merck under such a license from the Company, in some cases at the same rates as those the Company is eligible to receive from Merck for a Merck Licensed Program originating from the Company's own research and development efforts, provided that, but for use of the Company's confidential and proprietary information, Merck would not have discovered such small molecule compounds. However, the Company will not have the option to cost and profit share or the option to co-detail those small molecule products.

Under the current terms of the Collaboration Agreement, during the three-month period before the end of the research phase, Merck has the right to review the Company's then-existing programs and to elect to designate

one or more such programs for which the Company will be required to continue to conduct research and development for up to three years, referred to as the tail period. Merck will pay all of the Company's internal and external costs for its work on such Merck-designated programs, up to certain funding caps that decrease over the tail period and are each a specified percentage of certain funding actually provided to the Company by Merck during the last 12 months of the research phase. Merck also has the right to take over such Merck-designated programs and conduct such research and development activities itself or in partnership with a third party, at its own cost, or to terminate the tail period after a specified notice period. If Merck terminates the tail period, it has the right to elect to transition to itself or a third-party partner, at its own cost, any clinical trials that are then being conducted in such Merck-designated programs. If the Company completes a human proof-of-concept trial in one of such Merck-designated programs during the tail period or if Merck or its third-party partner completes a human proof-of-concept trial in one of such Merck-designated programs during or after the tail period, then Merck will have a one-time right to exercise its option to an exclusive, worldwide license for the collaboration product candidate tested in the proof-of-concept trial and certain related molecules in that program. Merck will lose its option rights at the end of the tail period with respect to all programs for which no collaboration product candidate has completed a human proof-of-concept trial by such time, except for Merck-designated programs that Merck is continuing to use commercially reasonable efforts to research and develop.

The Company evaluated the Collaboration Agreement with Merck under ASC 606. The Company identified the following promised goods or services at the inception of the Collaboration Agreement: (i) license to growth differentiation factor 15, or GDF15, agonist program; (ii) license to pursue research and development and commercialization of small molecule compounds; (iii) performance of research and development services for five years; (iv) two options to extend performance of the research and development services, each for two additional years; and (v) options to obtain licenses to additional compounds after proof-of-concept trials. The Company determined the GDF15 agonist program license and small molecule program license are not distinct from the research and development services, resulting in these items being combined into a single performance obligation.

The Company considered whether the options 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 options do not give rise to material rights, are not performance obligations in the Collaboration Agreement and, if and when exercised, will be accounted for as separate arrangements under ASC 606.

Additionally, if a separate arrangement is created by the exercise of an option, such amounts would then be contingent on events outside of either party's control, such as products proving to be commercially viable and governmental agencies granting regulatory approval. Such contingencies and uncertainties result in the amounts being constrained and withheld from inclusion in the estimated transaction price of a separate arrangement. Consequently, the estimated transaction price related to the Collaboration Agreement is comprised of the up-front payment and the ongoing research and development reimbursements.

Any fees associated with options, including upfront fees, funding fees and milestones, are not included in the transaction price as they are associated with options that are not material rights and, thus, are not performance obligations within the Collaboration Agreement. For example, in November 2018, Merck exercised its option for a license to further research and develop MK-3655, an agonistic antibody discovered by the Company that selectively activates fibroblast growth factor receptor 1c-beta-klotho, or FGFR1c/KLB, and other FGFR1c/KLB agonists and paid the Company \$20.0 million. The \$20.0 million license fee for MK-3655 was not included in the transaction price and was instead recognized in the period of exercise in the fourth quarter of 2018 as the Company had no further obligation related to that license. The Phase 3 clinical study for MK-3655 has not begun, and the Company has not made an election as to whether it will participate in the cost and profit share or receive milestone and royalty payments. The amounts do not impact the estimated transaction price associated with the single performance obligation identified in the Collaboration Agreement.

The transaction price associated with the initial five-year term of the Collaboration Agreement consisted of the \$94.0 million upfront fee and the funding amounts of up to \$75.0 million per year for each of the first five years of the Collaboration Agreement. No milestones or other forms of consideration were included in the transaction price as those amounts are contingent upon Merck exercising an option for licenses on additional compounds and would, therefore, be pursuant to separate arrangements and were not part of the Collaboration Agreement estimated transaction price. As there was only one performance obligation in the Collaboration Agreement, the transaction price was allocated entirely to that performance obligation.

At the end of the initial five-year term of the Collaboration Agreement, the remaining contract liability amount of \$4.9 million related to the upfront license fee included within the transaction price as of December 31, 2019 was fully earned and recognized during the three months ended March 31, 2020. The Company has fully recognized

revenue of approximately \$388.1 million related to the single performance obligation associated with the initial five-year term of the Collaboration Agreement.

Upon Merck exercising its option to extend the research phase of the collaboration through March 16, 2022, the Company deemed that a separate arrangement containing a distinct two-year performance obligation to provide distinct research and development services was created on March 17, 2020 in accordance with ASC 606. The transaction price of \$170.0 million for this two-year performance obligation consists of the potential funding amounts of up to \$75.0 million per year plus the additional funding amount of \$20.0 million to be made during 2021 and in the first quarter of 2022 if the Company exceeds the \$75.0 million funding cap. The Company also uses a cost-based input method to calculate the corresponding amount of revenue to recognize. In applying the cost-based input measure of revenue recognition, the Company measures actual costs incurred relative to budgeted costs to fulfill this distinct two-year performance obligation. These costs consist of full-time equivalent hours plus allowable external (third-party) costs incurred. Revenue is recognized based on actual costs incurred as a percentage of total budgeted costs as the Company completes its performance obligation applied to the transaction price. The Company re-evaluates the estimate of expected costs to satisfy the performance obligation each reporting period and makes adjustments for any significant changes. In addition, the Company also considers any necessary adjustments in an effort to ensure that the transaction price is within the range of potential funding amounts as described above. As such, management applies considerable judgment in estimating expected costs as such costs are key inputs when applying the cost-based input method. As the Company's estimated measure of progress is updated at each reporting period and revenue is recognized on a cumulative catch-up basis, a significant change in the estimate of expected costs for the remainder of the contract term could have a material impact on revenue recognized (including the possible reversal of previously recognized revenue) at each reporting period, as well as the related impact on contract assets and liabilities.

Since the transaction price includes an additional funding amount of \$20.0 million to be made during 2021 and in the first quarter of 2022, the timing of when the revenue is recognized for this additional funding amount for performance of the services and when this additional funding amount can be billed resulted in the recognition of a related party contract asset of \$4.6 million at March 31, 2021 and \$6.1 million at December 31, 2020.

In connection with Merck's purchase of approximately \$106.0 million of our Series E convertible preferred stock in 2015, the Company and Merck entered into an agreement whereby Merck agreed to purchase 4,121,683 shares of the Company's common stock in a separate private placement concurrent with the completion of the Company's IPO at a price per share equal to the public offering price of \$16.00, resulting in Merck owning approximately 19.9% of the Company's outstanding shares of common stock following the completion of the Company's initial public offering.

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

	<b>First Indication</b>	<b>Second Indication</b>	<b>Third Indication</b>
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

A breakout of the milestone payments in connection with the potential achievement of various regulatory events for each of the three indications, for each of the three geographic areas, is as follows (in thousands):

	<b>First Indication</b>	<b>Second Indication</b>	<b>Third Indication</b>	<b>Total</b>
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
	<u>\$ 165,000</u>	<u>\$ 123,750</u>	<u>\$ 82,500</u>	<u>\$ 371,250</u>

## Summary of Related Party Revenue

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

	Three Months Ended March 31,	
	2021	2020
Related party revenue	\$ 21,575	\$ 24,364

For the three months ended March 31, 2021, the Company recognized collaboration and license revenue under the Collaboration Agreement of \$21.6 million primarily related to reimbursable research and development activities associated with the performance obligation for the two-year extension period. For the three months ended March 31, 2020, the Company recognized collaboration and license revenue under the Collaboration Agreement of \$24.4 million of which \$4.9 million related to the upfront license fee under the initial five-year term that ended in March 2020.

## 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, 2021 and December 31, 2020, the Company recorded related party contract assets of \$4.6 million and \$6.1 million, respectively. 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, 2021 and December 31, 2020, there were no contract liabilities.

## 6. Commitments and Contingencies

### Operating Lease and Lease Guarantee

In December 2015, the Company entered into an operating lease for its corporate office space and laboratory facility at 333 Oyster Point Blvd, South San Francisco, California for approximately 122,000 square feet that expires in December 2023. The lease 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. The Company has the right to reduce the letter of credit amount by \$0.4 million on each of the third anniversary and fourth anniversary of the rent commencement date. In 2020, the Company reduced its letter of credit by \$0.4 million and reclassified that amount from restricted cash to cash and cash equivalents on the condensed consolidated balance sheets.

In September 2009, the Company entered into an operating lease for a corporate office space and laboratory facility at 630 Gateway Blvd, in South San Francisco, California for approximately 50,000 square feet, as amended in June 2014. In July 2016, the Company assigned the operating lease of 630 Gateway to Merck, as part of the Company's relocation to 333 Oyster Point. The operating lease expired in November 2020. Following expiration of the operating lease, the Company retains the obligation to indemnify the landlord and Merck under certain limited circumstances, but has no further payment obligations.

The Company recognizes rent expense on a straight-line basis over the lease period with the difference recorded as deferred rent. In addition, tenant improvement allowances recorded are amortized as a reduction to rent expense on a straight-line basis over the lease term. Rent expense under these facility operating leases was approximately \$0.5 million for each of the three months ended March 31, 2021 and 2020.

Future minimum payments under the unassigned lease obligations described above are as follows as of March 31, 2021 (in thousands):

<b>Year Ending December 31,</b>	
2021	\$ 3,874
2022	5,294
2023	5,455
Total	<u>\$ 14,623</u>

### ***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 fix the number, rights, preferences, privileges and restrictions for such series. 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, 2021, the Company did not have any shares of preferred stock issued or outstanding.

### ***Common Stock***

#### ***Public Offering of Common Stock***

In January 2021, the Company sold 5,324,074 shares of its common stock through an underwritten public offering at a price to the public of \$27.00 per share for aggregate net proceeds to the Company of \$134.6 million, after deducting underwriting discounts and commissions and other offering expenses paid by the Company. The offering closed on January 8, 2021.

As of March 31, 2021 and December 31, 2020, the Company had 76,913,578 and 70,585,364 shares of common stock outstanding, respectively, which included shares subject to repurchase of 938 and 6,508, respectively, as a result of early exercise of stock options not yet vested.

As of March 31, 2021 and December 31, 2020, the Company reserved shares of common stock for issuance as follows:

	March 31, 2021	December 31, 2020
Reserve balance for Sales Agreement	14,190,300	14,190,300
Common stock options outstanding	11,300,905	10,017,918
Common stock options available for grant	6,726,717	6,186,497
ESPP shares available for purchase	700,074	700,074
401(k) Matching Plan	21,930	21,930
Total	<u>32,939,926</u>	<u>31,116,719</u>

### ***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, 2021, \$127.4 million of the Company's common stock remained available to be sold under the Sales Agreement, subject to conditions specified in the Sales Agreement.

### ***Stock Option 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 will be reclassified into 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		Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In Thousands)
	Number of Options	Weighted Average Exercise Price		
Balances at December 31, 2020	10,017,918	\$ 10.52	6.45	\$ 198,097
Options granted	2,341,750	31.50		
Options exercised	(1,000,588)	5.90		
Options cancelled	(58,175)	14.79		
Balances at March 31, 2021	11,300,905	\$ 15.25	7.33	\$ 162,188
Vested and expected to vest at March 31, 2021	11,044,810	\$ 15.05	7.28	\$ 160,638
Exercisable at March 31, 2021	9,232,405	\$ 11.54	6.76	\$ 162,108

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest 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, 2021 and 2020 was \$19.83 and \$9.73 per share, respectively. The intrinsic value of stock options exercised was \$22.3 million and \$12.8 million for the three months ended March 31, 2021 and 2020, 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, 2021 and 2020.

## Employee Stock-Based Compensation Expense

Employee and director stock-based compensation expense for the three months ended March 31, 2021 and 2020 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures. The following table summarizes stock-based compensation expense related to stock-based payment awards previously granted to employees and directors and the Company's ESPP for the three months ended March 31, 2021 and 2020, which was allocated as follows (in thousands):

	Three Months Ended March 31,	
	2021	2020
Research and development	\$ 3,504	\$ 1,873
General and administrative	3,011	1,794
Total stock-based compensation expense	\$ 6,515	\$ 3,667

Stock-based compensation expense related to stock-based payment awards to non-employees for the three months ended March 31, 2021 and 2020 was \$67,000 and \$28,000, respectively.

## 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, 2021, 299,926 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, 2021. 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, 2021 and 2020.

## 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 the condensed consolidated financial statements and notes to the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. 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," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "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 therapeutics based on scientific understanding of key biological pathways underlying liver and metabolic diseases, retinal diseases and cancer. These diseases represent a significant burden for patients and healthcare systems and, in some cases, are leading causes of morbidity and mortality. Our strategy is to leverage a combination of interrogating human biology and engineering powerful biologics to discover and develop promising product candidates and seek to move them rapidly into proof-of-concept studies and late-stage development, with the goal of delivering impactful first-in-class or best-in-class treatments to underserved patients suffering from grievous diseases. Since the commencement of our operations in 2008, we have generated a robust portfolio of product candidates ranging from early discovery to late-stage development. We aspire to operate one of the most productive research and development engines in the biopharmaceutical industry.

### Pipeline Programs and Operations Updates

Our discovery engine supports our ability to advance multiple product candidates across our three key therapeutic areas. We currently have five ongoing Phase 2 and Phase 2b programs. In 2021 to date, we have continued to progress the development of our leading product candidates as described below:

- **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 and is in Phase 2b development for the treatment of patients with non-alcoholic steatohepatitis, or NASH, with liver fibrosis stage 2, 3 or 4, or F2, F3 or F4. To date in 2021, we:
  - completed treatment of patients in our Phase 2b ALPINE 2/3 clinical trial of aldafermin in patients with NASH with F2 and F3 liver fibrosis and
  - continued enrollment in our Phase 2b ALPINE 4 clinical trial of aldafermin in patients with NASH with F4 liver fibrosis and compensated cirrhosis, with a goal of enrolling approximately 160 patients across 70 sites in the United States, Europe, Hong Kong and Australia.
  - **Looking forward:** We expect to report topline results from the ALPINE 2/3 trial in the second quarter of 2021. We are leveraging the results of our completed clinical trials of aldafermin, as well as guidance from the U.S. Food and Drug Administration, or FDA, to support our design of a pivotal clinical trial program to enable a potential biologics license application, or BLA, submission.

- **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 is in Phase 2b development for the treatment of NASH and was optioned by Merck Sharp & Dohme Corp., or Merck, under our collaboration with Merck described below. To date in 2021, Merck:
  - continued the worldwide 52-week randomized, double-blind Phase 2b trial of MK-3655 in patients with NASH with F2 or F3 liver fibrosis that it initiated in the fourth quarter of 2020.
- **Retinal diseases.**
  - **NGM621.** NGM621 is a humanized Immunoglobulin 1, or IgG1, monoclonal antibody administered via intravitreal, or IVT, injection. NGM621 was engineered to potently inhibit the activity of complement C3 with the treatment goal of reducing disease progression in patients with geographic atrophy, or GA. Merck has a one-time option to license NGM621 upon completion of a proof-of-concept study in humans. To date in 2021, we:
    - continued enrollment in the Phase 2 CATALINA clinical trial of NGM621 in patients with GA to evaluate NGM621's effects on disease progression when given every four weeks or every eight weeks. The CATALINA trial was designed to be a Phase 3-supportive or -enabling clinical trial.
    - **Looking forward:** Subject to any future impact of the COVID-19 pandemic on enrollment, we expect to complete enrollment in the CATALINA trial in mid-2021.
- **Oncology.**
  - **NGM120.** NGM120 is an antagonistic antibody that binds glial cell-derived neurotrophic factor receptor alpha-like, or GFRAL, and inhibits growth differentiation factor 15, or GDF15, signaling, for the potential treatment of cancer and cancer-related cachexia. We are currently conducting clinical trials to assess NGM120's effect on cancer-related cachexia and on cancer in patients with select advanced solid tumors and metastatic pancreatic cancer. Merck has a one-time option to license NGM120 upon completion of a proof-of-concept study in humans. To date in 2021, we:
    - initiated a Phase 2 placebo-controlled component of the ongoing Phase 1/2 clinical trial of NGM120 described below. This portion of the trial is testing NGM120 in combination with gemcitabine and Abraxane® (paclitaxel protein bound) as first-line treatment in patients with metastatic pancreatic cancer to assess NGM120's effect on both cancer and cancer-related cachexia.
    - **Looking forward:** In the second half of 2021, we expect to report interim data from two Phase 1 dose-finding cohorts of the ongoing Phase 1/2 trial of NGM120: 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 Abraxane in patients with metastatic pancreatic cancer.
  - **NGM707.** NGM707 is a dual antagonist monoclonal antibody that inhibits Immunoglobulin-like transcript 2, or ILT2 (also known as LILRB1), and Immunoglobulin-like transcript 4, or ILT4 (also known as LILRB2). ILT2 and ILT4 are key myeloid and lymphoid checkpoints that may restrict anti-tumor immunity, enable tumors to evade immune detection and contribute to T-cell checkpoint resistance. Merck has a one-time option to license NGM707 upon completion of a proof-of-concept study in humans.
    - **Looking forward:** We expect to commence a first-in-human Phase 1 clinical trial of NGM707 in patients with advanced solid tumors in mid-2021.
  - **NGM438.** NGM438 is an antagonistic antibody that is designed to inhibit leukocyte-associated immunoglobulin-like receptor 1, or LAIR1, and promote immune detection and activation against advanced solid tumors. Merck has a one-time option to license NGM438 upon completion of a proof-of-concept study in humans. In 2021, we:
    - advanced the preparation of an investigational new drug, or IND, application for a planned submission in the second half of 2021.

- **Looking forward:** We expect to commence a first-in-human Phase 1 clinical trial of NGM438 in patients with advanced solid tumors in the fourth quarter of 2021.

We have additional undisclosed 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, 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.

Partnering has been and is expected to continue to be a key component of our strategy as we plan to continue to develop a broad portfolio of product candidates and, if approved, to commercialize the resulting products. Our existing research collaboration, product development and license agreement with Merck, or the Collaboration Agreement, which we entered into in 2015, has to date provided us with substantial financial support from Merck. The collaboration has also afforded us substantial freedom to pursue development efforts for our collaboration programs and product candidates. We are currently in discussions with Merck with respect to modifying certain terms of the collaboration, as described in more detail below. In addition, for any programs wholly-owned by us and not subject to the Merck collaboration, such as aldafermin, we may decide to pursue a strategic partner to progress, in whole or in part, the program or commercialize any resulting approved product.

In addition, 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, who 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 resources are focused, and will continue to be focused, on activities required to prepare aldafermin for potential regulatory approval for the treatment of NASH, including manufacturing of clinical trial materials and preparation for potential Phase 3 testing. If our CROs fail to satisfy their contractual duties to us or meet expected deadlines or if our CMOs experience difficulties in scaling production or procuring raw materials or components or experience 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, our ongoing and planned aldafermin trials would be delayed, perhaps substantially, which could materially and adversely affect our business.

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 the suspension of development activities on multiple viable product candidates for portfolio management reasons in order to concentrate our resources on what we consider our most promising product candidates. For example, in 2020, we suspended development activities related to multiple metabolic disease product candidates in order to concentrate our resources on aldafermin and certain other product candidates subject to our Merck collaboration.

#### **Status of Merck Collaboration**

The original research phase of our existing research collaboration, product development and license agreement with Merck, or the Collaboration Agreement, was for five years. In March 2019, Merck exercised its option to extend the research phase of the collaboration through March 16, 2022. Under the terms of the collaboration, Merck was required to notify us no later than March 17, 2021 of its unilateral decision whether to exercise its option to extend the research phase of the collaboration for an additional two-year term through March 16, 2024. In March 2021, Merck initiated discussions with us with respect to elements of the ongoing collaboration that might be optimized to better address the evolving interests and priorities of both NGM and Merck during the remainder of the current research phase through March 16, 2022 and during any extension of the current research phase and any tail period after the end of the research phase. In this regard, the parties continue to negotiate potential modifications to the terms of the collaboration. Such modifications may include, among other things, focusing NGM's research and development under the collaboration on therapeutic areas of particular interest to Merck, while enabling NGM to conduct research and development outside of these therapeutic areas, which would, if mutually agreed to, allow NGM to discover and develop product candidates on its own or with third parties in other areas of interest. In order to allow negotiations to proceed, the parties agreed to extend the March 17, 2021 deadline for Merck to deliver its extension notification decision until June 30, 2021. While we do not know whether or when Merck will elect to extend the research phase of the collaboration or on what terms, or whether or when we will reach agreement with Merck on the terms of a modified collaboration, we expect that any modified collaboration would result in a level of annual research support from Merck during any extension of the current research phase

after March 16, 2022 that is meaningfully lower than the annual research support Merck provided during the initial five-year term and is providing during the current two-year extension of the research phase. In this regard, we expect that under the terms of a modified collaboration, Merck will not provide research funding for certain of our product candidates. We also expect that if we are unable to reach agreement with Merck on modified terms, Merck will not elect to extend the research phase of the collaboration and will decide not to proceed with certain of our product candidates after the end of the research phase. In any event, we expect that following March 16, 2022, the end of the current two-year extension of the research phase, funding from Merck will substantially decrease and our funding for the development of our current and potential future product candidates will substantially increase regardless of whether we are able to reach agreement with Merck on modified terms.

### **Financial Highlights**

Since inception, we have funded our operations primarily through:

- fees received from collaboration partners, which since inception through March 31, 2021 includes reimbursement of research and development expenses of \$423.7 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 \$21.9 million from sales of 809,700 shares of our common stock at an average price of \$27.94 per share in December 2020 under an Open Market Sale Agreement<sup>SM</sup>, 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, 2021, we had \$412.7 million in cash, cash equivalents and short-term marketable securities.

We have incurred net losses each year since our inception. As of March 31, 2021, we had an accumulated deficit of \$326.2 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development, or R&D, programs and general and administrative 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 collaboration partners, including Merck. For further discussion of our financial position and future sources of funding, see "Liquidity and Capital Resources" below.

### **COVID-19 Business Update**

We continue 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, study investigators, clinical research staff and employees, while maintaining business continuity. Following guidance from federal, state and local authorities, we continue to operate with a substantially remote work model. Employees working on site continue to be primarily those individuals conducting essential in-person laboratory work and other business functions considered essential under COVID-19 regulations and guidance, and we are still encouraging all other individuals to work remotely where feasible. There have been relatively minor impacts on productivity overall, but future developments could more materially and adversely impact our productivity. In addition, in 2020 and early 2021, we experienced higher-than-normal employee turnover and an increased rate of hiring new employees. We cannot predict whether these trends will continue or be exacerbated, when we will be permitted to, and whether we will, return to a fully office-based working model or whether we will be required to adopt a more restrictive work model as the implications of the pandemic evolve.

For patients enrolled in our clinical trials, we continue to work closely with clinical trial investigators and site staff with the goal of continuing treatment in a manner designed to uphold trial integrity, while allowing some flexibility in the manner and timing of patient visits, and to observe government and institutional guidelines designed to safeguard the health and safety of patients, clinical trial investigators and site staff. We have experienced, from time to time, a slower pace of clinical trial site initiation and clinical trial enrollment than originally anticipated in certain of our clinical trials, including the ALPINE 4, CATALINA and NGM120 trials, and we experienced a higher dropout rate in our ALPINE 2/3 trial than we had anticipated based on our previous trials in patients with NASH. We

believe this may be due to factors such as the vulnerability of our studied patient populations, clinical trial site suspensions, reallocation of medical resources and the challenges of working remotely due to shelter-in-place and similar government orders.

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. For example, we have implemented additional 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, remote monitoring of patients and clinical trial sites and other measures, as appropriate, designed to ensure that data from clinical trials that may be disrupted as result of the pandemic are collected pursuant to the study protocol and consistent with current Good Clinical Practices, with any material protocol deviation reviewed and approved by the clinical trial site Institutional Review Board. Most of our clinical trial sites, both within and outside of the United States, continue to screen patients in our clinical trials, and new patients are being enrolled when appropriate. While the COVID-19 pandemic has not yet resulted in a significant impact to our disclosed clinical development timelines and we believe the higher-than-planned enrollment we achieved in our ALPINE 2/3 trial has mitigated the effects of the increased dropout rate, as the pandemic continues, there may be continuing negative impacts on our ability to initiate new clinical trial sites, maintain enrollment of existing patients and enroll new patients, which may result in increased clinical trial costs and negatively impact our timelines and our ability to obtain regulatory approvals of our product candidates in a timely fashion, if at all.

We also could see an adverse impact on our ability to report clinical trial results, or interact with regulators, institutional review boards 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.

In addition, while we have not experienced any disruption to drug or related component supply for our ongoing clinical trials, we could experience disruptions to our supply chain and operations due to the continuing pandemic, and associated delays in the manufacturing and supply of drug substance and drug product for our clinical trials, which could adversely affect our ability to conduct ongoing and future clinical trials of our product candidates. For example, our aldafermin drug product CMO has 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 become subject to acts or orders of U.S. or foreign government entities to allocate manufacturing capacity to the manufacture or distribution of COVID-19 vaccines or medical supplies needed to treat COVID-19 patients, this could also delay our clinical trials, perhaps substantially, particularly our ongoing and planned aldafermin trials, which could materially and adversely affect our business.

Finally, we 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 Collaboration Agreement, to exercise its remaining option to extend the research phase of the collaboration beyond March 16, 2022 or to reach agreement with us on the terms of a modified collaboration, if any. 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 Agreement with Merck. Merck is also a significant stockholder and, as such, collaboration revenue from Merck is referred to as related party revenue.

### *Merck Collaboration*

In 2015, we entered into the Collaboration Agreement with Merck, 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. Merck generally has a one-time right to exercise its option to an exclusive, worldwide license for any collaboration product candidate and related program when a human proof-of-concept trial is completed. In 2018, Merck exercised its option to license MK-3655, which is a potential treatment for NASH. Under the current terms of the Collaboration Agreement, for a program that Merck licenses, we retain an option, when a product candidate has advanced to Phase 3 clinical trials, to participate in up to 50% of the economic return from that product candidate if

it becomes an approved medicine by agreeing to share up to 50% of the costs of future development. If we do not elect this option, we will instead receive milestone and royalty payments and we will not be required to share in development costs.

The aldafermin program is not included in the Collaboration Agreement and it remains wholly-owned and controlled by us.

For a more detailed description of the current terms of the Collaboration Agreement and the status of the collaboration, see “Our Collaboration with Merck” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020 and “Overview of Our Business — Status of Merck Collaboration” above. Since inception through March 31, 2021, Merck had paid us \$518.5 million under the Collaboration Agreement. Due to the nature of our agreement 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.

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 for the remainder of the current two-year extension period 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,	
	2021	2020
Related party revenue	\$ 21,575	\$ 24,364

### **Research and Development Expenses**

R&D efforts include drug discovery 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 expenses related to the development of aldafermin, MK-3655, NGM621, NGM120, NGM707 and NGM438 (and prior to suspending these programs, NGM386, NGM395 and NGM217) 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, including continued testing, such as process validation and stability, 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.

Our clinical development efforts are spread across multiple programs, most of which are subject to the Merck collaboration. For the foreseeable future, we anticipate the majority of our financial resources, other than those received from Merck and dedicated to Merck collaboration activities, will be dedicated to activities required to prepare aldafermin for potential regulatory approval for the treatment of NASH, including manufacturing of clinical trial materials and preparation for a potential pivotal program.

In the future, we may devote financial resources to other programs in the event Merck does not elect to license these programs upon completion of a proof-of-concept study, in the event Merck elects to terminate its license to any program it licenses or in the event we opt to co-develop any Merck-licensed programs, or if Merck no longer funds such programs under modified terms of the collaboration.

Our R&D efforts under the Merck collaboration are extensive and costly and are currently subject to reimbursement under our Merck collaboration during the current two-year extension up to the funding caps provided in our Collaboration Agreement. If our R&D expenses for product candidates subject to the Merck collaboration, including the clinical development of product candidates subject to the Merck collaboration through completion of proof-of-concept studies, exceed the funding caps provided in the Collaboration Agreement, which happened in the fiscal year ended December 31, 2020 and could happen in the future, we will be required to devote our own financial resources toward the development of such product candidates or, if we are unwilling or unable to do so, pause or suspend such development to remain within the funding caps. In addition, while we do not know whether or when Merck will elect to extend the research phase of the collaboration through March 16, 2024 or on what terms, or whether or when we will reach agreement with Merck on the terms of a modified collaboration, we expect that any modified collaboration would result in a level of annual research support from Merck during any extension of the current research phase after March 16, 2022 that is meaningfully lower than the annual research support Merck provided during the initial five-year term and is providing during the current two-year extension of the research phase. In this regard, we expect that under the terms of a modified collaboration, Merck will not provide research funding for certain of our product candidates. We also expect that if we are unable to reach agreement with Merck on modified terms, Merck will not elect to extend the research phase of the collaboration and will decide not to proceed with certain of our product candidates after the end of the current research phase. In any event, we expect that following March 16, 2022, the end of the current two-year extension of the research phase, funding from Merck will substantially decrease and our funding for the development of our current and potential future product candidates will substantially increase, regardless of whether we are able to reach agreement with Merck on modified terms.

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;
- 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 and the timing of such election or termination;
- whether we exceed the current or any future funding caps provided in our Collaboration Agreement and whether Merck decides not to proceed with certain of our product candidates after the end of the research phase;
- 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.

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 and timing associated with the development of that product candidate. For example, if the FDA or another 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 Merck and Other Third Parties” and “—Risks Related to Regulatory Approvals” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

## General and Administrative Expenses

General and administrative 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 general and administrative expenses will increase in the future to support our continued 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 SOX 404 compliance. In addition, we may incur expenses associated 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,		Change
	2021	2020	
Related party revenue	\$ 21,575	\$ 24,364	\$ (2,789)
Operating expenses:			
Research and development	40,699	38,439	2,260
General and administrative	8,721	6,595	2,126
Total operating expenses	49,420	45,034	4,386
Loss from operations	(27,845)	(20,670)	(7,175)
Interest income	114	1,175	(1,061)
Other income, net	187	380	(193)
Net loss	\$ (27,544)	\$ (19,115)	\$ (8,429)

### *Related Party Revenue from Merck*

Revenue decreased \$2.8 million in the three months ended March 31, 2021 compared to the same period in 2020 primarily due to a decrease in the recognition of a portion of the initial upfront payment received from Merck in 2015 that was included within the transaction price and fully recognized over the initial five-year term of our Collaboration Agreement using the cost-based input model. The initial five-year term ended in the first quarter of 2020.

## Research and Development Expenses

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

	Three Months Ended March 31,	
	2021	2020
External R&D expenses:		
Aldafermin (FGF19 analog)	\$ 9,598	\$ 14,151
NGM621 (C3 inhibitor)	3,686	1,298
NGM120 (GFRAL antagonist)	1,361	1,365
NGM707 (Anti-ILT2/ILT4 dual antagonist)	1,165	760
NGM438 (LAIR1 antagonist)	1,515	42
NGM395 (GDF15 analog)	235	476
MK-3655 (FGFR1c/KLB agonist)	35	129
Other external R&D expenses	708	1,935
Total external R&D expenses	18,303	20,156
Personnel-related expenses	14,269	10,818
Internal and unallocated R&D expenses(1)	8,127	7,465
Total R&D expenses	\$ 40,699	\$ 38,439

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

R&D expenses increased \$2.3 million in the three months ended March 31, 2021 compared to the same period in 2020 primarily due to a \$3.5 million increase in personnel-related expenses and an increase in external expenses driven by our ongoing clinical and preclinical studies of NGM621, NGM438 and NGM707. These increases were partially offset by decreases of \$4.6 million in expenses for our manufacturing activities and our ongoing clinical trials of aldafermin and \$1.2 million in external expenses related to our other development programs.

We expect R&D expenses for the remainder of 2021 to increase compared to 2020 due to our ongoing activities, particularly as we advance our clinical development of aldafermin. In addition, 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 and Administrative Expenses

General and administrative expenses increased \$2.1 million in the three months ended March 31, 2021 compared to the same period in 2020 primarily due to an increase in personnel-related expenses due to increased headcount and an increase in stock-based compensation expense primarily related to the increase in our stock price.

We anticipate general and administrative expenses for the remainder of 2021 to increase compared to 2020 due to an increase in compensation-related expenses driven by higher headcount and other expenses related to the expansion and support of our business including expenses related to SOX 404 compliance.

## Interest Income

Interest income decreased \$1.1 million in the three months ended March 31, 2021 compared to the same period in 2020 primarily due to the decrease in market interest rates.

## Liquidity and Capital Resources

### Funding Requirements

We have incurred net losses every year since our inception. We have spent, and expect to continue to spend, significant resources to fund R&D of, and seek regulatory approvals for, our product candidates, particularly aldafermin. These activities require us to incur substantial costs related to research, development, manufacturing,

preclinical studies, clinical trial and related activities, as well as to cover other expenses related to our ongoing operations. For example, we will require substantial additional capital to achieve our development and commercialization goals for our aldafermin program that is being conducted outside of the Merck collaboration or for any other programs in the event Merck does not elect to license these programs upon completion of a proof-of-concept study, in the event Merck elects to terminate its license to any program it licenses or in the event we opt to co-develop any Merck-licensed programs, or if Merck no longer funds such programs under modified terms of the collaboration. In addition, while we do not know whether or when Merck will elect to extend the research phase of the collaboration through March 16, 2024 or on what terms, or whether or when we will reach agreement with Merck on the terms of a modified collaboration, we expect that any modified collaboration would result in a level of annual research support from Merck during any extension of the current research phase after March 16, 2022 that is meaningfully lower than the annual research support Merck provided during the initial five-year term and is providing during the current two-year extension of the research phase. See "Overview of Our Business – Status of Merck Collaboration" above. As a result, we expect to incur significant and increasing operating losses. 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. As of March 31, 2021, we had an accumulated deficit of \$326.2 million and we expect our accumulated deficit will increase significantly over time. The size of our future net losses will depend, in part, on the rate of future growth of our expenses, how much revenue, if any, continues to be generated under the Merck collaboration and our ability to generate revenue outside of the Merck collaboration.

In addition, if our R&D expenses for product candidates subject to the Merck collaboration exceed the funding caps provided in our current Collaboration Agreement, which happened in the fiscal year ended December 31, 2020 and could happen in the future, or if Merck no longer funds such programs under modified terms of the collaboration, we will be required to devote our own financial resources toward the development of such product candidates or, if we are unwilling or unable to do so, pause or suspend such development to remain within the funding caps or to proceed with development of unfunded programs.

## **Sources of Liquidity**

### ***Merck Collaboration***

The revenue we receive under our Collaboration Agreement with Merck is our only source of revenue. The original research phase of the Collaboration Agreement was for five years. As described in greater detail in "Overview of Our Business – Status of Merck Collaboration" above, the parties continue to negotiate potential modifications to the terms of the collaboration. While we do not know whether or when Merck will elect to extend the research phase of the collaboration or on what terms, or whether or when we will reach agreement with Merck on the terms of a modified collaboration, we expect that any modified collaboration would result in a level of annual research support from Merck during any extension of the current research phase after March 16, 2022 that is meaningfully lower than the annual research support Merck provided during the initial five-year term and is providing during the current two-year extension of the research phase. In this regard, we expect that under the terms of a modified collaboration, Merck will not provide research funding for certain of our product candidates. We also expect that if we are unable to reach agreement with Merck on modified terms, Merck will not elect to extend the research phase of the collaboration and will decide not to proceed with certain of our product candidates after the end of the research phase. In any event, we expect that following March 16, 2022, the end of the current two-year extension of the research phase, funding from Merck will substantially decrease and our funding with respect to the development of our current and potential future product candidates will substantially increase, regardless of whether we are able to reach agreement with Merck on modified terms. Accordingly, we will require significant additional capital in order to proceed with development and commercialization of our current and potential future product candidates, including any product candidate that had been subject to the Merck collaboration but Merck decides not to proceed with under the terms of a modified collaboration or after the end of the research phase, or we will need to enter into additional collaboration or license agreements in order to fund such development and commercialization. Neither may be possible and as a result, we may be required to delay, scale back or discontinue development of such product candidates.

### ***Other Sources of Liquidity***

In June 2020, we entered into the Sales Agreement with Jefferies relating to the sale of shares of our common stock. 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, 2021, \$127.4 million of our common stock remained available to be sold under the Sales Agreement, subject to conditions specified in the Sales Agreement.

In January 2021, we sold 5,324,074 shares of common stock (inclusive of shares sold pursuant to the full exercise of the option to purchase additional shares granted to the underwriters in connection with the offering) through an underwritten public offering at a price to the public of \$27.00 per share for aggregate net proceeds to the Company of \$134.6 million, or the follow-on offering.

As of March 31, 2021, we had cash and cash equivalents of \$148.1 million, short-term marketable securities of \$264.5 million, working capital of \$385.5 million and an accumulated deficit of \$326.2 million.

We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to fund our operations for at least the next twelve months. 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 under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q.

We plan to finance our future cash needs through public or private equity or debt offerings, including under the Sales Agreement, government or other third-party funding, product collaborations, strategic alliances, licensing arrangements or a combination of these. Additional capital may not be available in sufficient amounts, on reasonable terms or when we need it, if at all, and our ability to raise additional capital 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 resulting from, among other things, the evolving effects of the COVID-19 pandemic. 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. If we are unable to raise adequate additional capital, we may be prevented from pursuing 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 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Net cash provided by (used in):		
Operating activities	(22,225)	(19,110)
Investing activities	(117,156)	26,873
Financing activities	140,477	3,591
Net increase in cash and cash equivalents	\$ 1,096	\$ 11,354

### Cash Used in Operating Activities

During 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.

During the three months ended March 31, 2020, cash used in operating activities was \$19.1 million, which consisted of a net loss of \$19.1 million, adjusted for non-cash charges of \$5.4 million and cash used through changes in operating assets and liabilities of \$5.4 million. The non-cash charges consisted primarily of stock-based compensation expense of \$3.7 million and depreciation expense of \$1.7 million. The change in operating assets and liabilities was mainly driven by an increase in prepaid expenses and other assets of \$2.0 million and an

increase in accrued expenses of \$3.0 million. These increases were partially offset by a decrease in related party receivable from our Merck collaboration of \$4.5 million, a decrease in accounts payable of \$5.3 million, a decrease in deferred rent of \$0.7 million and a decrease in deferred revenue of \$4.9 million primarily attributable to the timing of advance payments from Merck related to the reimbursement of costs associated with R&D activities.

### ***Cash Provided by (Used in) Investing Activities***

During the three months ended March 31, 2021, cash used in investing activities was \$117.2 million, which consisted 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. During the three months ended March 31, 2020, cash provided by investing activities was \$26.9 million, which consisted of \$56.8 million in net proceeds on maturity of marketable securities, partially offset by purchases of marketable securities of \$29.4 million and purchases of property and equipment of \$0.5 million.

### ***Cash Provided by Financing Activities***

During the three months ended March 31, 2021 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. During the three months ended March 31, 2020, cash provided by financing activities was \$3.6 million and consisted of proceeds from employee equity incentive plans.

### **Off-Balance Sheet Arrangements**

We currently have not entered into and do not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

### **Contractual Obligations**

During the three months ended March 31, 2021, there were no material changes to our contractual obligations as set forth in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2020.

### **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. 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. 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 Annual Report on Form 10-K for the year ended December 31, 2020.

### **Newly Issued Accounting Pronouncements**

Except as described in Note 2 to the condensed consolidated financial statements under the headings "Recently Adopted Accounting Pronouncements" and "Recent Accounting Pronouncements Not Yet Adopted," there have been no new accounting pronouncements or changes to accounting pronouncements during the three months ended March 31, 2021, as compared to the recent accounting pronouncements described in our audited consolidated financial statements and notes for the year ended December 31, 2020, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, 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, 2021, 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 Annual Report on Form 10-K for the year ended December 31, 2020.

### **Item 4. Controls and Procedures.**

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

As of March 31, 2021, 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, 2021, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

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

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(f) and 15d-15(f) of the Exchange Act that occurred during the quarter ended March 31, 2021 that has materially affected, or is 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.

*Our business involves significant risks, some of which are described below. You should carefully consider the following risks, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. 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.*

#### 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 under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. 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 under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q as part of your evaluation of an investment in our common stock:

- our most advanced product candidate, aldafermin, an engineered analog of human hormone fibroblast growth factor 19, or FGF19, that is administered through a once-daily subcutaneous injection, is still only in Phase 2 development, may fail to demonstrate safety and efficacy in ongoing and future clinical trials, including ALPINE 2/3, our Phase 2b clinical trial of aldafermin in patients with non-alcoholic steatohepatitis, or NASH, with liver fibrosis stage 2 or 3, or F2 or F3, and ALPINE 4, our Phase 2b clinical trial of aldafermin in patients with NASH with F4 liver fibrosis and compensated cirrhosis, 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 our ongoing Phase 2 CATALINA trial of NGM621, a humanized Immunoglobulin 1 monoclonal antibody inhibiting complement C3 administered via intravitreal, or IVT, injection in patients with geographic atrophy, or GA, may fail to produce positive results or to demonstrate safety and efficacy to the satisfaction of health authorities;
- aldafermin and MK-3655, 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, are being developed for the treatment of 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;
- 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;
- we do not know whether Merck Sharp & Dohme Corp., or Merck, will elect to extend the research phase of our collaboration and the level of research funding support we may obtain during any such extension or whether we may otherwise be able to reach agreement with Merck on the terms of a modified collaboration, and regardless of whether we and Merck reach agreement on the terms of a modified collaboration, our collaboration with Merck involves numerous risks, any of which could materially and adversely affect our business and financial condition;
- we currently depend on our collaboration with Merck, and in the future may depend on collaborations with additional third parties, for the development and commercialization of our product candidates;
- we will require additional capital to finance our operations, which may not be available to us on acceptable terms, or at all, and as a result, we may not have the resources to complete the development and commercialization of our current and potential future product candidates;

- we will need to successfully complete rigorous preclinical and clinical testing of our product candidates before we can seek regulatory approval, which could delay or prevent commercialization of our product candidates;
- we may not successfully identify new product candidates to expand our development pipeline;
- the process of manufacturing aldafermin and our other biologic product candidates is complex, highly regulated and subject to many manufacturing risks, including difficulties in supply chain, including procuring raw materials and components and in production, particularly in scaling up and validating initial production and ensuring the avoidance of contamination, 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 regulatory approval processes of the U.S. Food and Drug Administration, or FDA, and comparable foreign health authorities are lengthy, time-consuming and inherently unpredictable;
- 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 Dr. Jin-Long Chen;
- the COVID-19 pandemic continues to adversely impact our business and could materially and adversely affect our operations, as well as the businesses or operations of our manufacturers, clinical research organizations or other third parties with whom we conduct business;
- 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;
- 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 may not be able to obtain and maintain the relationships with third parties that are necessary to develop, manufacture and commercialize some or all of our product candidates;
- we or third parties we rely on could experience a cybersecurity incident that could harm our business; and
- 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.

#### **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, and we expect to continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each year since commencing operations. Our net losses were \$102.5 million, \$42.8 million and \$0.5 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of March 31, 2021, we had an accumulated deficit of \$326.2 million.

We have spent, and expect to continue to spend, significant resources to fund research and development of, and seek regulatory approvals for, our product candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, manufacturing, preclinical studies, clinical trial and related activities increase. We also expect that following March 16, 2022, the end of the current two-year extension of the research phase, funding from Merck will substantially decrease and our funding with respect to the development of our current and potential future product candidates will substantially increase, regardless of whether we are able to reach agreement with Merck on modified terms. As a result, our expenses and accumulated deficit will also increase significantly in future periods. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business, including those resulting from the evolving effects of the COVID-19 pandemic. The size of our future net losses will depend, in part, on the rate of future growth of our expenses, whether Merck will exercise its option to extend the research phase of our collaboration or whether and on what terms we will reach agreement with Merck on a modified collaboration and our ability to otherwise continue to generate revenue, if at all, under the Merck collaboration, and to generate any revenue outside of the Merck collaboration. 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 future 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;
- 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. Even if we successfully complete development and regulatory processes, 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.***

In recent years, all of our revenue has been from our collaboration partner, Merck. Other than our agreement with Merck, we currently have no agreements that could provide us with material, ongoing future revenue and we may never enter into any agreements. As described under "Overview of Our Business – Status of Merck Collaboration" in Part I, Item 2 of this Quarterly Report on Form 10-Q, the parties continue to negotiate potential modifications to the terms of their Research Collaboration, Product Development and License Agreement with Merck, or the Collaboration Agreement. Under the current terms of the Collaboration Agreement, Merck agreed to reimburse us for research and development activities up to certain specified funding caps during the current two-year extension of the research phase through March 16, 2022. If our research and development expenses for product candidates subject to the Merck collaboration exceed the funding caps provided in our Collaboration Agreement, which happened in the fiscal year ended December 31, 2020 and could happen in the future, we will be required to devote our own financial resources toward the development of such product candidates or, if we are unwilling or unable to do so, pause or suspend such development to remain within the funding caps. In addition, while we do not know whether or when Merck will elect to extend the research phase of the collaboration through March 16, 2024 or on what terms, or whether or when we will reach agreement with Merck on the terms of a modified collaboration, we expect that any modified collaboration would result in a level of annual research support from Merck during any extension of the current research phase after March 16, 2022 that is meaningfully lower than the annual research support Merck provided during the initial five-year term and is providing during the current two-year extension of the research phase. In this regard, we expect that under the terms of a modified collaboration, Merck will not provide research funding for certain of our product candidates. We also expect that if we are unable to reach agreement with Merck on modified terms, Merck will not elect to extend the research phase of the collaboration and will decide not to proceed with certain of our product candidates after the end of the current research phase. In any event, we expect that following March 16, 2022, the end of the current two-year extension of the research phase, funding from Merck will substantially decrease and our funding with respect to the development of our current and potential future product candidates will substantially increase, regardless of whether we are able to reach agreement with Merck on modified terms. Accordingly, we will require significant additional capital in order to proceed with development and commercialization of our current and potential future product candidates, including

any product candidate that had been subject to the Merck collaboration but Merck decides not to proceed with under the terms of a modified collaboration or after the end of the research phase, or we will need to enter into additional collaboration or license agreements in order to fund such development and commercialization. Neither may be possible and as a result, we may be required to delay, scale back or discontinue development of such product candidates. For more information, see “Risks Related to Our Dependence on Merck and Other Third Parties” below.

***We will require substantial additional capital to finance our operations, which may not be available to us on acceptable terms, or at all. As a result, we may not have the resources to complete the development and commercialization of our current and potential future product candidates.***

As a research and development 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. In this regard, we do not have any committed external source of funds, other than pursuant to the current terms of our collaboration with Merck, which is limited in scope and duration, and may be unilaterally terminated by Merck under certain circumstances. In addition, as described in more detail under “Risks Related to Our Dependence on Merck and Other Third Parties” below, the level of future annual research support or other funding from Merck following the end of the current research phase is uncertain, and even if Merck elects to extend the current research phase, such annual research support from Merck is expected to be meaningfully lower than the annual research support Merck provided during the initial five-year term and is providing during the current two-year extension of the research phase through March 16, 2022. We also expect our research and development expenses to increase substantially in connection with our ongoing activities regardless of whether we are able to reach agreement with Merck on the terms of a modified collaboration, particularly to the extent that product candidates whose costs will not be included in a modified Merck collaboration, such as aldafermin and other product candidates Merck decides not to proceed with under the terms of a modified collaboration or after the end of the research phase, advance in clinical development. In addition, 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 research and development expenses.

We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to fund our operations for at least the next twelve months. 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. Our future funding requirements, both short- and long-term, will depend 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 and on what terms Merck exercises, if at all, its remaining option to extend the research phase of the collaboration, including whether such exercise would trigger an extension payment to us under the terms of a modified collaboration;
- whether and on what terms we and Merck agree to a modified collaboration, including the level of annual research support from Merck, if any, under a modified collaboration and, relatedly, the scope and extent of our need to fund the development of our current and potential future product candidates, including with respect to any such product candidates whose costs will not be included in a modified Merck collaboration such as aldafermin and other product candidates Merck decides not to proceed with under the terms of a modified collaboration or after the end of the research phase;
- whether Merck exercises its option to license product candidates upon completion of proof-of-concept studies for each such candidate in humans;
- whether Merck terminates the research phase of the collaboration under pre-specified circumstances set forth in the Collaboration Agreement or terminates a program that it has licensed (such as Merck’s termination of its license for our growth differentiation factor 15, GDF15, agonist program, including the NGM395 and NGM386 product candidates);
- whether we exceed the funding caps provided in the 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 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 acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with partners; and
- the extent to which any of the foregoing costs are the responsibility of Merck.

We plan to finance our future cash needs through public or private equity or debt offerings, including under the Open Market Sale Agreement<sup>SM</sup>, or the Sales Agreement, we entered into with Jefferies LLC in June 2020, government or other third-party funding, product collaborations, strategic alliances, licensing arrangements or a combination of these. Additional capital may not be available in sufficient amounts, on reasonable terms or when we need it, if at all, and our ability to raise additional capital 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 resulting from, among other things, the evolving effects of the COVID-19 pandemic. If we are unable to raise adequate additional capital, we may be prevented from pursuing 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, as we did most recently in January 2021, 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. If adequate funds are not available when we need them, we may need to:

- significantly delay, scale back or discontinue research and discovery efforts and the development or commercialization of any product candidates, or cease all operations;
- seek strategic alliances for research and development 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 would generally require us to relinquish, or license on potentially unfavorable terms, our rights to intellectual property, product candidates or products that we otherwise would seek to develop or commercialize ourselves, and we may not be able to enter into such agreements on acceptable terms, if at all.

***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 ending 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 Tax Cuts and JOBS Act, or 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, or IPO, 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 recently 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.

#### **Risks Related to Our Dependence on Merck and Other Third Parties**

***We depend on our collaboration with Merck and may depend in the future on collaborations with additional third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.***

The Merck collaboration involves a complex allocation of rights, provides for substantial research and development support, currently provides for additional payments upon Merck’s election, if exercised in its unilateral discretion, to further extend the term of the research phase for an additional two years and 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 sharing 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. In addition, as described under “Overview of Our Business – Status of Merck Collaboration” in Part I, Item 2 of this Quarterly Report on Form 10-Q, the parties continue to negotiate potential modifications to the terms of the collaboration. In this regard, we do not know whether or when Merck will elect to extend the research phase of the collaboration or on what terms, or whether or when we will reach agreement with Merck on the terms of a modified collaboration. We also do not know whether Merck will exercise its option to license additional product candidates or whether Merck will terminate its license to a licensed program under the terms of a modified collaboration or otherwise. See also the risk factor titled “Merck may elect not to extend the research phase of our collaboration and we may otherwise be unable to reach agreement with Merck on the terms of a modified collaboration and regardless of whether we and Merck reach agreement on the terms of a modified collaboration, our collaboration with Merck involves numerous risks, any of which could materially and adversely affect our business and financial condition” below.

We may seek other third-party collaborators for the development and commercialization of any product candidates that are not subject to the Merck collaboration, including aldafermin, NGM395 and NGM386 or any other product candidate that Merck decides not to proceed with under the terms of a modified collaboration or after the end of the research phase. If we enter into any such arrangements with any third parties, 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 these arrangements will depend on our collaborators’ abilities to successfully perform the functions assigned to them in these arrangements.

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 current terms of our collaboration with Merck, once proof-of-concept data in humans has been generated and Merck has exercised its option to acquire an exclusive license for a product candidate, 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-sharing arrangement. Even after we exercise that right to participate in a cost and profit-sharing 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, we and Merck are continuing to negotiate potential modifications to the terms of our collaboration, that may include, among other things, focusing NGM's research and development under the collaboration on therapeutic areas of particular interest to Merck, and we expect that any modified collaboration would result in a level of annual research support from Merck during any extension of the current research phase after March 16, 2022 that is meaningfully lower than the annual research support Merck provided during the initial five-year term and is providing during the current two-year extension of the research phase. In addition, under the current terms of the 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 sharing option) upon prior written notice, such as it did for NGM386 and NGM395, without triggering a termination of the remainder of the Collaboration Agreement. Moreover, regardless of our current negotiations with Merck and the terms of any modified Collaboration Agreement, Merck may elect not to exercise its option to extend the research phase, and Merck might also opt not to designate any of our 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 that has generated proof-of-concept data.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our medicines or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- 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 medicines or 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.

***Merck may elect not to extend the research phase of our collaboration and we may otherwise be unable to reach agreement with Merck on the terms of a modified collaboration and regardless of whether we and Merck reach agreement on the terms of a modified collaboration, our collaboration with Merck involves numerous risks, any of which could materially and adversely affect our business and financial condition.***

Under the terms of the collaboration, Merck was required to notify us no later than March 17, 2021 of its unilateral decision whether to exercise its option to extend the research phase of the collaboration for an additional two-year term through March 16, 2024. In March 2021, Merck initiated discussions with us with respect to elements of the ongoing collaboration that might be optimized to better address the evolving interests and priorities of both NGM and Merck during the remainder of the current research phase through March 16, 2022 and during any extension of the current research phase and any tail period (which tail period is discussed under "Business—Our Collaboration with Merck" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020). In this regard, the parties continue to negotiate potential modifications to the terms of the collaboration. Such modifications may include, among other things, focusing our research and development under the collaboration on therapeutic areas of particular interest to Merck, while enabling us to conduct research and development outside of these therapeutic areas, which would, if mutually agreed to, allow us to discover and develop product candidates on

our own or with third parties in other areas of interest. In order to allow negotiations to proceed, the parties agreed to extend the March 17, 2021 deadline for Merck to deliver its extension notification decision until June 30, 2021. While we do not know whether or when Merck will elect to extend the research phase of the collaboration or on what terms, or whether or when we will reach agreement with Merck on the terms of a modified collaboration, we expect that any modified collaboration would result in a level of annual research support from Merck during any extension of the current research phase after March 16, 2022 that is meaningfully lower than the annual research support Merck provided during the initial five-year term and is providing during the current two-year extension of the research phase. In this regard, we expect that under the terms of a modified collaboration, Merck will not provide research funding for certain of our product candidates. We also expect that if we are unable to reach agreement with Merck on modified terms, Merck will not elect to extend the research phase of the collaboration and will decide not to proceed with certain of our product candidates after the end of the current research phase. In any event, we expect that following March 16, 2022, the end of the current two-year extension of the research phase, funding from Merck will substantially decrease and our funding with respect to the development of our current and potential future product candidates will substantially increase, regardless of whether we are able to reach agreement with Merck on modified terms.

In addition, the level of future research funding from Merck following the end of the current research phase is uncertain. For example, if Merck does not elect to extend the research phase, we expect that Merck would decide not to designate certain of our product candidates for development during the tail period and could decide not to designate any of our product candidates for development during the tail period, in which case research funding from Merck would be either substantially reduced or eliminated as applicable, following the end of the current research phase. In addition, Merck is not required to designate any of our product candidates for development during the tail period until the three-month period prior to the end of the research phase, which could delay or preclude our ability to move forward with the development of certain of our product candidates, and could otherwise result in uncertainty regarding the future prospects of certain of our product candidates. Moreover, our stock price could decline as a result of such uncertainty and/or Merck's failure to designate certain of our product candidates for development during the tail period. Even if Merck elects to designate certain product candidates for development during the tail period, there are limits on Merck's funding obligations and Merck has the ability to terminate the tail period early. In addition, in the event that Merck decides to take over any designated product candidates for development during the tail period, we could be subject to disputes with Merck with respect to their obligation to use commercially reasonable efforts with respect to such development, which could delay or preclude the further development 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 Collaboration Agreement.

In addition, under the 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 annual funding of the research program prior to the end of the research phase if we are acquired by a third party or if we are in material uncured breach of our obligations under the research and early development program. After the current research phase of the collaboration or, if Merck again exercises its option to extend the research phase under modified collaboration terms, after such extension period, Merck may unilaterally terminate the overall agreement for convenience upon written notice and subject to certain limitations.

Subject to certain limitations, Merck may partially terminate the Collaboration Agreement for convenience as it relates to MK-3655 or any future licensed program. For example, Merck terminated its license to our GDF15 agonist program, including NGM395 and NGM386, in May 2019. Merck may also unilaterally terminate the agreement as it relates to its rights to research and develop small molecule compounds. It may also unilaterally terminate the 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 global cost and profit sharing 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 Collaboration Agreement, if we are unable to reach agreement with Merck on the terms of a modified collaboration and Merck decides not to extend the research phase of the collaboration or shifts the focus of its research and development funding or if Merck declines to designate our product candidates for development during the tail period, it would delay or preclude our ability to complete our research and development programs, which would materially and adversely affect our business and our stock price would likely decline.

***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, we expect to depend on other collaborators, partners, licensees, contract research organizations, or CROs, clinical data management organizations, clinical investigators, contract manufacturing organizations/contract development and manufacturing organizations, or CMOs, and other third parties 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, commercialization and manufacturing of our products or product candidates, which could harm our results of operations.

We cannot guarantee that we or, as applicable, our collaborator will be able to successfully negotiate agreements for, or maintain relationships with, collaborators, partners, licensees, CROs, clinical data management organizations, clinical investigators, CMOs and other third parties on favorable terms, if at all. If we or our collaborator are unable to obtain or 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 our collaborator need to enter into alternative arrangements, it would delay our product development 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 research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. However, we cannot control the amount or timing of resources our contract partners will devote to our research and development 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 in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines. 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 these third parties 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 research and development, 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 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 may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.***

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For product candidates not partnered with Merck, such as aldafermin, NGM395 and NGM386 or any other product candidate that Merck decides not to proceed with under the terms of a modified collaboration or after the end of the research phase, we may decide to collaborate with other pharmaceutical and biotechnology companies for their development and potential commercialization. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors, including the potential market for the subject product candidate.

We also may be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. For example, under the current terms of our Collaboration Agreement with Merck, we may not directly or indirectly research, develop, manufacture or commercialize, except pursuant to the Collaboration Agreement, any medicine or product candidate that modulates a target then subject to the collaboration with specified activity. The FGF19 program, including aldafermin, is excluded from this provision, notwithstanding that both aldafermin and MK-3655 signal, in part, through the FGFR1c pathway. During the tail period following the research term of the collaboration, we may not directly or indirectly research, develop or commercialize, outside of the collaboration, any medicine or product candidate with specified activity against any collaboration target that has been designated a tail target.

We may not be able to 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 the development of any product candidate for which we are seeking a collaboration, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense.

### **Risks Related to Our Business and Industry**

#### ***Our product candidates must undergo rigorous clinical trials before seeking regulatory approvals, which could delay or prevent commercialization of our product candidates.***

All of our product candidates will be subject to rigorous and extensive clinical trials before we can seek regulatory approval from the FDA and comparable foreign health authorities. Clinical trials may be delayed, suspended or terminated at any time for reasons including:

- ongoing discussions with the FDA or comparable foreign health authorities regarding the scope or design of our clinical trials, including discussions with the FDA regarding initiation of our planned Phase 3 trial of aldafermin;
- delays in obtaining, or the inability to obtain, required approvals from institutional review boards, or IRBs, or other governing entities at clinical trial sites selected for participation in our clinical trials;
- delays in key trial activities and patient enrollment, including as a result of the evolving effects of the COVID-19 pandemic;
- delays in reaching agreement on acceptable terms with prospective CROs;
- 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;
- delays in patients completing a trial or returning for post-treatment follow-up;
- failure of third parties, such as CROs, to satisfy their contractual duties to us or meet expected deadlines;
- 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 or 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.

In particular, we or our partners may be unable to enroll the patients we need to complete clinical trials on a timely basis, or at all. For example, there is significant competition for recruiting patients with NASH in clinical trials. In the first quarter of 2020, we announced that enrollment in our ALPINE 2/3 clinical trial of aldafermin had been delayed beyond our initial projections. In addition, clinical trial enrollment generally continues to be negatively affected by the effects of the COVID-19 pandemic as a result of delays in additional clinical trial site initiation, suspension of enrollment at clinical trial sites or patient reluctance to participate in a clinical trial during quarantines or shelter-in-place orders or otherwise, particularly in medically vulnerable patient populations. This has impacted site initiation and enrollment in our ongoing Phase 2b ALPINE 4 clinical trial of aldafermin in patients with NASH with F4 liver fibrosis and compensated cirrhosis, and in our trials of NGM120, an antagonistic antibody that binds glial cell-derived neurotrophic factor receptor alpha-like, or GFRAL, and inhibits GDF15 signaling, for the potential treatment of cancer and cancer-related cachexia. If the evolving effects of the COVID-19 pandemic persist or become more severe, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects.

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. 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. We also 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 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 various stages of development and our most advanced product candidate, aldafermin, is still 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. 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. Moreover, additional clinical trials may be required if clinical trial results are negative or inconclusive, which would require us to incur additional costs and significant delays. 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. Owing in part to the complexity of biological pathways, our product candidates might not demonstrate in patients 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.

In addition, 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.

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 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.

If we are unable to successfully discover, develop or enable our collaborators to develop drugs that are effective and safe in humans, we will not have a viable business.

***Our most advanced clinical-stage product candidate, aldafermin, and 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 our collaborator 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 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. 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.

***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. 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 our immuno-oncology product candidates, NGM707 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, the results we obtained in our Phase 1 trials of aldafermin and in our completed Phase 2 trial, including the data from the fourth and final 24-week expansion cohort of that trial in patients with NASH with fibrosis stage F2 or F3, may not be indicative of the future results we obtain from our ALPINE 2/3 trial, our ongoing ALPINE 4 trial and any Phase 3 trial. In addition, some of our 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.

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

The success of our business depends primarily upon our ability to identify and validate new therapeutic candidates, and to identify, develop and commercialize 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 or new product candidates. In addition, our drug discovery efforts tend to 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 new product candidates to advance into clinical trials could have a material adverse effect on our business, operating results and prospects.

***We are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates and any future products.***

We have limited process development capabilities and have access only to external 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. Our reliance on third-party manufacturers 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 regulatory compliance and quality assurance, 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.

To date, aldafermin and our other product candidates have been manufactured by third-party manufacturers solely for preclinical studies and relatively small clinical trials. These manufacturers may not be able to scale production to the larger quantities required for large clinical trials and for commercialization. In this regard, if any of our product candidates are approved by the FDA or other regulatory agencies for commercial sale, we or our collaborator may need to manufacture it in large quantities. We intend to use third-party manufacturers for commercial quantities of aldafermin, NGM120, NGM621, NGM707 and NGM438, to the extent we advance these product candidates, and will rely on Merck to determine whether to utilize a third-party manufacturer or Merck's internal manufacturing capacity for MK-3655 and other licensed product candidates. The process of manufacturing aldafermin and our other product candidates is complex, highly regulated and subject to several risks, including:

- a third-party manufacturer may experience product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;
- a third-party manufacturer of a product candidate subject to our collaboration with Merck may fail to qualify upon an audit by Merck or by us;
- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, turnover of qualified staff, financial difficulties of our contract manufacturers, including as a result of the evolving effects of the COVID-19 pandemic, natural disasters, power failures, local political unrest and numerous other factors; and
- any adverse developments affecting manufacturing operations or the scale up of manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to record inventory write-offs and incur other charges and expenses for product candidates or drug substances that fail to meet specifications or cannot be used before their expiration dates. In addition, for out of specification materials, we may need to undertake costly remediation efforts or seek costlier manufacturing alternatives.

We also have a single source of supply for aldafermin and most of our other product candidates, including the drug substances used in manufacturing them. Single sourcing minimizes our leverage with our contract manufacturers, who may take advantage of our reliance on them to increase the pricing of their manufacturing services. Single sourcing also imposes a risk of interruption in supply in the event of manufacturing, quality or compliance difficulties. In addition, we do not currently have arrangements in place for redundant supply for bulk drug substances or drug product. If one of our suppliers fails or refuses to supply us for any reason, it would take a significant amount of time and cost to implement and execute the necessary technology transfer to, and to qualify, 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.

In addition, 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 in a way that delays or interrupts our supply of clinical trial material.

We have entered into third-party supply agreements for the production of aldafermin for our clinical trials with Lonza Ltd, or Lonza, for Phase 3 and commercial supplies of the aldafermin drug substance. If our third-party suppliers, including Lonza or our aldafermin drug product manufacturer, are not able to provide us with sufficient quantities of aldafermin for our clinical trials on a timely basis, or at all, whether due to production shortages or other supply delays or interruptions resulting from the ongoing COVID-19 pandemic or otherwise, our clinical trials or regulatory approval may be delayed. In this regard, although significant portions of our research and development resources are focused, and will continue to be focused, on activities required to prepare aldafermin for potential regulatory approval for the treatment of NASH, including manufacturing of clinical trial material and preparation for potential Phase 3 testing, if Lonza and/or our drug product manufacturer experience difficulties in scaling production or experience 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, the potential Phase 3 testing of aldafermin would be delayed, perhaps substantially, which could materially and adversely affect our business. Moreover, our aldafermin drug product manufacturer has 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 Lonza and/or our aldafermin drug product manufacturer become subject to acts or orders of U.S. or foreign government entities to allocate manufacturing capacity to the manufacture or distribution of COVID-19 vaccines or medical supplies needed to treat COVID-19 patients, this could also delay, perhaps substantially, our ongoing and planned aldafermin trials, which could materially and adversely affect our business.

Each of our product candidates uses certain raw materials for its manufacture, such as reagents that support cell growth, purification materials or testing 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 require the use of pre-filled syringes or syringe components that have been the subject of shortages amplified by the COVID-19 pandemic due to their use in, among other things, COVID-19 vaccine production. Any significant delay in the acquisition or decrease in the availability of these raw materials, pre-filled syringes or syringe components could considerably delay the manufacture of our product candidates or the conduct of our clinical trials, 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.

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. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up and validating initial production and ensuring the avoidance of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot ensure that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

Any delay or interruption in the supply of clinical trial material could delay the completion of 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 or terminate clinical trials completely.

***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 evaluate the safety profile of our product candidates. Patients in certain of our ongoing or planned clinical trials, particularly those with NASH with more advanced fibrosis and patients with cancer, also often commonly 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 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.

In clinical trials of aldafermin to date, a number of serious adverse events, or SAEs, most of which have been classified as mild to moderate, have been reported in the treatment arms of our completed Phase 1 and Phase 2 clinical trials, including one patient in Cohort 1 of our Phase 2 clinical trial who experienced an SAE, acute pancreatitis, that was assessed as possibly related to aldafermin. Patients have also experienced, and we have reported, SAEs in our completed trials of MK-3655, NGM621 and NGM120. Ocular SAEs reported in our ongoing Phase 2 CATALINA trial of NGM621, which remains masked to treatment assignment, include worsening of vision due to GA worsening and retinal detachment in the non-study eye and worsening of vision due to GA worsening in the 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. 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, or LDL, cholesterol were observed in clinical trials of aldafermin in patients with NASH and type 2 diabetes. Serum levels of LDL cholesterol were brought back to baseline levels with concomitant statin use in patients with NASH; however, the impact of these drug-induced changes in LDL cholesterol are unknown. Generally, sustained and prolonged LDL cholesterol elevations in untreated patients are associated with cardiovascular disease through atherosclerotic plaque development. While in Cohorts 2, 3 and 4 of our completed Phase 2 clinical trial of aldafermin we demonstrated the ability of concomitant statin use to mitigate the serum LDL cholesterol elevations driven by aldafermin activity, aldafermin's impact on LDL may negatively impact market acceptance of an approved aldafermin product.

Our product candidates, including aldafermin, which is an engineered variant of the FGF19 protein, 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 have 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 IVT injections, including by most investigators in the Phase 2 CATALINA trial, has 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 have 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.

***Our most advanced clinical-stage product candidate, aldafermin, is a modified version of a human hormone that has been associated with liver cancer in rodent testing.***

The investigational new drug, or 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. Aldafermin is a modified version of FGF19 that we believe does not exhibit the cancer-causing effects of native human FGF19 in rodents. We believe that aldafermin will have a superior therapeutic profile to FGF19 based on preclinical data showing reduced fasting blood glucose levels, fed insulin levels and bile acid suppression in animals. However, we may be incorrect in these beliefs, and we cannot be sure that regulators will view our product candidate as safe or that physicians will view our product candidates as safe and superior to alternative treatments. Concerns about the association between FGF19 and liver cancer could have an adverse effect on our ability to develop and commercialize aldafermin.

***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, 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.

***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 research and development, 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 to concentrate our resources elsewhere, also may be incorrect and could cause us to miss valuable opportunities.

Under the current terms of our 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-sharing 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 Dr. Jin-Long Chen, or 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 research and development 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.

To fully realize the research and development support committed under our collaboration with Merck, we will need to maintain a significant number of qualified research and development personnel. There is intense competition for qualified personnel, including management, in the technical fields in which we operate, 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. 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 may encounter difficulties in managing our growth, which could adversely affect our operations.***

Since executing the Collaboration Agreement in 2015, 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, remote work policies, reporting systems and operational, financial and management controls, particularly in light of the evolving effects of the COVID-19 pandemic. We may not be able to expand or identify sufficiently-sized facilities to accommodate our growth, particularly given our location in South San Francisco, California and the current high demand for, and restricted supply of, research and development facilities in this market. 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.

***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 target the same diseases that are targeted by our most advanced product candidates. It is probable that the number of companies seeking to develop products and therapies for the treatment of liver and metabolic diseases, retinal diseases and cancer 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 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-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) 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 Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2020.

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

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. Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. 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 clinics and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the inclusion or exclusion of the product candidate from treatment guidelines established by various physician groups and the viewpoints of influential physicians with respect to the product candidate;
- the cost of treatment relative to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities as described below;
- 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. 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” above. 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 commercialize any of our product candidates, alone or with our partners, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, 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 Europe, Japan and Canada, the pricing of prescription drugs is controlled by the government. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. 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. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay 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. 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 medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we or our partners commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our partners obtain marketing approval. If coverage and reimbursement are not available

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

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

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

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

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.

In addition, while Congress has not passed comprehensive legislation repealing the ACA, it has introduced legislation to modify certain provisions. Congress likely will consider other legislation to modify or replace additional elements of the ACA. It is unclear how these efforts to repeal and replace the ACA, or other appeals, will impact the ACA and our business. For example, 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. The Supreme Court of the United States is currently reviewing this case, although it is unclear when a decision will be made. It is also unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the ACA or our business.

Recently, 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. 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. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. 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.

We cannot predict the likelihood, nature or extent of healthcare reform initiatives that may arise from future legislation or administrative action, particularly under the Biden administration. 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 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 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, 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, 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 and transmission of individually identifiable health information;
- the federal Open Payments program, created under Section 6002 of the ACA 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 United States Department of Health and Human Services, or HHS, information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to the HHS ownership and investment interests held by physicians (as defined above) and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and transfers of value to physician assistants, nurse practitioners, anesthesiologist assistants, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; 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 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, 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.

***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 substance for NGM120, NGM621, NGM707 and NGM438 is located in a region that has experienced political unrest. If our operations or the operations of third parties providing services to us experiences are disrupted by any such occurrences, our business and future prospects may be negatively affected.

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

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. Following guidance from federal, state and local authorities, we continue to operate with a substantially remote work model. Employees working on site continue to be primarily those individuals conducting essential in-person laboratory work that cannot be conducted remotely, with heightened safety measures designed to minimize occupational exposure and reduce transmission of COVID-19 within our workplace. Although we have re-opened our laboratory facilities under these heightened safety measures, 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 we first transitioned to a remote work model in March 2020, we experienced higher-than-normal employee turnover and an increased rate of hiring new employees. We cannot predict whether this higher turnover rate will continue and what its impact will be on productivity, whether these trends will continue or be exacerbated, when we will be permitted to, and whether we will, return to a fully office-based working model or whether we will be required to adopt a more restrictive work model as the pandemic evolves. Continuation of current or 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 pandemic continues, there may be continuing negative impacts on our ability to initiate new clinical trial sites, maintain enrollment of existing patients and enroll new patients, which may affect timelines in the future. 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, we have experienced, from time to time, a slower pace of clinical site initiation and clinical trial enrollment than originally anticipated in certain of our clinical trials, including the ALPINE 4, CATALINA and NGM120 trials, and we experienced a higher dropout rate in our ALPINE 2/3 trial than we had anticipated based on our previous trials in patients with NASH. We believe this may be due to factors such as the vulnerability of our studied patient populations, clinical trial site suspensions, reallocation of medical resources and the challenges of working remotely due to shelter-in-place and similar government orders, 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 patients from COVID-19 exposure as a result of their trial participation, which include the use of telemedicine visits, remote monitoring of patients and clinical trial sites and other measures designed to ensure that data from clinical trials that may be disrupted as result of the 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 site IRB. If any of the foregoing efforts to mitigate the impact of the COVID-19 pandemic 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 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. 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. Refer the risk factor titled "We are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates and any future products." 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 economic impact caused by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic 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, the current 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 Collaboration Agreement, to exercise its remaining option to extend the research phase of the collaboration beyond March 16, 2022 or to reach agreement with us on the terms of a modified collaboration, if any.

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 ultimate duration and severity of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of 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.

***We, our CROs, our CMOs and other third parties we rely on 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. The information and data processed and stored in our technology systems, and those of 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 also may result from errors or malfeasance by our personnel or the personnel of the third parties we work with, malware, viruses, software vulnerabilities, hacking, denial of service attacks, social engineering (including phishing), ransomware, credential stuffing or other cyberattacks, including attacks by state-sponsored organizations or sophisticated groups of hackers.

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 have implemented 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.

As a result of the ongoing COVID-19 pandemic, certain functional areas of our workforce remain in a remote work environment and 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, any of which could have a material adverse effect on our business.

Despite our efforts to strengthen security and authentication measures, we have experienced an overall increase in cybersecurity incidents, none of which have caused material disruption to our business, or to our knowledge, involved a material security breach. In June 2019, a vendor that conducted bioanalytical services for

some of our aldafermin clinical trials experienced a ransomware attack that resulted in a significant disruption to its IT systems but did not affect the integrity of our clinical sample data for aldafermin, as verified by independent vendors. More 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 could experience a material system failure, security breach or other cybersecurity incident 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 could also result in substantial remediation costs and expose us to litigation, regulatory enforcement action, fines, penalties and other liabilities.

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 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.

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

We may collect, use or transfer personal information from clinical trials participants and other individuals located in the EU. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the EU. The collection and use of personal information, including health data, in the EU and EEA are governed by the General Data Protection Regulation ((EU) 2016/679), or GDPR. Companies that violate the GDPR can face private litigation, prohibitions on data processing and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue. The GDPR requires us to 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.

European data protection laws, including the GDPR, generally restrict the transfer of personal information from Europe, including the European Economic Area, United Kingdom and Switzerland, to the United States and most other countries unless the receiving country offers comparable data protection laws. Decisions by the Court of Justice of the European Union, or CJEU, indicate that the United States does not offer adequate data protection that is comparable to the GDPR; however, one of the primary safeguards allowing United States companies to continue to import personal information from the EU 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. The CJEU adopted a decision in July 2020 validating that the SCCs can lawfully be used for personal information transfers from the EU to the United States, provided that the party exporting personal information from the EU conduct an analysis of the level of data protection available and take additional steps to guarantee adequate data protection, if needed. If adequate data protection cannot be guaranteed, EU citizens may complain to the data protection authorities, which may require data transfer under the contract to be suspended.

We continue to monitor changes in European data protection laws; however, uncertainty remains regarding any future regulations, interpretations or guidance that may be issued by the European authorities. At present, we primarily rely on individuals' explicit consent to transfer their personal information from Europe 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 Europe, which can be revoked, or implement another valid compliance solution, we will face increased exposure to substantial fines under European data protection laws as well as injunctions against the export and processing of personal information from Europe. Our inability to import personal information from the European Economic Area, United Kingdom or Switzerland may also restrict our clinical trial activities in Europe; limit our ability to collaborate with CROs, service providers, contractors and other companies subject to European data protection laws; and require us to increase our data processing capabilities in Europe at significant expense.

In addition, there is currently a lack of clarity regarding the process for transferring personal information from the EU to the United Kingdom in compliance with the GDPR in light of Brexit. Pursuant to a post-Brexit trade deal between the United Kingdom and the EU, transfers of personal information from the European Economic Area to the United Kingdom are not considered restricted transfers under the GDPR for a period of up to six months from January 1, 2021. However, unless the EU Commission makes an adequacy finding with respect to the United Kingdom before the end of that period, transfers of European personal information to the United Kingdom will require an approved compliance mechanism to render such transfers lawful under the GDPR. As of February 2021, the European Commission has launched a process towards the adoption of an adequacy decision for transfers of personal data from the EU to the United Kingdom, having concluded that the United Kingdom ensures an essentially equivalent level of protection to that guaranteed under the GDPR; however, uncertainty remains regarding how data transfers to and from the United Kingdom ultimately will be regulated after Brexit. The UK has incorporated an amended version of the GDPR into UK law, which is independent from but aligned with the EU's GDPR. Non-compliance with the UK data protection law may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Additionally, other countries outside of Europe 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 are increasingly complex and changing rapidly. Just over a month after the 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 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. 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 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, 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, which may increase our compliance costs, exposure to regulatory enforcement action and other liabilities.

***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.

**Risks Related to Regulatory Approvals**

***The regulatory approval processes of the FDA and comparable foreign health authorities are lengthy, time-consuming 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 approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition, and the FDA may grant accelerated approval based on a surrogate endpoint reasonably likely to predict clinical benefit. However, Fast Track designation does not guarantee, or in any way change the standards for, full product approval. Accordingly, although 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 seek accelerated approval for one of our product candidates, including aldafermin for NASH, 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.

***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 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 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.

In addition, manufacturers of drug substance and drug products and their facilities are subject to continual review and periodic inspections by the FDA and other health authorities for compliance with 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 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 will heavily scrutinize advertising and promotion of any product candidate that obtains approval 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.

***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 aldafermin or any of our other product candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved 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 aldafermin and our other 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 do not currently own or have a license to any issued patents that cover our NGM621 product candidate, although it is disclosed and claimed in our pending U.S. non-provisional and/or national stage applications in particular foreign countries. Likewise, we do not currently own or have a license to any issued patents that cover our NGM707 and NGM438 product candidates, although these product candidates are disclosed and claimed in our pending U.S. provisional 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, nor can there be any assurance that we would obtain sufficiently broad claims to be able to prevent others from selling competing products.

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 our aldafermin molecule, including half-life extending formulation enhancements or the half-life extended variants of FGF19 that we are developing, NGM621, NGM707 and NGM438 or any of our other 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 liver and metabolic diseases, retinal diseases and cancer fields, 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, lengthy 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, lengthy 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 in this “Risk Factors” section, these factors include:

- developments associated with our collaboration with Merck, including our failure to reach agreement with Merck on the terms of a modified collaboration, Merck’s decision to not exercise its remaining unilateral option to extend the research phase of the collaboration, investor perceptions as to the terms of a modified Collaboration Agreement, if any, 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, 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, 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 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 entitled

“Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.”

***An active trading market for our common stock may not be sustained.***

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.

***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 such stocks, our stock price could fall.

***We are an “emerging growth company” as defined in the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.***

For so long as we remain an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not “emerging growth companies” including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the “say on pay” provisions (requiring a non-binding stockholder vote to approve compensation of certain executive officers) and the “say on golden parachute” provisions (requiring a non-binding stockholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer; and
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation.

Because our independent registered public accounting firm is not required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an “emerging growth company,” the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected may be increased. Likewise, our election not to provide certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the U.S. Securities and Exchange Commission, or SEC, may make it more difficult for investors and securities analysts to evaluate our company.

We may take advantage of these reporting exemptions until we are no longer an “emerging growth company”, which in certain circumstances could be for up to five years. We will cease to be an “emerging growth company” upon the earliest of: (1) December 31, 2024; (2) the last day of the first fiscal year in which our annual gross revenue is \$1.07 billion or more; (3) the date on which we have, during the previous rolling three-year period, issued more than \$1 billion in non-convertible debt securities; and (4) the date on which we are deemed to be a “large accelerated filer” as defined in the Exchange Act.

With respect to the JOBS Act, we are also taking advantage of some, but not all, of the reduced regulatory and reporting requirements that are available to us so long as we qualify as an “emerging growth company.” For example, we are not subject to the same new or revised accounting standards as other public companies that are

not “emerging growth companies.” As a result, changes in U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions and reduced requirements. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and may decline. In addition, if we lose our “emerging growth company” status sooner than anticipated, we may incur additional costs to comply with rules and regulations required for public companies, which may impact our financial position and results of operations.

***Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.***

For the trading days during the three months ended December 31, 2020, the average daily trading volume for our common stock on The Nasdaq Global Select Market was only 175,778 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 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 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**

***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 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 incur increased costs as a result of operating as a public company, and our management devotes substantial time to new compliance initiatives.***

As a public company, we incur significant legal, accounting, insurance and other expenses that we did not incur as a private company, and these expenses may further increase after we are no longer an “emerging growth company.” 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 implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires 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. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, 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 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, 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.**

### **Recent Sales of Unregistered Securities**

During the quarter ended March 31, 2021, we did not issue or sell any unregistered securities.

### **Use of Proceeds from Our Initial Public Offering of Common Stock**

In April 2019, we completed our IPO pursuant to a Registration Statement on Form S-1 (No. 333-227608), which was declared effective by the SEC on April 3, 2019. We issued and sold an aggregate of 7,521,394 shares of our common stock, including 854,727 shares sold pursuant to the underwriters' exercise of their option to purchase additional shares, at a public offering price of \$16.00 per share. We received net proceeds of \$107.8 million, after deducting underwriting discounts, commissions and offering expenses. No payments were made from our net proceeds directly or indirectly to our officers or directors, to persons owning 10% or more of any class of our equity securities or to any of our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for Board or Board committee service. Goldman Sachs & Co. LLC, Citigroup Global Markets Inc. and Cowen and Company, LLC acted as joint book-running managers for the offering. As of March 31, 2021, we have used all of the net proceeds, primarily to advance the development of our product candidates and our clinical trials and research programs, and for working capital and general corporate purposes. There was no material change in the use of proceeds as described in our prospectus filed with the SEC on April 4, 2019 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended.

### **Issuer Purchases of Equity Securities**

On February 3, 2021, we repurchased a total of 230 shares of our common stock for \$8.14 per share. All of the shares repurchased were repurchases of unvested shares of our common stock that had been issued upon early exercise of stock options. Upon termination of employment of a person holding unvested shares, we are entitled to repurchase the unvested shares.

## **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	<a href="#">Amended and Restated Certificate of Incorporation</a>	8-K	001-38853	3.1	4/8/19
3.2	<a href="#">Amended and Restated Bylaws</a>	S-1	333-227608	3.4	9/28/18
10.1	<a href="#">Letter Agreement, dated as of March 12, 2021, by and between Merck Sharp &amp; Dohme Corp. and NGM Biopharmaceuticals, Inc.</a>	8-K	001-38853	10.1	3/15/21
10.2+*	<a href="#">Offer Letter Agreement, by and between the Registrant and Hsiao D. Lieu, M.D., dated as of January 16, 2019.</a>				
10.3+*	<a href="#">Offer Letter Agreement, by and between the Registrant and Valerie L. Pierce, dated as of August 6, 2019, and related information.</a>				
31.1+	<a href="#">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</a>				
31.2+	<a href="#">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</a>				
32.1+**	<a href="#">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</a>				
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.

\* Indicates management contract or compensatory plan or arrangement.

\*\* The certification attached as Exhibit 32.1 accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

**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 6, 2021

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

Date: May 6, 2021

By: /s/ Siobhan Nolan Mangini  
Siobhan Nolan Mangini  
**Chief Financial Officer**  
**(Principal Financial Officer)**



January 16, 2019

Hsiao D. Lieu, M.D.

Dear Hsiao,

On behalf of NGM Biopharmaceuticals, Inc. ("NGM" or the "Company"), we are pleased that you will be joining the Company as Senior Vice President, Chief Medical Officer reporting to me. We believe this position represents an extraordinary opportunity, and we look forward to your joining our exceptional team.

Below are details of the compensation and benefits program we are offering as part of your employment with NGM, as well as other terms of your employment. Should you have questions regarding any part of this offer, or wish to receive additional details, please let us know. Your annual base salary will be \$420,000.00, less payroll deductions and all required withholdings, paid semi-monthly over 24 pay periods per year. In addition, you will be eligible to participate in the NGM Incentive Bonus Plan. You will also be eligible to receive a one-time sign-on bonus of \$225,000.00, payable within the first two pay periods of your employment with NGM. Should you voluntarily resign from NGM within two (2) years from your start date, you will be required to repay the pro-rated portion of the sign-on bonus payment based on the number of months you were employed by the Company following receipt of the sign-on bonus payment.

NGM provides all eligible employees with a comprehensive benefits program. You will have the opportunity to participate in these benefits, which include medical, dental and vision coverage for you and your eligible dependents, if you choose to enroll in them. In addition, we provide life insurance, LTD and AD&D coverage, along with a comprehensive 401(k) program. NGM also provides benefits including Company holidays, vacation, sick leave and Health Care and Dependent Flexible Spending Accounts. The Company may change compensation and benefits from time to time in its discretion. There is a formal performance review period once a year.

An important component of your compensation includes the opportunity for ownership in the Company. After you commence employment, and subject to the approval of our Board of Directors (the "Board"), NGM will grant you an option to purchase 400,000 shares of the Company's common stock (subject to adjustment for stock splits, stock dividends, reclassification and the like) at the fair market value determined by the Board as of the date of grant (the "Option"). The Option will be subject to the terms and conditions of the Company's Equity Incentive Plan (the "Plan") and your grant agreement. Your grant agreement will reflect a four year vesting schedule, under which 25% of your Option will vest after 12 months and 1/48th of the total will vest at the end of each month thereafter, until either the Option is fully vested or your employment ends, whichever occurs first.

As a condition of your employment, you will be required to abide by the Company's policies and procedures, including those outlined in our employee handbook. You also agree to read, sign and comply with the Company's Employee Proprietary Information and Inventions Agreement ("Proprietary Information Agreement").

In your work for the Company, you will be expected to not make any unauthorized use of, or disclose, the confidential information or materials, including trade secrets, of any former employer or other third party to whom you owe an obligation of confidentiality. Rather, you will be expected to use only that information generally known and used by persons with training and experience comparable to your own, which information is common knowledge in the industry or otherwise legally available in the public domain, or which is otherwise provided or developed by the Company. By accepting employment with the Company, you are representing to us that you will be able to perform your duties within the guidelines described in this paragraph. You represent further that you have disclosed to the Company any contract you have signed that may restrict your activities on behalf of the Company in any manner.

This offer is contingent upon our verification of your employment history. Any intentional misrepresentation concerning your employment history may result in actions up to and including revocation of this offer or termination of your employment at NGM.

Your employment relationship is at-will. Accordingly, you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company. Likewise, the Company may terminate your employment at any time and for any reason, with or without cause or advance notice.

This letter, together with your Proprietary Information Agreement, forms the complete and exclusive statement of your agreement with the Company concerning this offer. The terms of this letter supersede any other representations or agreements made to you by any party, whether oral or written. The terms of our agreement cannot be changed (except those changes expressly reserved to the Company's discretion in this letter) other than by a written agreement signed by you and a duly authorized officer of the Company. This agreement is to be governed by the laws of the state of California without reference to its conflicts of law principles. In case any provision contained in this agreement shall, for any reason, be held invalid or unenforceable in any respect, such invalidity or unenforceability will not affect the other provisions of this agreement, and such provision will be construed and enforced so as to render it valid and enforceable consistent with the general intent of the parties insofar as possible under applicable law. With respect to the enforcement of this agreement, no waiver of any right hereunder will be effective unless it is in writing. This agreement may be executed in more than one counterpart, and signatures transmitted electronically will be deemed equivalent to originals. As required by law, this offer is subject to satisfactory proof of your identity and right to work in the United States.

Hsiao, we are thrilled that you have decided to accept our employment offer. Under the terms described above, please sign and date this letter and the Proprietary Information Agreement, and return them by January 23, 2019. It is our expectation that you will join NGM in March 2019.

NGM is an ambitious undertaking, and we fully expect our company to become a force in the development and commercialization of pharmaceutical therapies. To this end, we are assembling a team of uniquely qualified individuals with extraordinary knowledge, skills and drive. Your leadership of the development area will be a critical part of our success and we look forward to you joining our team.

Sincerely,

/s/ David J. Woodhouse

\_\_\_\_\_  
David J. Woodhouse, Ph.D.  
Chief Executive Officer

Exhibit A — Employee Proprietary Information and Inventions Agreement

Understood and Accepted

/s/ Hsiao D. Lieu

\_\_\_\_\_  
Hsiao D. Lieu, M.D.

1/22/2019

\_\_\_\_\_  
Date



August 6, 2019

Valerie L. Pierce, Esq.

Dear Valerie,

On behalf of NGM Biopharmaceuticals, Inc. ("NGM" or the "Company"), we are pleased that you will be joining the Company as Senior Vice President, General Counsel and Chief Compliance Officer reporting to me. We believe this position represents an extraordinary opportunity, and we look forward to your joining our exceptional team.

Below are details of the compensation and benefits program we are offering as part of your employment with NGM, as well as other terms of your employment. Should you have questions regarding any part of this offer, or wish to receive additional details, please let us know. Your annual base salary will be \$390,000.00, less payroll deductions and all required withholdings, paid semi-monthly over 24 pay periods per year. In addition, you will be eligible to participate in the NGM Incentive Bonus Plan. You will also be eligible to receive a one-time sign-on bonus of \$75,000.00, payable within the first two pay periods of your employment with NGM. Should you voluntarily resign from NGM within two (2) years from your start date, you will be required to repay the pro-rated portion of the sign-on bonus payment based on the number of months you were employed by the Company following receipt of the sign-on bonus payment. In addition, you will be eligible to receive a one-time retention bonus of \$75,000.00 payable within the first two pay periods following the one-year anniversary of your employment. Should you voluntarily resign from NGM within two (2) years from the receipt of your retention bonus payment, you will be required to repay the pro-rated portion of the retention bonus payment based on the number of months you were employed by the Company following receipt of the retention bonus payment.

NGM provides all eligible employees with a comprehensive benefits program. You will have the opportunity to participate in these benefits, which include medical, dental and vision coverage for you and your eligible dependents, if you choose to enroll in them. In addition, we provide life insurance, LTD and AD&D coverage, along with a comprehensive 401(k) program. NGM also provides benefits including Company holidays, vacation, sick leave and Health Care and Dependent Flexible Spending Accounts. The Company may change compensation and benefits from time to time in its discretion. There is a formal performance review period once a year.

An important component of your compensation includes the opportunity for ownership in the Company. After you commence employment, and subject to the approval of our Board of Directors (the "Board"), NGM will grant you an option to purchase 200,000 shares of the Company's common stock (subject to adjustment for stock splits, stock dividends, reclassification and the like) at the fair market value determined by the Board as of the date of grant (the "Option"). The Option will be subject to the terms and conditions of the Company's Equity Incentive Plan (the "Plan") and your grant agreement. Your grant agreement will reflect a four year vesting schedule, under which 25% of your Option will vest after 12 months and 1/48th of the total will vest at the end of each month thereafter, until either the Option is fully vested or your employment ends, whichever occurs first.

As a condition of your employment, you will be required to abide by the Company's policies and procedures, including those outlined in our employee handbook. You also agree to read, sign and comply with the Company's Employee Proprietary Information and Inventions Agreement ("Proprietary Information Agreement").

In your work for the Company, you will be expected to not make any unauthorized use of, or disclose, the confidential information or materials, including trade secrets, of any former employer or other third party to whom you owe an obligation of confidentiality. Rather, you will be expected to use only that information generally known

and used by persons with training and experience comparable to your own, which information is common knowledge in the industry or otherwise legally available in the public domain, or which is otherwise provided or developed by the Company. By accepting employment with the Company, you are representing to us that you will be able to perform your duties within the guidelines described in this paragraph. You represent further that you have disclosed to the Company any contract you have signed that may restrict your activities on behalf of the Company in any manner.

This offer is contingent upon our verification of your employment history. Any intentional misrepresentation concerning your employment history may result in actions up to and including revocation of this offer or termination of your employment at NGM.

Your employment relationship is at-will. Accordingly, you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company. Likewise, the Company may terminate your employment at any time and for any reason, with or without cause or advance notice.

This letter, together with your Proprietary Information Agreement, forms the complete and exclusive statement of your agreement with the Company concerning this offer. The terms of this letter supersede any other representations or agreements made to you by any party, whether oral or written. The terms of our agreement cannot be changed (except those changes expressly reserved to the Company's discretion in this letter) other than by a written agreement signed by you and a duly authorized officer of the Company. This agreement is to be governed by the laws of the state of California without reference to its conflicts of law principles. In case any provision contained in this agreement shall, for any reason, be held invalid or unenforceable in any respect, such invalidity or unenforceability will not affect the other provisions of this agreement, and such provision will be construed and enforced so as to render it valid and enforceable consistent with the general intent of the parties insofar as possible under applicable law. With respect to the enforcement of this agreement, no waiver of any right hereunder will be effective unless it is in writing. This agreement may be executed in more than one counterpart, and signatures transmitted electronically will be deemed equivalent to originals. As required by law, this offer is subject to satisfactory proof of your identity and right to work in the United States.

Valerie, we are thrilled that you have decided to accept our employment offer. Under the terms described above, please sign and date this letter and the Proprietary Information Agreement, and return them by August 13, 2019. It is our expectation that you will join NGM in September 2019.

NGM is an ambitious undertaking, and we fully expect our company to become a force in the development and commercialization of pharmaceutical therapies. To this end, we are assembling a team of uniquely qualified individuals with extraordinary knowledge, skills and drive. Your leadership of the legal area will be a critical part of our success and we look forward to you joining our team.

Sincerely,

/s/ David J. Woodhouse

David J. Woodhouse, Ph.D.  
Chief Executive Officer

Exhibit A — Employee Proprietary Information and Inventions Agreement

Understood and Accepted

/s/ Valerie L. Pierce  
Valerie L. Pierce, Esq.

8/6/19  
Date

## **ADDITIONAL INFORMATION REGARDING SEVERANCE AND CHANGE IN CONTROL ARRANGEMENTS**

In addition to the employment offer letter with Ms. Pierce entered into on August 6, 2019, in May 2020 the Compensation Committee of the NGM Biopharmaceuticals, Inc. Board of Directors determined that, in the event of a termination without cause (and other than as a result of death or disability) or resignation for good reason, in either case on or within 18 months after the effective date of a change in control, and contingent on execution of an effective release of claims against us and satisfaction of certain other conditions, Ms. Pierce will be entitled to (i) continued payment of her base salary for 6 months; (ii) payment or reimbursement of COBRA premiums for her and her eligible dependents for up to 6 months; and (iii) full vesting of any unvested equity awards held by Ms. Pierce.

**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)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; 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 6, 2021

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

**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)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; 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 6, 2021

By: \_\_\_\_\_  
**Siobhan Nolan Mangini**  
**Chief Financial Officer**  
**(Principal Financial Officer)**

**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**

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, 2021, 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.

Date: May 6, 2021

The undersigned have set their hands hereto as of the 6th day of May, 2021.

*/s/ David J. Woodhouse*

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

*/s/ Siobhan Nolan Mangini*

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**Siobhan Nolan Mangini**  
**Chief Financial Officer**  
***(Principal Financial Officer)***

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