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 September 30, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38853

NGM BIOPHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**26-1679911**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
333 Oyster Point Boulevard South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

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

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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 9, 2020, the registrant had 69,019,269 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)

	September 30, 2020	December 31, 2019*
Assets		
Current assets:		
Cash and cash equivalents	$ 253,976	$ 245,598
Short-term marketable securities	33,973	98,913
Related party receivable from collaboration	7,215	5,206
Prepaid expenses and other current assets	7,076	5,531
Total current assets	302,240	355,248
Property and equipment, net	15,773	19,475
Restricted cash	1,499	1,874
Other non-current assets	6,570	3,806
Total assets	$ 326,082	$ 380,403
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,613	$ 9,026
Accrued liabilities	28,579	22,991
Deferred rent, current	2,938	2,829
Deferred revenue, current	4,586	4,872
Total current liabilities	37,716	39,718
Deferred rent, non-current	7,179	9,392
Other non-current liabilities	4,315	—
Early exercise stock option liability	169	574
Total liabilities	49,379	49,684
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 September 30, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.001 par value; 400,000,000 shares authorized; 68,934,767 and 66,960,279 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	69	67
Additional paid-in capital	547,259	526,771
Accumulated other comprehensive gain	15	25
Accumulated deficit	(270,640)	(196,144)
Total stockholders' equity	276,703	330,719
Total liabilities and stockholders' equity	$ 326,082	$ 380,403

See accompanying notes to unaudited condensed consolidated financial statements.

*The condensed consolidated balance sheet as of December 31, 2019 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Related party revenue	$ 23,482	$ 21,568	$ 67,601	$ 72,461
Operating expenses:				
Research and development	46,979	28,953	123,912	87,299
General and administrative	6,460	5,612	19,849	17,208
Total operating expenses	53,439	34,565	143,761	104,507
Loss from operations	(29,957)	(12,997)	(76,160)	(32,046)
Interest income	260	1,984	1,823	5,138
Other income (expense), net	(68)	96	(159)	54
Net loss	$ (29,765)	$ (10,917)	$ (74,496)	$ (26,854)
Net loss per share, basic and diluted	$ (0.43)	$ (0.17)	$ (1.09)	$ (0.60)
Weighted average shares used to compute net loss per share, basic and diluted	68,815,696	65,948,207	68,174,654	44,828,596

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Net loss	$ (29,765)	$ (10,917)	$ (74,496)	$ (26,854)
Other comprehensive gain (loss), net of tax:				
Net unrealized gain (loss) on available-for-sale marketable securities	(122)	(3)	(10)	366
Total comprehensive loss	$ (29,887)	$ (10,920)	$ (74,506)	$ (26,488)

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	Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity
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
Issuance of common stock upon exercise of stock options	680	1	2,365	—	—	2,366
Issuance of common stock in connection with employee stock purchase plan	109	—	1,285	—	—	1,285
Issuance of common stock under 401(k) Plan	6	—	119	—	—	119
Vesting of common stock from early exercises	16	—	123	—	—	123
Stock-based compensation expense	—	—	3,723	—	—	3,723
Changes in unrealized gain on available-for-sale securities	—	—	—	192	—	192
Net loss	—	—	—	—	(25,616)	(25,616)
Balance at June 30, 2020	68,702	$ 69	$ 541,833	$ 137	$ (240,875)	$ 301,164
Issuance of common stock upon exercise of stock options	195	—	1,257	—	—	1,257
Vesting of common stock from early exercises	17	—	120	—	—	120
Stock-based compensation expense	—	—	4,049	—	—	4,049
Changes in unrealized loss on available-for-sale securities	—	—	—	(122)	—	(122)
Net loss	—	—	—	—	(29,765)	(29,765)
Balance at September 30, 2020	68,914	$ 69	$ 547,259	$ 15	$ (270,640)	$ 276,703

See accompanying notes to unaudited condensed consolidated financial statements.

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(Unaudited)
(In Thousands)

	Convertible Preferred Stock		Common Stock[1]		Additional Paid-In Capital	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity(Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	47,267	$ 294,874	6,733	$ 7	$ 39,258	$ (267)	$ (147,193)	$ (108,195)
Issuance of common stock upon exercise of stock options	—	—	80	—	279	—	—	279
Issuance of common stock under 401(k) Plan	—	—	8	—	98	—	—	98
Vesting of common stock from early exercises	—	—	34	—	237	—	—	237
Stock-based compensation expense	—	—	—	—	2,605	—	—	2,605
Changes in unrealized gain on available-for-sale securities	—	—	—	—	—	222	—	222
Net exercise of preferred stock warrant to Series A preferred stock	16	198	—	—	—	—	—	-
Cumulative effect adjustment upon adoption of ASU 2014-09	—	—	—	—	—	—	(6,156)	(6,156)
Net loss	—	—	—	—	—	—	(8,268)	(8,268)
Balance at March 31, 2019	47,283	$ 295,072	6,855	$ 7	$ 42,477	$ (45)	$ (161,617)	$ (119,178)
Conversion of Series A, B, C, D, E convertible preferred stock to common stock concurrent with initial public offering	(47,283)	(295,072)	47,283	47	295,025	—	—	295,072
Issuance of common stock upon initial public offering, net of issuance cost	—	—	7,521	8	107,748	—	—	107,756
Issuance of common stock upon private placement	—	—	4,122	4	65,943	—	—	65,947
Issuance of common stock upon exercise of stock options	—	—	86	—	258	—	—	258
Vesting of common stock from early exercises	—	—	32	—	245	—	—	245
Stock-based compensation expense	—	—	—	—	3,552	—	—	3,552
Changes in unrealized gain on available-for-sale securities	—	—	—	—	—	147	—	147
Net loss	—	—	—	—	—	—	(7,669)	(7,669)
Balance at June 30, 2019	—	—	65,899	$ 66	$ 515,248	$ 102	$ (169,286)	$ 346,130
Issuance of common stock upon exercise of stock options	—	—	116	—	643	—	—	643
Vesting of common stock from early exercises	—	—	32	—	244	—	—	244
Stock-based compensation	—	—	—	—	3,089	—	—	3,089
Changes in unrealized loss on available-for-sale securities	—	—	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	—	—	(10,917)	(10,917)
Balance at September 30, 2019	—	—	66,047	$ 66	$ 519,224	$ 99	$ (180,203)	$ 339,186

(1) In April 2019, the Company completed its initial public offering ("IPO") and concurrent private placement with Merck Sharp & Dohme Corp. ("Merck"), in which the Company issued an aggregate of 7,521,394 and 4,121,683 shares of common stock, respectively, for net proceeds of $107.8 million and $65.9 million, respectively. Upon the closing of the IPO, all of the then outstanding shares of convertible preferred stock were automatically converted into shares of common stock and its related carrying amount of $295.1 million was reclassified to common stock and additional paid-in-capital.

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (74,496)	$ (26,854)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	5,002	5,838
Amortization of discount on marketable securities	(208)	(1,024)
Stock-based compensation expense	11,467	9,246
Other non-cash expenses	236	212
Changes in operating assets and liabilities:		
Related party receivable from collaboration	(2,009)	3,669
Prepaid expenses and other assets	(3,715)	(4,334)
Accounts payable	(7,108)	(1,318)
Accrued expenses and other liabilities	9,765	4,485
Deferred rent	(2,104)	(1,994)
Deferred revenue	(286)	(14,499)
Net cash used in operating activities	(63,456)	(26,573)
Cash flows from investing activities		
Purchase of marketable securities	(29,399)	(75,224)
Proceeds from sales and maturities of marketable securities	94,537	172,767
Purchase of property and equipment	(1,605)	(2,430)
Net cash provided by investing activities	63,533	95,113
Cash flows from financing activities		
Proceeds from issuance of common stock upon initial public offering, net of issuance costs	—	110,078
Proceeds from issuance of common stock upon completion of private placement	—	65,947
Proceeds from issuance of common stock upon exercise of stock options	7,214	1,153
Proceeds from issuance of common stock in connection with employee stock purchase plan	1,285	—
Payments of deferred financing costs	(573)	—
Net cash provided by financing activities	7,926	177,178
Net increase in cash and cash equivalents	8,003	245,718
Cash, cash equivalents and restricted cash at beginning of period	247,472	59,172
Cash, cash equivalents and restricted cash at end of period	$ 255,475	$ 304,890
Non-cash investing and financing activities:		
Net exercise of convertible preferred stock warrant to Series A preferred stock	$ —	$ 198
Vesting of common stock from early exercises	405	726
Deferred offering costs accrued but not yet paid	21	-

See accompanying 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 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. The six most advanced proprietary product candidates in the Company's portfolio are aldafermin (NGM282), NGM313, NGM621, NGM120, NGM395 and NGM707.

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 generally accepted accounting principles in the United States of America ("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, 2019 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the United States Securities and Exchange Commission ("SEC") on March 17, 2020 (the "Annual Report"). 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 ("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.

Need for Additional Capital

Since inception, the Company has incurred net losses and negative cash flow from operations. During the three and nine months ended September 30, 2020, the Company incurred net losses of $29.8 million and $74.5 million, respectively, compared to $10.9 million and $26.9 million, respectively, for the three and nine months ended September 30, 2019. As of September 30, 2020, the Company had an accumulated deficit of $270.6 million and does not expect to experience positive cash flows from operations in the near future. The Company had $287.9 million of cash, cash equivalents and marketable securities as of September 30, 2020, which it considers sufficient to fund its operations for a period of at least one year from the date these unaudited condensed consolidated financial statements are available for issuance. The Company plans to continue to fund its operations and pursue its strategy through public or private equity or debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements or a combination of these.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, receivables from collaborations, the related party receivables from collaboration and other current assets and liabilities approximate their respective fair values because of the short-term nature of those instruments.

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 September 30, 2020 and December 31, 2019, 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 available-for-sale, carried at estimated fair values and reported in cash equivalents, short-term marketable securities or long-term marketable securities. Unrealized gains and losses on available-for-sale securities are excluded from net loss and reported in accumulated other comprehensive loss as a separate component of stockholders' equity. 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 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 September 30, 2020, 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 represents collateral in connection with the lease on the Company's headquarters entered into in 2015 and is classified as a non-current asset on the condensed consolidated balance sheets as the collateral will not be returned to the Company in less than 12 months *(Note 6)*.

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 collaboration agreements *(Note 5)* are typically unsecured. Accordingly, the Company may be exposed to credit risk generally associated with its Research Collaboration, Product Development and License Agreement with Merck ("Collaboration Agreement"). To date, the Company has not experienced any losses related to these receivables.

Merck accounted for 100% of the Company's revenue for the three and nine months ended September 30, 2020 and 2019.

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 applicable 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 applicable 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 September 30, 2020 and December 31, 2019, 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 asset and 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

The Company adopted Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers (Topic 606), and subsequent amendments, on January 1, 2019. ASC 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 ("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 regulatory 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 (“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 options and shares issued under the Company’s 2019 Employee Stock Purchase Plan (“ESPP”). Stock-based compensation to employees is valued on the grant date of each award using the Black-Scholes option-pricing model, and its estimated fair value is recognized over the period during which the employee is required to provide services in exchange for the award, which is generally the vesting period of each award. Stock-based compensation expense for non-employee stock-based awards is also measured based on the fair value on grant date with its estimated fair value recorded over the period for which the non-employee is required to provide services in exchange for the award. As non-cash stock-based compensation expense is based on awards ultimately expected to vest, it is reduced by an estimate for future forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures materially differ from estimates.

Foreign Currency Transactions

The functional currency of NGM Biopharmaceuticals Australia Pty Ltd., NGM Biopharmaceuticals, Inc’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 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 comprised of net loss and certain changes in equity that are excluded from net loss. For the three and nine months ended September 30, 2020, the difference between comprehensive loss and net loss consisted of changes in net unrealized gain on available-for-sale marketable securities of $0.1 million and zero , respectively, compared to zero and $0.4 million for the three and nine months ended September 30, 2019, respectively.

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 awards and warrants. Diluted net loss per share is computed giving effect to all potentially dilutive shares, including common stock issuable upon exercise of stock options, shares committed under the ESPP and unvested restricted common stock and stock units. As the Company incurred net losses for the three and nine months ended September 30, 2020 and 2019, all potential common shares were determined to be anti-dilutive and have been excluded in the diluted net loss per share calculations.

The following table sets forth the computation of net loss per common share (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,		
	2020	2019	2020	2019	
Numerator:					
Net loss	$ (29,765)	$ (10,917)	$ (74,496)	$ (26,854)	
Denominator:					
Weighted average number of shares used in calculating net loss per share—basic and diluted	68,815,696	65,948,207	68,174,654	44,828,596	(1)
Net loss per share—basic and diluted	$ (0.43)	$ (0.17)	$ (1.09)	$ (0.60)	

(1) In April 2019, the Company completed its IPO and concurrent private placement with Merck, in which the Company issued an aggregate of 7,521,394 and 4,121,683 shares of common stock, respectively, and all of the then outstanding shares of convertible preferred stock were automatically converted into shares of common stock upon the closing of the IPO.

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

	For the Three and Nine Months Ended September 30,	
	2020	2019
Options to purchase common stock	10,651,475	11,328,508
Shares committed under ESPP	353,754	429,369
Total	11,005,229	11,757,877

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 and nine months ended September 30, 2020 and 2019, the Company's revenues were entirely within the United States based upon the location of its partner.

Recent Accounting Pronouncements

New accounting pronouncements are issued by the Financial Accounting Standards Board ("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 our condensed consolidated financial statements 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 August 2018, the FASB issued ASU 2018-13, Fair Value Measurements (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement, as part of the FASB's disclosure framework project. ASU 2018-13 modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurements by removing the requirement to disclose amounts of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels and the valuation process for Level 3 fair value measurements. ASU 2018-13 also modifies existing disclosure requirements by clarifying that the measurement uncertainty disclosure is to communicate information about the uncertainty in measurement as of the reporting date, and adds required disclosures for the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The Company adopted ASU 2018-13 effective January 1, 2020, noting no material impact on the Company's condensed consolidated financial statements.

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 ("ROU") assets and lease liabilities arising from lease arrangements on the consolidated balance sheets, with the exception of leases with a term of 12 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 condensed consolidated 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. The new guidance 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 accordance with the new guidance in the fiscal year beginning after 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 will continue to evaluate the effect that this guidance will have on our condensed consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The new standard amends guidance on reporting credit losses for financial assets held at amortized cost basis, including accounts receivable, investments classified as available for sale, such as our debt securities, and unbilled related party revenue. Estimated credit losses will be recorded as an allowance rather than a write-down. In November 2019, the FASB issued ASU 2019-10, which deferred the effective date for certain ASUs including ASU 2016-13. This standard is now effective for the Company's fiscal year beginning after December 15, 2022. Early adoption is permitted for all entities. The Company is currently assessing the timing of adoption and the impact that the adoption of ASU 2016-13 will have on its condensed consolidated financial statements.

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 the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement and presentation and disclosure requirements. ASU 2018-18 adds unit-of-account guidance in ASC 808 to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606, and requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under ASC 606 is precluded if the collaborative arrangement participant is not a customer. ASU 2018-18 will be effective for the Company's fiscal year beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. The Company is currently assessing the timing of adoption and the impact that the adoption of ASU 2018-18 will have on its condensed consolidated financial statements.

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. ASU 2019-12 will be effective for the Company for its fiscal year beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022, and is required to be adopted prospectively, with the exception of certain specific amendments. The Company is currently assessing the timing of adoption and the impact that the adoption of ASU 2019-12 will have on its condensed consolidated financial statements.

3. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The carrying amount of certain financial instruments, including cash and cash equivalents, receivable from collaboration, related party receivable from collaboration and other current assets and liabilities approximate fair value due to their relatively short maturities. Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value accounting is applied to the convertible preferred stock warrant liabilities that are recorded at their estimated fair value in the condensed consolidated financial statements.

The FASB has defined fair value as the exchange price that would be received for an asset or paid to transfer a liability, or an exit price, in the principal or most advantageous market for that asset or liability in an orderly transaction between market participants on the measurement date, and established a fair value hierarchy that requires an entity to maximize the use of observable inputs, where available, and minimize the use of unobservable inputs when measuring fair value. The FASB set forth three levels of inputs that may be used to measure fair value:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

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.

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. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data and other observable inputs.

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

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
As of September 30, 2020				
Money market funds	$ 247,666	$ —	$ —	$ 247,666
Corporate and agency bonds	17,008	15	—	17,023
Commercial paper	16,950	—	—	16,950
Total	$ 281,624	$ 15	$ —	$ 281,639
Classified as:				
Cash and cash equivalents				$ 247,666
Short-term marketable securities (amortized cost of $33,958)				33,973
Total cash and cash equivalents and marketable securities				$ 281,639

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
As of December 31, 2019				
Money market funds	$ 244,973	$ —	$ —	$ 244,973
Corporate and agency bonds	66,063	28	(14)	66,077
Commercial paper	24,840	—	—	24,840
U.S. government agencies securities	7,985	11	—	7,996
Total	$ 343,861	$ 39	$ (14)	$ 343,886
Classified as:				
Cash and cash equivalents				$ 244,973
Short-term marketable securities (amortized cost of $98,888)				98,913
Total cash and cash equivalents and marketable securities				$ 343,886

Cash and cash equivalents in the table above excludes cash on deposit with banks of $6.3 million and $0.6 million as of September 30, 2020 and December 31, 2019, respectively.

As of September 30, 2020 and December 31, 2019, the Company's marketable securities had remaining contractual maturities less than one year. As of September 30, 2020, there were no marketable securities in an unrealized loss position compared to four marketable securities in an unrealized loss position as of December 31, 2019. Marketable securities that had been in an unrealized loss position as of December 31, 2019 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 sets forth the estimated fair value of the Company's financial assets and liabilities that were measured at fair value on a recurring basis as of September 30, 2020 and December 31, 2019 (in thousands):

	Fair Value Measurements			
As of September 30, 2020	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds	$ 247,666	$ —	$ —	$ 247,666
Corporate and agency bonds	—	17,023	—	17,023
Commercial paper	—	16,950	—	16,950
	$ 247,666	$ 33,973	$ —	$ 281,639

	Fair Value Measurements			
As of December 31, 2019	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds	$ 244,973	$ —	$ —	$ 244,973
Corporate and agency bonds	—	66,077	—	66,077
Commercial paper	—	24,840	—	24,840
U.S. government agencies securities	—	7,996	—	7,996
	$ 244,973	$ 98,913	$ —	$ 343,886

There were no transfers of assets or liabilities between the fair value measurement levels during the nine months ended September 30, 2020 and year ended December 31, 2019.

4. Balance Sheet Components

Cash, Cash Equivalent 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):

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 253,976	$ 245,598
Restricted cash	1,499	1,874
Total cash, cash equivalents and restricted cash	$ 255,475	$ 247,472

Property and Equipment

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

	September 30, 2020	December 31, 2019
Computer equipment	$ 1,239	$ 1,201
Laboratory equipment and office furniture	23,389	21,652
Leasehold improvements	25,880	25,880
Construction in process	23	498
Total property and equipment, gross	50,531	49,231
Less: accumulated depreciation and amortization	(34,758)	(29,756)
Total property and equipment, net	$ 15,773	$ 19,475

Depreciation expense was approximately $1.6 million and $5.0 million for the three and nine months ended September 30, 2020, respectively, compared to $1.9 million and $5.8 million for the three and nine months ended September 30, 2019, respectively.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	September 30, 2020	December 31, 2019
Accrued expenses	$ 4,674	$ 2,901
Clinical trials and research and development costs	9,705	11,051
Personnel-related costs	7,244	6,446
Manufacturing costs	6,956	2,593
Total accrued liabilities	$ 28,579	$ 22,991

5. Research Collaboration and License Agreements

Merck

In February 2015, the Company entered into the Collaboration Agreement with Merck, covering the discovery, development and commercialization of novel therapies across a range of therapeutic areas. Pursuant to this agreement, the Company received an upfront payment of $94.0 million in April 2015. Concurrent with entry into the Collaboration Agreement, the parties entered into a Stock Purchase Agreement in which Merck agreed to purchase 8,833,333 shares of Series E convertible preferred stock at a price of $12.00 per share, resulting in net proceeds of approximately $106.0 million. 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 overall 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 became effective in March 2015 with an original non-cancellable five-year term that ran through March 16, 2020. The collaboration includes a broad, multiyear drug discovery and early development program financially supported by Merck. The Company determines the scientific direction and areas of therapeutic interest, with input from Merck through various governance committees, and the Company is primarily responsible for the conduct of all research, preclinical and early clinical development activities through human proof of concept. The Company makes the final determinations as to which compounds to advance into and through initial clinical trials, which to progress into human proof-of-concept studies and the design of any such studies, with input from Merck through various governance committees. The Company may terminate its participation in any of the governance committees by providing written notice to Merck of its intention to disband and no longer participate. Merck funded both the internal and external costs of the Company's research and early development activities up to $75.0 million each year of the initial five-year term.

The Collaboration Agreement included an option to extend the research phase of the collaboration for two additional years through March 16, 2022 after the initial five-year term and a second option to further extend the research phase for two additional years through March 16, 2024. In March 2019, Merck exercised its option to extend the research phase of the collaboration for an additional two years through March 16, 2022. In connection with this extension, Merck agreed to continue to fund the Company's research and development efforts during the extension at the same levels as existed during the five-year initial 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 under the collaboration across 2021 and the first quarter of 2022. Under the terms of the Collaboration Agreement, Merck is required to pay a $20.0 million extension fee if it elects to exercise its second option to extend the research phase of the collaboration through March 16, 2024. During any extension, including the current extension and, if exercised, the potential second extension, the Company will provide distinct research and development services. Each extension is considered to be and is accounted for as a separate arrangement, if and when the option is exercised by Merck. Merck funded both the internal and external costs of the Company's research and early development activities up to $75.0 million each year of the initial five-year term and continues to do so during the current two-year extension.

When signed, the Collaboration Agreement included an exclusive worldwide license to the Company's growth differentiation factor 15 ("GDF15") receptor agonist program. In May 2019, Merck terminated its license to the GDF15 receptor agonist program.

Upon completion of a human proof-of-concept study for a particular compound, regardless of the results of such study, Merck has the one-time option, at a cost of $20.0 million, to obtain an exclusive, worldwide license, on specified terms, to that compound, as well as to other related compounds that are directed against the same target in the same manner. In 2018, Merck exercised its option on the NGM313 compound. If Merck exercises an option, Merck is responsible, at its own cost, for any further development and commercialization activities for compounds within that licensed program. Upon such exercise by Merck, the Company in turn has the right, at the start of the first Phase 3 clinical study for that compound, to elect to participate in a worldwide cost and profit share with Merck, as well as the option to co-detail the compound in the United States, or the Company can elect instead to receive milestone and royalty payments from Merck based on Merck's further development and commercialization of the compound. If the Company elects to participate in the cost and profit share, subject to certain limitations, Merck will provide the Company with financial assistance in the form of interest-bearing advances of the Company's share of the overall development costs, which Merck will recoup from the Company's share of any profit ultimately resulting from sales of the compound and other compounds that reach commercialization. If the Company does not opt in to the cost and profit sharing option, the Company is eligible to receive an aggregate of $449.0 million in milestone payments, of which $77.7 million relates to the potential achievement of specific clinical development events and $371.3 million relates to the potential achievement of certain regulatory events with respect to the licensed compound on an indication-by-indication basis for up to three indications in the United States, the European Union ("EU") and Japan. The Company may also receive commercial milestone payments up to $125.0 million and royalty payments of varying percentages based on the achievement of certain levels of net sales.

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

	First Indication	Second Indication	Third Indication
Upon administration of an applicable product to the first patient in the first Phase 3 clinical trial for such product for the given indication	$ 35,000	$ 25,250	$ 17,500

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

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

Under the Collaboration Agreement, the Company also granted Merck a worldwide, exclusive right to conduct research and development on small molecule compounds generated by Merck that have specified activity against any target that the Company is researching or developing during the research phase of the collaboration and about which the Company has generated unique biological insights. If Merck ultimately does not exercise its license option to the 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 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 the 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 license from the Company, in some cases at the same rates as those the Company is eligible to receive from Merck for a licensed program originating from the Company's own research and development efforts, provided that, but for use of the Company's 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 such small molecule compounds.

At the end of the research phase, Merck has the right to either require the Company to continue to conduct research and development activities with respect to certain of the then-existing programs for a "tail period" of up to three years by agreeing to pay the Company's internal and external costs for the related work subject to certain funding limitations that will decline over the course of the tail period, or to take over such selected programs and conduct such research and development activities itself, at its own cost.

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 Arrangement: (i) license to GDF15 receptor agonist program; (ii) license to pursue research and development and commercialization of certain 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 receptor 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 fees attached to the exercise of such options approximated the SSP of the promised, distinct services included in the options. Therefore, the options do not give rise to material rights, are not performance obligations in the Collaboration Agreement and will be accounted for as separate arrangements under ASC 606, if and when exercised by Merck. This also includes license options, such as the $20.0 million license fee that was triggered by the exercise of Merck's license option on NGM313 in November 2018. The Company recognized the license fee as revenue in the period of exercise (i.e., the fourth quarter of 2018) as the Company has no further obligations related to such license. A Phase 3 clinical study for NGM313 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 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.

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 initial five-year term of the Collaboration Agreement is comprised of the upfront payment and the ongoing research and development reimbursements.

As there is only one performance obligation in the Collaboration Agreement, the transaction price was allocated entirely to that performance obligation. The Company uses a cost-based input method to calculate the corresponding amount of revenue to recognize. The Company believes this is the best measure of progress given that other measures do not reflect how the Company transfers its performance obligation to Merck. In applying the cost-based input measure of revenue recognition, the Company measures actual costs incurred relative to budgeted costs to fulfill the combined 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. The Company re-evaluates the estimate of expected costs to satisfy the performance obligation each reporting period and makes adjustments for any significant changes. For example, in May 2019, Merck terminated its license to the GDF15 receptor agonist program. The research and development services within the Collaboration Agreement are not affected by the GDF15 receptor agonist program license termination and are expected to continue through the remainder of the research program term. Therefore, there were no changes to the transaction price as a result of this license termination. At the end of the initial five-year term of the Collaboration Agreement, the remaining deferred revenue 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 across 2021 and 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 deferred revenue or contract assets. As of September 30, 2020, the Company has recognized revenue of approximately $42.4 million associated with the performance obligation for the two-year extension period.

In connection with the Series E convertible preferred stock purchase agreement, the Company and Merck entered into an agreement whereby Merck agreed to purchase 4,121,683 shares of our 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 IPO.

Summary of Related Party Revenue

The Company recognized revenue from the Collaboration Agreement as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Related party revenue	$ 23,482	$ 21,568	$ 67,601	$ 72,461

For the three and nine months ended September 30, 2020, the Company recognized related party revenue under the Collaboration Agreement of $23.5 million and $67.6 million, respectively, of which zero and $4.9 million, respectively, were recognized from the upfront license fee that was previously included in the transaction price associated with the initial five-year term of the Collaboration Agreement that concluded in March 2020, with the remaining balances related to the reimbursable research and development activities, all of which were recognized using the cost-based input model.

For the three and nine months ended September 30, 2019, the Company recognized related party revenue under the Collaboration Agreement of $21.6 million and $72.5 million, respectively, of which $5.4 million and $16.8 million, respectively, were recognized from the upfront license fee that was previously included in the transaction price associated with the initial five-year term of the Collaboration Agreement that concluded in March 2020, with the remaining balances related to the reimbursable research and development activities, all of which were recognized using the cost-based input model.

Contract Assets and Liabilities

Changes in related party contract liabilities were as follows (in thousands):

	Amounts
Balance at December 31, 2019	$ 4,872
Revenue recognized through March 16, 2020	(4,872)
Increases as a result of research and development expenses to be earned under the Collaboration Agreement	4,586
Balance at September 30, 2020	$ 4,586

There were no contract assets for all the periods presented.

6. Commitments and Contingencies

Operating Lease and Lease Guarantee

In September 2009, the Company entered into an operating lease (as amended in June 2014, the “2014 Lease Amendment”) for a corporate office space and laboratory facility at 630 Gateway Blvd, in South San Francisco, California (“630 Gateway”) for approximately 50,000 square feet, which expires in November 2020. The 2014 Lease Amendment provided for tenant improvement allowances of $0.8 million. The 2014 Lease Amendment contains scheduled rent increases over the lease term and has an option for the Company to extend the lease for an additional three-year term.

In December 2015, the Company entered into an operating lease for its current corporate office space and laboratory facility at 333 Oyster Point Blvd, South San Francisco, California (“333 Oyster Point”) for approximately 122,000 square feet, which 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 requires 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 3rd anniversary and 4th anniversary of the rent commencement date. In September 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 July 2016, the Company assigned its operating lease of 630 Gateway to Merck, a related party, due to the Company's relocation to 333 Oyster Point. As part of the assignment of the lease, the Company is liable to the lessor if Merck defaults on its lease obligations. Therefore, in substance, the Company has guaranteed the lease payments for 630 Gateway, including lease-related expenses such as utilities, property tax, and common area maintenance, without any limitations. The Company assessed the need for a potential guarantee liability on the assigned lease, and concluded that the value of the guarantee was insignificant as of September 30, 2020 because of the short duration of the remaining lease term through November 2020, and Merck's credit rating of AA- and subsequent investment in tenant improvements to the facility. As of September 30, 2020 and 2019, the remaining lease payment obligations that are due for 630 Gateway were approximately $0.4 million and $2.4 million, respectively, which are to be paid directly from Merck to the lessor.

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 September 30, 2020 and 2019 and $1.6 million for each of the nine months ended September 30, 2020 and 2019.

Future minimum payments under the unassigned lease obligations described above are as follows as of September 30, 2020 (in thousands):

Year Ending December 31,		
2020	$	1,267
2021		5,141
2022		5,294
2023		5,455
Total	$	17,157

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 is subject to 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 September 30, 2020, the Company did not have any shares of preferred stock issued or outstanding.

Common Stock

As of September 30, 2020 and December 31, 2019, the Company had 68,934,767 and 66,960,279 shares of common stock outstanding, respectively, which includes shares subject to repurchase of 21,899 and 74,454, respectively, as a result of early exercise of stock options not yet vested. As of September 30, 2020 and December 31, 2019, the Company reserved shares of common stock for issuance as follows:

	September 30, 2020	December 31, 2019
Common stock options outstanding	10,651,475	10,824,780
Common stock options available for grant	6,309,573	5,316,066
401(k) Matching Plan	21,930	28,274
ESPP shares available for purchase	788,120	897,255
Total	17,771,098	17,066,375

Stock Option Plan

In 2018, the Company adopted the 2018 Equity Incentive Plan (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 over 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. The Company's 2008 Equity Incentive Plan (the "2008 Plan") expired at the beginning of 2018.

Stock Option Activity

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

		Outstanding Options			
	Options Available for Grant	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In Thousands)
Balances at December 31, 2019	5,316,066	10,824,780	$ 7.52	6.29	$ 118,770
Additional shares reserved	2,678,411				
Options granted	(2,357,601)	2,357,601	17.39		
Options exercised	—	(1,858,209)	3.88		
Options cancelled	672,697	(672,697)	12.37		
Balances at September 30, 2020	6,309,573	10,651,475	$ 10.03	6.52	$ 66,241
Vested and expected to vest at September 30, 2020		10,542,700	$ 9.98	6.49	$ 66,082
Outstanding and exercisable at September 30, 2020		10,651,475	$ 10.03	6.52	$ 66,241

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 nine months ended September 30, 2020 and 2019 was $10.32 and $7.93 per share, respectively. The intrinsic value of stock options exercised was $27.0 million and $3.0 million for the nine months ended September 30, 2020 and 2019, 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 and nine months ended September 30, 2020 and 2019.

Employee Stock-Based Compensation Expense

Employee and director stock-based compensation expense for the three and nine months ended September 30, 2020 and 2019 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 and nine months ended September 30, 2020 and 2019, which was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Research and development	$ 2,117	$ 1,652	$ 6,039	$ 5,114
General and administrative	1,867	1,405	5,300	4,030
Total stock-based compensation expense	$ 3,984	$ 3,057	$ 11,339	$ 9,144

Non-employee Stock-Based Compensation Expense and Grants

The Company grants stock options to non-employees in exchange for services performed for the Company. The Company granted 67,500 stock options to non-employees during the nine months ended September 30, 2020 and granted 22,500 stock options to non-employees during the nine months ended September 30, 2019. Stock-based compensation expense related to stock-based payment awards to non-employees for the three and nine months ended September 30, 2020 was $65,000 and $128,000, respectively, compared to $32,000 and $102,000 for the three and nine months ended September 30, 2019, respectively.

Employee Stock Purchase Plan

Under the ESPP, eligible employees are granted the right to purchase shares of our 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 September 30, 2020, 211,880 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, 2020. Additionally, the Company's net deferred tax assets have been fully offset by a valuation allowance. Therefore, the Company has not recorded a tax provision for income taxes for the three and nine months ended September 30, 2020.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") was enacted. Under U.S. GAAP, the Company is required to recognize the tax effects of new legislation in the reporting period in which the legislation was enacted. The CARES Act included changes to current U.S. tax provisions that benefit business entities and modified certain tax provisions of the 2017 Tax Cuts and Jobs Act (the "2017 Tax Act"). The tax relief measures included a five-year net operating loss carryback, suspension of the annual deduction limitation of 80% of taxable income from net operating losses generated in a tax year beginning after December 31, 2017, changes in the deductibility of interest, acceleration of alternative minimum tax credit refunds, payroll tax relief and a technical correction to allow accelerated deductions for qualified improvement properties. The CARES Act also provided other non-tax benefits to assist business entities impacted by the ongoing COVID-19 pandemic. The Company has evaluated the CARES Act and concluded that it did not result in any material adjustments to the Company's income tax provision or net deferred tax assets for the three and nine months ended September 30, 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

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 leading causes of morbidity and mortality and a significant burden for healthcare systems. Since the commencement of our operations in 2008, we have generated a robust portfolio of product candidates. Our most advanced product candidate, aldafermin, previously known as NGM282, is wholly-owned and entered Phase 2b development for the treatment of non-alcoholic steatohepatitis ("NASH") in 2019. Aldafermin is an engineered variant of the human hormone fibroblast growth factor 19 ("FGF19"). In July, our NGM621 product candidate entered Phase 2 development for the treatment of geographic atrophy ("GA"), an advanced form of age-related macular degeneration ("AMD"). Our partner Merck Sharp & Dohme Corp.("Merck") plans to move MK-3655, previously referred to as NGM313, an FGFR1c/KLB agonistic antibody discovered at NGM and optioned by Merck in 2018 under our collaboration with Merck as described below, into a Phase 2b study for NASH in the fourth quarter of 2020. In addition to three product candidates in Phase 2 trials, a systemically administered version of NGM621 and two of our other product candidates are in Phase 1 clinical trials. Our NGM120 product candidate is being studied in an ongoing Phase 1a/1b study to assess the anti-cancer anorexia/cachexia syndrome ("CACS") and anti-cancer effect of NGM120 in patients with advanced solid tumors. NGM395 is being studied in a Phase 1 clinical trial evaluating the safety, tolerability and pharmacokinetics of NGM395 in obese but otherwise healthy adults. We are conducting investigational new drug ("IND")-enabling activities on NGM707 with a goal of initiating a Phase 1 study in mid-2021. NGM707 is a novel dual antagonist antibody designed to inhibit ILT2 (Immunoglobulin-like transcript 2) and ILT4 (Immunoglobulin-like transcript 4) with the goal of improving patient immune responses to tumors through myeloid reprogramming. Certain other undisclosed programs are in preclinical studies. All of our product candidates other than aldafermin and NGM395 are subject to our Merck collaboration as described below.

In February 2015, we entered into a research collaboration, product development and license agreement (the "Collaboration Agreement") with Merck that allows us, through the current two-year extension of the research phase of the collaboration, to develop multiple product candidates in parallel without bearing substantially greater costs or incurring significantly greater risk compared to developing product candidates, such as aldafermin and NGM395, on our own. Since inception through September 30, 2020, Merck had paid us $479.8 million, of which $20.0 million was to license NGM313 and related compounds and $459.8 million was an upfront payment and reimbursement of research and development expenses. In March 2019, Merck exercised its option to extend the research phase of the collaboration through March 16, 2022 and has the right to extend it again through March 16, 2024. As part of the extension through March 16, 2022, Merck agreed to continue to fund our research and development efforts at the same levels as existed during the initial five-year term and, in lieu of a $20.0

million extension fee payable to us, Merck agreed to make additional payments totaling up to $20.0 million in support of our research and development activities across 2021 and the first quarter of 2022.

In April 2019, we completed the IPO of our common stock, in which we issued an aggregate of 7,521,394 shares of common stock, including 854,727 shares of common stock issued pursuant to the over-allotment option granted to the underwriters, at a price of $16.00 per share, before underwriting discounts and commissions. We received approximately $107.8 million in net proceeds, after deducting underwriting discounts, commissions and offering expenses of $4.1 million. The offering expenses were offset against the net proceeds received from the sale of common stock. At the closing of the IPO, all shares of outstanding convertible preferred stock were automatically converted to 47,283,839 shares of common stock. Concurrent with the completion of the IPO, we also issued 4,121,683 shares of common stock to Merck in a private placement at a price of $16.00 per share for proceeds of $65.9 million, which resulted in Merck owning approximately 19.9% of our outstanding shares of common stock immediately following the IPO.

We have incurred net losses in each year since our inception. Our net losses were $29.8 million and $74.5 million for the three and nine months ended September 30, 2020, respectively, compared to net losses of $10.9 million and $26.9 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $270.6 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from 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 revenue recognition, our clinical trials and our expenses on other research and development and related activities.

Since inception, we have funded our operations primarily through the private placement of convertible preferred stock totaling $295.1 million, net proceeds from our IPO of $107.8 million, proceeds from a private placement of shares of common stock to Merck of $65.9 million, research and development service fees provided by collaboration partners, primarily Merck, of $382.3 million, upfront license fees paid by collaboration partners, primarily Merck, of $123.0 million and the license fee from Merck for NGM313 and related compounds of $20.0 million. We do not have any products approved for sale and do not anticipate generating revenue from product sales for the foreseeable future, if ever.

We plan to continue to fund our operations and pursue our strategy through public or private equity or debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements or a combination of these. In June 2020, we entered into an Open Market Sale Agreement℠ (the “Sales Agreement”) with Jefferies LLC (“Jefferies”) pursuant to which we may elect to issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $150.0 million through Jefferies acting as our sales agent and/or principal. We are not obligated to make any sales of common stock under the Sales Agreement, and we have not yet sold any common stock pursuant to the Sales Agreement. Refer to the *"Liquidity and Capital Resources"* section of this MD&A for more details. The sale of convertible debt or additional equity, including pursuant to the Sales Agreement, could result in additional dilution to our stockholders. Incurring indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. We cannot ensure that financing will be available in the amounts we need or on terms acceptable to us, if at all. 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 not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or delay, scale back or discontinue planned programs. Any of these actions could materially harm our business, financial condition, results of operations and future prospects. To the extent we obtain additional funding through collaborations, these arrangements would generally require us to relinquish rights to some of our technologies, product candidates or products, and we may not be able to enter into such agreements on acceptable terms, if at all.

We have no manufacturing facilities and all of our manufacturing activities are contracted out to third parties who are generally single source suppliers. We also utilize third-party CROs to carry out certain clinical development activities.

COVID-19 Business Update

We are continuing to closely monitor the impact of the global COVID-19 pandemic on our business and have taken and continue to take proactive efforts designed to protect the health and safety of our patients, study investigators, clinical research staff and employees, and to maintain business continuity. We will continue to closely monitor conditions and guidance from governmental authorities and adjust our activities as appropriate.

Based on guidance issued by federal, state and local authorities, we transitioned to a remote work model for a majority of our employees in March 2020, while maintaining essential in-person laboratory functions in order to advance key research and development initiatives, supported by the implementation of updated onsite safety procedures. In June 2020, following updated guidance issued by federal, state and local authorities, we re-opened our laboratory facilities for research activities 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. 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. These and similar, and perhaps more severe, disruptions in our operations could materially and adversely impact our business, financial condition, results of operations and growth prospects.

In the conduct of our business activities, we have taken and continue to take actions designed to protect the safety and well-being of patients, healthcare workers and employees. 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 been evaluating and, when necessary, will continue to evaluate clinical trial site initiations and patient enrollment on a case-by-case and patient-by-patient basis in coordination with clinical trial investigators and site staff. Most 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. These internal and external efforts have allowed us to continue progress across our clinical development programs and, while 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 our Phase 2b clinical trial of aldafermin for the treatment of NASH patients with fibrosis stage F4 (the “ALPINE 4 trial”) and our Phase 2 clinical trial of NGM621 for the treatment of GA (the “CATALINA trial”), the impact of the COVID-19 pandemic to date has not resulted in a significant impact to our clinical development timelines and we currently remain on track with previously provided timelines.

While the COVID-19 pandemic has not yet resulted in a significant impact to our clinical development timelines, 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 impact 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 to COVID-19, may be unwilling to enroll in, and enrolled patients may be unwilling to continue to participate in, our clinical trials due to an unwillingness to travel to sites for required screening and clinical trial visits and procedures. Enrolled patients may 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. As such, 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, 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 ("cGCPs"), with any material protocol deviation reviewed and approved by the clinical trial site Institutional Review Boards ("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 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 could also see an 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 regulatory 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 supply for our ongoing clinical trials due to the effects of the COVID-19 pandemic, we could experience disruptions to our supply chain and operations resulting from the evolving effects of the COVID-19 pandemic, and associated delays in the manufacturing and supply of 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, 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 materials and preparation for potential Phase 3 testing, if Lonza Sales AG, our manufacturer of the aldafermin drug substance, and/or our aldafermin 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 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 Sales AG 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, the potential Phase 3 testing of aldafermin which could materially and adversely affect our business. In any event, if the evolving effects of the COVID-19 pandemic 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.

In addition, 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 or to exercise its remaining option to extend the research phase of the collaboration beyond March 16, 2022.

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 as 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. 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"* under Part II, Item 1A in 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 research and development service funding pursuant to our collaboration agreements, the most significant of which is our Collaboration Agreement with Merck. Merck is also a significant stockholder and, as a result, considered a related party. Collaboration revenue from Merck is therefore referred to as related party revenue. Under the Collaboration Agreement, we receive research and development funding and we may be entitled to receive additional milestone and other contingent payments in the future upon the occurrence of specific events.

We use the cost-based input method in accordance with 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 two-year extension period could have a material impact on revenue recognized (including the possible reversal of previously recognized revenue) at each reporting period. Due to the nature of the Collaboration Agreement and our revenue recognition policy, our revenue has fluctuated from period to period in the past and we expect that it will continue to fluctuate in future periods.

The following table summarizes our related party revenue for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Related party revenue	$ 23,482	$ 21,568	$ 67,601	$ 72,461

Research and Development Expenses

Research and development 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 research and development expenses consist of both internal and external costs. Our internal costs include employee, consultant, facility and other research and development 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 costs related to manufacturing drug substance, drug product and other clinical trial materials.

Our clinical development efforts are spread across multiple programs, some of which are subject to the Merck collaboration and two of which, aldafermin and NGM395 (a product candidate within our GDF15 receptor agonist program), are wholly-owned and funded by us. Our lead product candidate, aldafermin, is being studied in two ongoing Phase 2b clinical trials for the treatment of NASH. 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 the development of aldafermin. We are also devoting financial resources to the development of NGM395, a long-acting GDF15 analog. 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 or in the event Merck elects to terminate its license to a program, or for any Merck-licensed programs that we opt to co-develop.

In the first quarter of 2020, we completed the fourth and final 24-week expansion cohort of a Phase 2 trial of aldafermin, a double-blind, placebo-controlled study of once-daily 1 mg aldafermin for the treatment of patients with fibrosis stage F2 or F3 NASH. Our ongoing Phase 2b clinical trials include our ALPINE 2/3 clinical trial, a double-blind, placebo-controlled study testing 0.3 mg, 1 mg and 3 mg daily doses of aldafermin for 24 weeks for the treatment of NASH patients with fibrosis stage F2 or F3, which has completed enrollment, and our ALPINE 4 trial, a double-blind, placebo-controlled study testing 0.3 mg, 1 mg and 3 mg daily doses of aldafermin for 48 weeks for the treatment of fibrosis stage F4 NASH patients with compensated cirrhosis. The ALPINE 4 trial was initiated in the first quarter of 2020. Significant portions of our research and development resources are focused, and will continue to be focused, on these clinical trials and other 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.

NGM395 and NGM386 comprise our GDF15 receptor agonist program and both were licensed to Merck at the inception of the Merck collaboration. Substantially all of the related research and development expenses for these product candidates were borne directly by Merck under our Collaboration Agreement until May 2019, when Merck terminated its license to the GDF15 receptor agonist program and we regained full rights to NGM395 and NGM386. Following our assessment of the NGM386 study results, we decided to suspend activities related to NGM386 and focus on advancing NGM395. In the first quarter of 2020, we initiated a Phase 1 clinical trial evaluating the safety, tolerability and pharmacokinetics of NGM395 in obese but otherwise healthy adults. As a result, we expect to continue to incur research and development expenses with respect to NGM395 in the future.

Our research and development efforts under the Merck collaboration are also extensive and costly and are subject to reimbursement under our Merck collaboration during the current two-year extension up to the funding caps provided in the Collaboration Agreement. If our research and development expenses related 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 our Collaboration Agreement, which we expect to happen in the fiscal year ending December 31, 2020 and potentially thereafter, we will be required to devote our own financial resources toward the development of programs and product candidates subject to the Merck collaboration or pause or suspend such development to remain within the funding caps.

NGM621 is a humanized IgG1 monoclonal antibody engineered to inhibit activity of complement C3 with the goal of reducing disease progression in patients with GA. We recently completed a Phase 1 study of NGM621 assessing the safety and tolerability of single- and multiple-dose intravitreal injections of NGM621 in patients with GA. This clinical trial demonstrated that NGM621 was well tolerated at all doses studied and supported the initiation of a Phase 2 clinical trial in July 2020. The CATALINA trial is a multicenter, randomized, double-masked, sham-controlled study designed to evaluate the safety and efficacy of NGM621 intravitreal injections compared to sham control and to serve as a proof-of-concept trial under the Collaboration Agreement. Merck has a one-time option to license NGM621 upon our completion of a proof-of-concept study in humans.

Our NGM120 product candidate, an antagonistic antibody binding glial cell-derived neurotrophic factor receptor alpha-like (“GFRAL”), is designed to block the effects of elevated GDF15 levels to treat CACS, and, possibly, tumors. In our completed Phase 1 clinical trial assessing safety, tolerability and pharmacokinetics, NGM120 was well tolerated at all doses studied and the pharmacokinetics supported once-monthly dosing. In the first quarter of 2020, we initiated a Phase 1a/1b study to assess the anti-CACS and anti-cancer effect of NGM120 in patients with advanced solid tumors and to serve as a proof-of-concept trial under the Collaboration Agreement. Merck has a one-time option to license NGM120 upon our completion of a proof-of-concept study in humans.

Our research and development expenses related to the development of our product candidates consist primarily of:

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

The process of supplying materials for and conducting preclinical studies and clinical trials necessary to obtain regulatory approval of our product candidates is costly and time consuming. We may never succeed in achieving marketing approval for any of our product candidates. The success of each product candidate may be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability, our sales capabilities, our ability to work effectively with our collaboration partners, regulatory matters, third-party payor matters and commercial viability.

In 2018, Merck exercised its option to license our NGM313 program. NGM313, now known as MK-3655, is an agonistic antibody selectively modulating fibroblast growth factor receptor 1c-beta-klotho (“FGFR1c/KLB”). Upon exercising its license, Merck became responsible for all future development expenses for NGM313 unless we elect to exercise our worldwide cost and profit sharing option at the commencement of Phase 3 testing, at which point we would be responsible for a portion of the future development expense. NGM313 completed the single ascending dose and multiple ascending dose portions of Phase 1 testing in overweight or obese but otherwise healthy adults, as well as a Phase 1b study in obese insulin resistant subjects with nonalcoholic fatty liver disease. Merck is expected to initiate a Phase 2b study of NGM313 in NASH patients in the fourth quarter of 2020.

The following is a comparison of research and development expenses for our programs, including programs that are subject to our Collaboration Agreement with Merck, for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
External research and development expenses:				
Aldafermin (FGF19 analog)	$ 15,212	$ 8,840	$ 40,649	$ 21,554
NGM313 (FGFR1c/KLB agonist)	51	215	583	1,998
NGM621 (Anti-Complement C3)	5,204	781	9,099	3,263
NGM120 (GFRAL antagonist)	1,146	431	4,040	2,614
NGM395 (GDF15 analog)	317	31	1,924	457
NGM707 (Anti-ILT2/ILT4 dual antagonist)	1,240	-	3,843	-
Other external research and development expenses	2,719	1,126	7,027	5,179
Total external research and development expenses	25,889	11,424	67,165	35,065
Personnel-related expenses	10,755	9,180	32,348	27,594
Internal and unallocated research and development expenses(1)	10,335	8,349	24,399	24,640
Total research and development expenses	$ 46,979	$ 28,953	$ 123,912	$ 87,299

(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.

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 and if or when we may receive any significant revenue from sales of any approved product candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- delays in key trial activities and patient enrollment or diversion of healthcare resources as a result of the evolving effects of the COVID-19 pandemic or otherwise;
- manufacturing scale-up challenges or production shortages or other supply interruptions in clinical trial materials resulting from the evolving effects of the COVID-19 pandemic or otherwise;
- our ability to hire and retain key research and development personnel;
- whether Merck will elect to license or terminate its license to any of our programs and the timing of such election or termination;
- the scope, rate of progress, results and expense of our ongoing, as well as any additional, clinical trials and other research and development activities; and
- the timing and receipt of any regulatory approvals.

A change in the outcome of any of the risks and uncertainties associated with the development of a product candidate, including those risks and uncertainties associated with the evolving effects of the COVID-19 pandemic, could mean a significant change in the costs and timing associated with the development of that product candidate and its likelihood of potential approval. For example, if the U.S. Food and Drug Administration (“FDA”) or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in the initiation, enrollment or completion of any of our clinical trials, whether due to the evolving effects of the COVID-19 pandemic or otherwise, we could be required to expend significant additional financial resources and time on the completion of clinical development. For additional information about risks and uncertainties related to our research and development efforts, see the section titled “*Risk Factors*” under Part II, Item 1A in 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 research and development 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 research and development activities. These increases will likely include increased costs related to the hiring of additional personnel and fees 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 SEC requirements and insurance and investor relations costs. 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

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

The following table summarizes our results of operations for the three and nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
Related party revenue	$ 23,482	$ 21,568	$ 1,914	$ 67,601	$ 72,461	$ (4,860)
Operating expenses:						
Research and development	46,979	28,953	18,026	123,912	87,299	36,613
General and administrative	6,460	5,612	848	19,849	17,208	2,641
Total operating expenses	53,439	34,565	18,874	143,761	104,507	39,254
Loss from operations	(29,957)	(12,997)	16,960	(76,160)	(32,046)	44,114
Interest income	260	1,984	(1,724)	1,823	5,138	(3,315)
Other income (expense), net	(68)	96	(164)	(159)	54	(213)
Net loss	$ (29,765)	$ (10,917)	$ 18,848	$ (74,496)	$ (26,854)	$ 47,642

Related Party Revenue. Related party revenue was $23.5 million and $21.6 million for the three months ended September 30, 2020 and 2019, respectively. The increase of $1.9 million in revenue was primarily attributable to a $6.6 million increase in research and development revenue, partially offset by a decrease of $4.7 million related to the partial recognition of an initial upfront payment received from Merck that was included within the transaction price that was recognized over the initial five-year term of the Collaboration Agreement using the cost-based input model, which ended in the first quarter of 2020.

For the nine months ended September 30, 2020 and 2019, related party revenue was $67.6 million and $72.5 million, respectively. The decrease of $4.9 million in revenue was primarily attributable to a decrease of $10.2 million related to the partial recognition of an initial upfront payment received from Merck that was included within the transaction price that was recognized over the initial five-year term of the Collaboration Agreement using the cost-based input model, which ended in the first quarter of 2020. The revenue decreases were offset by an increase of $5.3 million in research and development revenue.

Research and Development Expenses. Research and development expenses were $47.0 million and $29.0 million for the three months ended September 30, 2020 and 2019, respectively. The increase in research and development expenses of $18.0 million was primarily attributable to an increase of $12.8 million in external expenses, mainly driven by our manufacturing activities, ongoing clinical trials for aldafermin, NGM621, NGM120 and NGM395, and ongoing research activities for our preclinical product candidates, including manufacturing activities for NGM707. Additionally, our internal unallocated research and development expenses relating to multiple research and development programs and personnel-related expenses increased by a net $5.2 million.

For the nine months ended September 30, 2020 and 2019, research and development expenses were $123.9 million and $87.3 million, respectively. The increase in research and development expenses of $36.6 million was primarily attributable to an increase of $31.2 million in external expenses, mainly driven by our manufacturing activities, ongoing clinical trials related to aldafermin, NGM621, NGM120 and NGM395 and an increase of $5.4 million in personnel-related expenses due to increased headcount and internal and unallocated research and development expenses related to multiple research and development programs.

We expect our research and development expenses will continue to increase substantially in connection with our ongoing activities, particularly to the extent that product candidates whose costs are not included in the Merck collaboration, such as aldafermin and NGM395, 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.

General and Administrative Expenses. General and administrative expenses were $6.5 million and $5.6 million for the three months ended September 30, 2020 and 2019, respectively. The increase in general and administrative expenses of $0.9 million was primarily driven by personnel-related expenses due to increased headcount.

For the nine months ended September 30, 2020 and 2019, general and administrative expenses were $19.8 million and $17.2 million, respectively. The increase in general and administrative expenses of $2.6 million was primarily attributable to personnel-related expenses due to increased headcount.

Interest Income. Interest income was $0.3 million and $2.0 million for the three months ended September 30, 2020 and 2019, respectively, and $1.8 million and $5.1 million for the nine months ended September 30, 2020 and 2019, respectively. The decrease in interest income is primarily driven by the decrease in market interest rates and a reduction in our cash balance.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operating activities since our inception. To date, our operations have been funded primarily through the private placement of convertible preferred stock, net proceeds from our IPO and proceeds from the concurrent private placement to Merck, research and development service fees provided by collaboration partners, primarily Merck, upfront license fees paid by collaboration partners and the license fee from Merck for NGM313. As of September 30, 2020, we had cash and cash equivalents of $254.0 million, short-term marketable securities of $34.0 million, working capital (excluding deferred revenue) of $269.1 million and an accumulated deficit of $270.6 million.

We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development of our product candidates, maintain our expanded corporate infrastructure to support operations as a public company and conduct pre-commercialization activities. We will require substantial additional capital to achieve our development and commercialization goals for our programs being conducted outside of the Merck collaboration, aldafermin and NGM395, as they advance in clinical development, for any future programs that Merck does not opt to license under the Collaboration Agreement and that we choose to develop, for any Merck-licensed programs that we opt to co-develop, and for any programs that Merck chooses to license under the Collaboration Agreement and later elects to terminate. Additionally, if our research and development expenses for product candidates subject to the Merck collaboration exceed the funding caps provided in our Collaboration Agreement, which we expect to happen in the fiscal year ending December 31, 2020 and potentially thereafter, we will be required to devote our own financial resources toward the development of such product candidates or pause or suspend such development to remain within the funding caps. In addition, if Merck elects not to extend our collaboration for a second additional two-year period, we would require significant additional capital in order to proceed with development and commercialization of any product candidates that had been subject to the Merck collaboration but for which Merck decides not to proceed after termination, or we will need to enter into additional collaboration or license agreements in order to fund such development and commercialization or delay, scale back or discontinue development of such product candidates.

We plan to continue to fund our operations and pursue our strategy through public or private equity or debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements or a combination of these. For example, in June 2020, we entered into the Sales Agreement with Jefferies, which provides that, upon the terms and subject to the conditions and limitations set forth in the Sales Agreement, we may elect to issue and sell, from time to time, shares of our common stock having an aggregate offering price of up to $150.0 million through Jefferies acting as our sales agent and/or principal. Under the Sales Agreement, Jefferies may sell the shares of common stock by any method permitted by law deemed to be an “at the market offering” as defined under the Securities Act of 1933, as amended (the “Securities Act”), in block transactions or in privately-negotiated transactions with our consent. Jefferies will use commercially reasonable efforts to sell the shares of common stock subject to the Sales Agreement from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions that we may impose). We will pay Jefferies a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Jefferies under the Sales Agreement. We are not obligated to make any sales of common stock under the Sales Agreement, and we have not yet sold any common stock pursuant to the Sales Agreement.

The sale of convertible debt or additional equity, including pursuant to the Sales Agreement, could result in additional dilution to our stockholders. Incurring indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations. We cannot ensure that financing will be available in the amounts we need or on terms acceptable to us, if at all. Our ability to raise additional capital may be adversely impacted by worsening global economic conditions and 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. In addition, extreme price and volume fluctuations in the stock market in general, and the Nasdaq Global Select Market, in particular, have resulted in volatile and sometimes decreased stock prices for many companies, including us. 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, and impact our ability to raise sufficient additional capital on acceptable terms, if at all. If we are not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible and/or delay, scale back or discontinue planned programs. Any of these actions could materially harm our business, results of operations and future prospects. To the extent we obtain additional funding through collaborations, these arrangements would generally require us to relinquish rights to some of our technologies, product candidates or products, and we may not be able to enter into such agreements on acceptable terms, if at all.

We believe that our existing $287.9 million of cash, cash equivalents and marketable securities as of September 30, 2020 will be sufficient to fund our operations for a period of at least one year from the date these unaudited condensed consolidated financial statements are available for issuance. We plan to continue to fund our operations and pursue our strategy through public or private equity or debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements or a combination of these. However, 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.

The following table shows a summary of our cash flows for the nine months ended September 30, 2020 and 2019 (in thousands):

	Nine Months Ended September 30,	
	2020	**2019**
Net cash provided by (used in):		
Operating activities	$ (63,456)	$ (26,573)
Investing activities	63,533	95,113
Financing activities	7,926	177,178
Net increase in cash and cash equivalents	$ 8,003	$ 245,718

Cash Used in Operating Activities

During the nine months ended September 30, 2020, cash used in operating activities was $63.5 million, which consisted of a net loss of $74.5 million, adjusted for non-cash charges of $16.5 million and cash used through

changes in operating assets and liabilities of $5.5 million. The non-cash charges consisted primarily of stock-based compensation expense of $11.5 million and depreciation expense of $5.0 million. The change in operating assets and liabilities was mainly driven by an increase in accrued expenses and other liabilities of $9.8 million. These increases were partially offset by decreases in prepaid expenses and other assets of $3.7 million, related party receivables of $2.0 million from Merck, accounts payable of $7.2 million, deferred rent of $2.1 million and deferred revenue of $0.3 million. The decrease in deferred revenue is primarily attributable to the completion of all remaining obligations associated with the initial upfront payment included within the transaction price received from Merck and the timing of revenue recognition as determined by using the cost-based input method of revenue recognition in accordance with ASC 606.

During the nine months ended September 30, 2019, cash used in operating activities was $26.6 million, which consisted of a net loss of $26.9 million, adjusted for non-cash charges of $14.3 million and cash used through changes in operating assets and liabilities of $14.0 million. The non-cash charges consisted primarily of stock-based compensation expense of $9.4 million and depreciation expense of $5.8 million. The change in operating assets and liabilities was primarily due to a decrease in related party receivables of $3.7 million, an increase in prepaid expenses and other current assets of $4.3 million, a decrease in accounts payable of $1.3 million, increase in accrued expenses and other liabilities of $4.4 million and decreases in deferred rent and deferred revenue of $2.0 million and $14.5 million, respectively. The decrease in deferred revenue is primarily attributed to changes in revenue from the adoption of ASC 606 and the timing of advance payments from Merck related to the reimbursement of costs associated with research and development activities.

Cash Provided by Investing Activities

During the nine months ended September 30, 2020, cash provided by investing activities was $63.5 million, which consisted of $94.5 million in proceeds from the maturities of marketable securities, partially offset by purchases of marketable securities of $29.4 million and purchases of property and equipment of $1.6 million.

During the nine months ended September 30, 2019, cash provided by investing activities was $95.1 million, which consisted of $172.8 million in proceeds from the maturities of marketable securities, partially offset by purchases of marketable securities of $75.2 million and purchases of property and equipment of $2.4 million.

Cash Provided by Financing Activities

During the nine months ended September 30, 2020, cash provided by financing activities was $7.9 million, which consisted of proceeds from the issuance of common stock upon the exercise of previously granted stock options of $7.2 million and proceeds from the issuance of common stock in connection with our ESPP of $1.3 million, partially offset by deferred offering costs of $0.6 million associated with the filing of our registration statement on Form S-3 and the execution of the Sales Agreement with Jefferies.

During the nine months ended September 30, 2019, cash provided by financing activities was $177.2 million, which consisted of net proceeds from issuance of common stock upon completion of our IPO of $110.1 million, issuance of common stock upon completion of the private placement with Merck of $65.9 million and the issuance of common stock upon the exercise of previously granted stock options of $1.2 million. The net proceeds from the completion of the IPO of $110.1 million were comprised of our proceeds of $111.9 million, after deducting underwriting discounts and commissions, less offering expenses of $4.1 million, of which $2.3 million was paid in 2018.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Contractual Obligations

During the nine months ended September 30, 2020, there were no material changes to our contractual obligations and commitments reported in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 17, 2020.

Critical Accounting Policies and Estimates

Our MD&A is based on our condensed consolidated financial statements, which we have prepared in accordance with U.S. GAAP. The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our condensed consolidated financial statements, as well as revenue and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. 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, 2019, filed with the SEC on March 17, 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 nine months ended September 30, 2020, as compared to the recent accounting pronouncements described in our audited consolidated financial statements and notes for the year ended December 31, 2019, included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 17, 2020, that are of significance or potential significance to us.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

During the nine months ended September 30, 2020, there were no material changes to our market risk disclosures reported in our Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 17, 2020.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of September 30, 2020, management, with the participation of our Chief Executive Officer and our 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 (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 our Chief Executive Officer and our 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 our Chief Financial Officer concluded that, as of September 30, 2020, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2020, there were no changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

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 the material factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Our business involves significant risks that may have a material adverse effect on our business, financial condition, results of operations, prospects and stock price. These risks are more fully described below and include, among others:

- Our most advanced product candidate, aldafermin, is still in Phase 2 development and may fail to demonstrate safety and efficacy in ongoing and future clinical trials, may never achieve regulatory approval and may not be able to be successfully commercialized due to competition or other factors;
- We have incurred net losses every year since our inception, expect to incur significant and increasing operating losses and may never become profitable;
- All of our revenue for recent periods has been received from a single collaboration partner, Merck, and, under certain circumstances, Merck may unilaterally terminate its annual funding of our research and development programs, or terminate or shift the focus of its research and development funding;
- We 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 complete the development and commercialization of our current product candidates or develop new product candidates;
- We currently have no approved products or product revenue, and we will need to successfully complete preclinical and clinical testing of our product candidates before we can seek regulatory approval and potentially generate commercial sales;
- Our product candidates must undergo rigorous clinical trials before seeking regulatory approvals, which could delay or prevent commercialization of our product candidates;
- Clinical trials of our product candidates may fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise produce positive results;
- The process of manufacturing aldafermin and our other biologic product candidates is complex, highly regulated and subject to several risks, including difficulties in production, particularly in scaling up and validating initial production and ensuring the avoidance of contamination and the risk of our reliance on single source suppliers;
- The regulatory approval processes of the FDA and comparable foreign regulatory 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, CROs 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 upon our ability to obtain and maintain intellectual property protection for our products and technologies, and we may not be able to protect our intellectual property rights throughout the world;
- Our principal stockholders, including entities affiliated with The Column Group, Merck and management, own a significant 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, commercialize and manufacture some or all of our product candidates; 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 Results and Capital Needs

We have incurred net losses every year since our inception, expect to incur significant and increasing operating losses and may never be profitable. Our stock is a highly speculative investment.

We are a biopharmaceutical company that was incorporated in 2007 and commenced operations in early 2008. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect and/or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we 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. For the three and nine months ended September 30, 2020, our net losses were $29.8 million and $74.5 million, respectively, compared to net losses of $10.9 million and $26.9 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $270.6 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 will require substantial additional capital to achieve our development and commercialization goals for our programs being conducted outside of the Merck collaboration, aldafermin and NGM395, for any future programs that Merck does not opt to license under the Collaboration Agreement and that we choose to develop, for any Merck-licensed programs that we opt to co-develop, and for any programs that Merck chooses to license under the Collaboration Agreement and later elects to terminate. 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. As a result, our accumulated deficit will also increase significantly. 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 and our ability to generate revenue beyond those generated pursuant to 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. Even if we eventually generate product revenue, we may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

All of our revenue for recent periods has been received from a single collaboration partner.

Since 2017, all of our revenue has been from our collaboration partner, Merck. Under the collaboration, Merck reimburses us for research and development activities up to $50 million per year, plus additional amounts up to the agreed upon annual caps, if certain conditions are met. Merck has exercised its option to extend the initial five-year research and early development program, which we refer to as the research phase of the collaboration, for an additional two years through March 16, 2022 and has the right to extend it again through March 16, 2024. If our research and development expenses for product candidates subject to the Merck collaboration exceed the funding caps provided in our Collaboration Agreement, which we expect to happen in the fiscal year ending December 31, 2020 and potentially thereafter, we will be required to devote our own financial resources toward the development of such product candidates or pause or suspend such development to remain within the funding caps. For example, we recently decided to suspend activities related to NGM386 and NGM217 to concentrate our resources on our other Merck collaboration product candidates. In addition, if Merck elects not to exercise its remaining option to extend the research phase of the collaboration beyond March 16, 2022, which Merck may unilaterally elect to do at its sole discretion at any time before March 16, 2021, we would require significant additional capital in order to proceed with development and commercialization of any product candidates that had been subject to the Merck collaboration but Merck decides not to proceed with after termination of the research phase, or we will need to enter into additional collaboration or license agreements in order to fund such development and commercialization, which may not be possible, or we may be required to delay, scale back or discontinue development of such product candidates.

We currently have no source of product revenue and may never become profitable.

Our product candidates are in the early stages of development. To date, we have not generated any revenue from commercialization of our product candidates. 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 revenue from those product candidates for a number of years, if ever. We may seek to obtain revenue from collaboration or licensing agreements with third parties. Other than our agreement with Merck, we currently have no such agreements that could provide us with material, ongoing future revenue and we may never enter into any such agreements.

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, successfully establish a sales force, 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.

In addition, because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance through development or achieve applicable endpoints in clinical trials, we are unable to predict if or when we will achieve or maintain profitability. Even if we successfully complete development and regulatory processes, we anticipate incurring significant costs associated with launching and commercializing these products.

Even if we generate revenue from the sale of any of our products that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. 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.

We will require 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 complete the development and commercialization of our current product candidates or develop new product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception and we will require additional capital to finance our operations and pursue our strategy, which may not be available to us on acceptable terms, or at all. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly to the extent that product candidates whose costs are not included in the Merck collaboration, such as aldafermin and NGM395, 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 $287.9 million of cash, cash equivalents and marketable securities as of September 30, 2020 will be sufficient to fund our operations for a period of at least one year from the date these unaudited condensed consolidated financial statements are available for issuance. We plan to continue to fund our operations and pursue our strategy through public or private equity or debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements or a combination of these. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially as a result of a number of factors, including the factors discussed elsewhere in this *"Risk Factors"* section.

We 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.

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 product candidates and any future product candidates we may develop;
- whether Merck exercises its option to license product candidates upon our 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 NGM395 and NGM386);
- whether Merck exercises its remaining option to extend the research phase of the collaboration which would trigger an extension payment to us;
- whether we exceed the funding caps provided in our Collaboration Agreement, which we expect to happen in the fiscal year ending December 31, 2020 and potentially thereafter, which would require us to devote our own financial resources toward the development of programs and product candidates subject to the Merck collaboration during the current two-year extension of the research phase or delay, scale back or discontinue such development;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory 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.

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

Unless and until we can generate a sufficient amount of revenue from approved products, we will require additional capital to discover, develop, obtain regulatory approval for and commercialize our current and future product candidates. We do not have any committed external source of funds, other than pursuant to our collaboration with Merck, which is limited in scope and duration, and may be unilaterally terminated by Merck under certain circumstances.

We plan to finance our future cash needs through the Sales Agreement or other public or private equity or debt offerings, 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, including pursuant to the Sales Agreement, 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. Our existing stockholders could suffer dilution or be negatively affected by fixed payment obligations we may incur if we raise additional funds through the issuance of additional equity securities or debt, including pursuant to the Sales Agreement. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants or protective rights that would restrict 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, including pursuant to the Sales Agreement, we may not be able to expand our operations or otherwise capitalize on our business opportunities, our business and financial condition will be negatively impacted, and 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 operations altogether;

- seek strategic alliances for research and development programs when we otherwise would not, or 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.

Accordingly, 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.

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 2017 Tax Act, as modified by the CARES Act, our federal net operating losses generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of 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, 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 IPO and subsequent shifts in our stock ownership, we have experienced ownership changes in the past and may experience ownership changes in the future, 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. 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 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 they can seek regulatory approval from the FDA and comparable foreign regulatory authorities. Clinical trials may be delayed, suspended or terminated at any time for reasons including:

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in obtaining, or the inability to obtain, required approvals from IRBs or other governing entities at clinical trial sites selected for participation in our clinical trials;
- delays in enrolling participants into clinical trials, such as the slower pace of enrollment we have experienced, from time to time, in our ALPINE 4 and CATALINA trials, including as a result of the evolving effects of the COVID-19 pandemic;
- delays in key trial activities and patient enrollment or diversion of healthcare resources as a result of the evolving effects of the COVID-19 pandemic, such as the slower pace of clinical trial site initiation in our ALPINE 4 and CATALINA trials;
- lower than anticipated retention rates of participants in clinical trials;
- implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign authorities with respect to approval pathways for product candidates we are pursuing, 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 ("EMA") that issued in 2018;
- the need to repeat clinical trials as a result of inconclusive or negative results, poorly executed testing or changes in required endpoints by the FDA or comparable foreign authorities;
- insufficient supply or deficient quality of drug substance, drug product or other clinical trial materials necessary to conduct our clinical trials;
- unfavorable FDA or comparable foreign authority inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related adverse effects experienced by participants in our clinical trials; or
- the placement of a clinical hold on a trial by the FDA or comparable foreign authorities.

Positive or timely results from preclinical studies and early clinical trials do not ensure positive or timely results in late-stage clinical trials or product approval by the FDA or any other regulatory authority. Product candidates that show positive preclinical or early clinical results often fail in later stage clinical trials. Data obtained from preclinical and clinical activities is susceptible to varying interpretations, which could delay, limit or prevent regulatory approvals.

We have limited experience in conducting late-stage clinical trials required to obtain regulatory approval. We may not be able to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. Our current clinical trials may be insufficient to demonstrate that our potential products will be safe or effective. Additional clinical trials may be required if clinical trial results are negative or inconclusive, which will require us to incur additional costs and significant delays. If we do not successfully conduct clinical trials supporting the necessary regulatory approvals, we will not be able to generate product revenue and may not become profitable.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory 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. A failure of one or more clinical trials can occur at any stage of testing.

To date, the data supporting our drug discovery and development programs are derived from laboratory and preclinical studies and earlier-stage clinical trials. Despite the results reported in our Phase 1 and 2 clinical trials for aldafermin, in Phase 1 clinical trials for NGM313, NGM621 and NGM120 and in preclinical studies for our other product candidates, 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. 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, these compounds 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.

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 regulatory 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.

Success in preclinical studies or earlier-stage clinical trials may not be indicative of results in future 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. Similarly, preliminary data and interim results from clinical trials may not be predictive of final results. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. 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 fibrosis stage F2 or F3 NASH, may not be indicate of the future results we obtain from our ongoing ALPINE 2/3 and ALPINE 4 trials and any Phase 3 trial.

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. 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.

In addition, there is a high failure rate for drugs and biologic products proceeding through clinical trials. 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, the outcome of preclinical studies may not predict the success of clinical trials. Moreover, data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

If we continue to experience delays in clinical testing, we will be delayed in commercializing our product candidates, our costs may increase and our business may be harmed.

Conducting clinical trials for any of our product candidates for approval in the United States requires filing an IND application and reaching agreement with the FDA on clinical protocols, finding appropriate clinical trial sites and clinical investigators, securing approvals for such studies from the IRB for each such site, manufacturing clinical quantities of product candidates and supplying drug product to clinical trial sites. Currently, we have regulatory approval to conduct clinical trials in the United States for aldafermin for the treatment of NASH and primary biliary cholangitis (“PBC”), for NGM621 for the treatment of GA secondary to AMD and for systemic administration and for NGM120 for treatment of solid tumors and pancreatic cancer. We also have regulatory approval to conduct clinical trials in Australia for aldafermin for the treatment of NASH and for NGM395 for the treatment of metabolic syndrome. More recently, we obtained regulatory approval to conduct clinical trials in Spain, France, the United Kingdom, Belgium and Poland for aldafermin for the treatment of NASH.

We cannot guarantee that we will be able to successfully accomplish required regulatory 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. For example, we have experienced, from time to time, a slower pace of clinical trial site initiation and enrollment than originally anticipated in certain of our clinical trials, including the ALPINE 4 and the CATALINA trials, as a result of the evolving effects of the COVID-19 pandemic, and if the evolving effects of the COVID-19 pandemic 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. 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. Events that may result in a delay or failure to successfully complete clinical development include:

- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- FDA comments on ongoing clinical trials and potential regulatory holds imposed if such comments are not adequately addressed;
- deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements;
- failure of third parties, such as CROs, to satisfy their contractual duties to us or meet expected deadlines;

- delays in the testing, validation, manufacturing and delivery to clinical trial sites of the product candidates or other study materials;
- delays in key trial activities, clinical trial site initiation and patient enrollment or diversion of healthcare resources as a result of the evolving effects of the COVID-19 pandemic;
- 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;
- delays in patient enrollment, such as the slower pace of enrollment we have experienced, from time to time, in our ALPINE 4 and CATALINA trials, including as a result of the evolving effects of the COVID-19 pandemic;
- delays in patients completing a trial or returning for post-treatment follow-up;
- delays caused by patients dropping out of a trial, including due to side effects, disease progression or concerns about the COVID-19 pandemic;
- demonstration of a significant adverse safety or tolerability signal limiting the utility of the product candidate;
- changes in regulatory authority recommendations or guidance regarding development of drugs for a particular indication that we are pursuing, such as draft guidance documents from the FDA for the development of NASH that issued in 2018 and 2019 and from the EMA that issued in 2018;
- 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; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

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 we or our partners are unable to enroll patients in clinical trials, we will be unable to complete these trials on a timely basis.

The timely completion of clinical trials largely depends on patient enrollment. Many factors affect patient enrollment, including:

- the size and nature of the patient population we enroll;
- the number and location of clinical trial sites;
- delays in enrollment due to travel or quarantine policies, behaviors or other factors related to COVID-19;
- competition with other companies for clinical trial sites or patients;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- risk that enrolled participants will drop out before completion; and

- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In particular, there is significant competition for recruiting NASH patients 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 affected by the effects of the COVID-19 pandemic, including due to 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. We or our partners may be unable to enroll the patients we need to complete clinical trials on a timely basis, or at all.

We may not successfully identify, develop or commercialize our product candidates.

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. 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 a number of reasons, including:

- our research methodology may not successfully identify medically-relevant protein or antibody therapeutics or potential product candidates;
- 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;
- we may need to rely on third parties to generate protein or antibody candidates for some of our product candidate programs;
- we may encounter product manufacturing difficulties that limit yield or produce undesirable characteristics that increase the cost of manufacturing our product candidates, cause delays or make the product candidates unmarketable;
- our product candidates may cause adverse effects in patients or subjects, even after successful initial toxicology studies, which may make the product candidates unmarketable;
- our product candidates may not demonstrate a meaningful benefit to patients or subjects; and
- our partners may change their development profiles or plans for product candidates or abandon a therapeutic area, the development of a partnered product or the commercialization of any future approved partnered product.

If any of these events occur, we may be forced to abandon our development efforts for one or more programs, which could have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations. For example, we suspended activities related to NGM386 and NGM217 to concentrate our resources on our other product candidates. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

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.

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. The process of manufacturing aldafermin and our other product candidates is complex, highly regulated and subject to several risks, including:

- the process of manufacturing biologics is susceptible to 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;

- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, 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, undertake costly remediation efforts or seek costlier manufacturing alternatives.

We also have a single source of supply for most of our product candidates, including the drug substances used in manufacturing them. Single sourcing minimizes our leverage with our 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. 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 regulatory 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 regulatory 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, President Trump has invoked the Defense Production Act 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 materials.

For example, we have entered into a Development and Manufacturing Services Agreement with Lonza Sales AG ("Lonza") for the production of Phase 3 and commercial supplies of the aldafermin drug substance. If Lonza or our 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 materials 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 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 Sales AG 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, the potential Phase 3 testing of aldafermin which could materially and adversely affect our business. Refer also to the risk factor entitled *"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."*

Each of our product candidates uses certain raw materials for its manufacture, such as reagents that support cell growth. Some of these materials only have a single supplier and are purchased as necessary without a long-term supply agreement in place. Any significant delay in the acquisition or decrease in the availability of these raw materials could considerably delay the manufacture of our product candidates, which could adversely impact the timing of any planned trials or the regulatory approvals of our product candidates.

The manufacture of biologic products is complex 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.

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. Any delay or interruption in the supply of clinical trial materials 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 have other properties that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Additional clinical trials may be required to evaluate the safety profile of our product candidates. Serious adverse events that were reported in the aldafermin treatment arms from our completed Phase 1 and Phase 2 clinical trials of aldafermin include: moderate dizziness, community acquired pneumonia, iron deficiency anemia, fractured finger, pneumonitis/alveolitis, acute pancreatitis, pneumonia, pleurisy, non-myocardial infarction cardiac arrest, chest pain, vertigo, headache, accelerated hypertension, kidney mass, bowel obstruction, bilirubin increase, cholangitis, progression of primary sclerosing cholangitis ("PSC"), intervertebral discitis, rectal bleeding and post-biopsy bleeding. In our ongoing Phase 2 study with aldafermin, the following serious adverse events were reported, but were deemed by the investigators to be unrelated to the treatment with aldafermin: gallbladder injury due to biopsy, suicide attempt and bronchogenic cyst. In our completed Phase 1 and Phase 1b clinical trials of NGM313, there were two reported serious adverse events in the NGM313 treatment arms: cholecystitis and rectal bleeding due to hemorrhoids, both of which were deemed by the investigators to be unrelated to treatment with NGM313. In our completed Phase 1 clinical trial of NGM120, there were two reported serious adverse events in the NGM120 treatment arms: renal colic and bipolar disorder, both of which were deemed by the investigators to be unrelated to treatment with NGM120. In our ongoing Phase 1a/1b trial of NGM120 evaluating NGM120 as a monotherapy in patients with select advanced tumors and in combination with two chemotherapeutic agents in patients with metastatic pancreatic cancer, there have been a number of serious adverse events, including sepsis, neutropenia, pulmonary embolism, pleural effusion, non-cardiac chest pain, renal failure, acute kidney injury and encephalopathy, none of which were deemed related to treatment with NGM120 after medical safety review. In our completed Phase 1 and ongoing Phase 2 clinical trials of NGM621, there have been no reported serious adverse events.

Significant increases in serum levels of low density lipoprotein ("LDL") cholesterol were observed in clinical trials of aldafermin in NASH and type 2 diabetes. The drug-induced changes in LDL cholesterol were brought back to baseline levels with concomitant statin use in NASH patients, however, sustained LDL cholesterol elevations in untreated patients can be associated with cardiovascular disease. We have not observed any significant changes in LDL cholesterol with aldafermin in trials we have conducted in patients with cholestatic liver disease, such as PBC and PSC.

Protein and antibody therapeutics can sometimes induce host immune responses that can cause the production of anti-drug-antibodies ("ADA"). Our product candidates, including aldafermin, which is an engineered variant of the human FGF19 protein, are protein and antibody therapeutics. In some instances, certain ADA called neutralizing antibodies can neutralize the therapeutic effects of the treatment. ADA can also sometimes cross-react with substances naturally occurring in a subject's body (in the case of aldafermin, FGF19) which can cause unintended effects, including potential impacts on efficacy and, in rare cases, even adverse events. One subject in a Phase 2 clinical trial investigating aldafermin as an intervention for type 2 diabetes developed ADA against aldafermin; however, this patient did not demonstrate any biochemical or clinically relevant safety concerns while in the study, and we have not identified any safety concerns while monitoring the subject following the study. In the Phase 2 PBC extension clinical trial of aldafermin, 18 of the 36 subjects tested positive for aldafermin-specific ADA at one or more time points using a preliminary assay. Six of these 36 subjects tested positive for neutralizing antibodies using an assay that was subsequently validated, of which two subjects developed antibodies that appeared to cross-react with their naturally occurring FGF19. These subjects have not demonstrated any biochemical or clinically relevant safety signals that were different from observations in subjects that did not generate ADA against aldafermin. We are developing an assay to measure the presence of ADA against aldafermin for our ongoing NASH program, which will need to be evaluated by regulatory agencies. The subjects who were found to develop ADA in both the type 2 diabetic and PBC populations may not be predictive of future test results in NASH patients due to differences in disease setting, study design, dose regimen and the use of a different ADA assay. If we are required to do substantial additional testing as a result of the detection of high amounts of ADA in subjects using aldafermin or any other product candidate, the costs of our clinical trials may increase.

Future results of our trials could reveal a high and unacceptable severity and prevalence of side effects or ADAs that have negative effects or other unexpected characteristics. In such an event, we may need to suspend or

terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment, the ability of enrolled subjects to complete the trial or result in potential product liability claims. 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.

Aldafermin is an engineered variant of the human hormone FGF19 that has been associated with liver cancer in rodent testing. The IND that we filed 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 Gastroenterology and Inborn Errors Products, 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. We believe we have identified a modified version of FGF19 that 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 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, which will be expensive and time-consuming, 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 and financial condition.

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 activities related to NGM386 and NGM217 to concentrate our resources on our other product candidates, may also be incorrect and could cause us to miss valuable opportunities.

Under 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 ("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.

Disputes under key agreements or conflicts of interest with our scientific advisors or clinical investigators could delay or prevent development or commercialization of our product candidates.

Any agreements we have or may enter into with third parties, such as collaboration, license, supplier, manufacturing, sponsored research, CRO or clinical trial agreements, 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.

We work with outside scientific advisors and collaborators at academic and other institutions that assist us in our research and development efforts. Our scientific advisors are not our employees and may have other

commitments that limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services.

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 effects of the evolving 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 may acquire additional assets, intellectual property and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management's attention from core business concerns, failure to effectively exploit acquired assets or intellectual property, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses.

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 companies, including AbbVie, Allergan, AstraZeneca, Bayer, Boerhinger Ingelheim, Bristol-Myers Squibb, Eisai, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi and Takeda, as well as large and small biotechnology companies such as 89Bio, Akero, Albireo, Alentis, Amgen Inc. ("Amgen"), Apellis, Ascletis, Axcella, Bird Rock, Can-Fite, Cirius, Enanta, Galectin, Galmed, Gilead, Glympse, Immuron, Intercept, Inventiva, Iveric, Madrigal, MannKind, MediciNova, Metacrine, Mirum, Nalpropion, North Sea, Promethera, Salix, Scholar Rock, Seal Rock, Terns, Tiziana, Viking and Vivus, 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. This would adversely affect our ability to generate revenue. Our competitors 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.

There are no currently approved therapies for NASH. Although we believe there are no 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.

If aldafermin or NGM313 were approved for the treatment of NASH, future competition could also arise from products currently in development, including: cenicriviroc, an immunomodulator that blocks CCR2 and CCR5, from Allergan; firsocostat, an ACC inhibitor, and cilofexor, an FXR agonist, both from Gilead; OCA, an FXR agonist, from Intercept; resmetirom, a beta-thyroid hormone receptor agonist, from Madrigal; pegbelfermin, a PEGylated FGF21 analog, from Bristol-Myers Squibb; AKR-001, an Fc conjugated FGF21 analog, from Akero; FXR agonists from Metacrine; FXR agonists from Novartis; a beta-thyroid hormone receptor agonist from Viking; semaglutide, a GLP-1 analog, from Novo Nordisk; and lanifibranor, a pan-PPAR agonist from Inventiva. The foregoing competitive risks apply to aldafermin, any variants of aldafermin, including the second-generation, half-life extended version of FGF19 we are currently developing, and NGM313.

If any of our product candidates were approved for the treatment of type 2 diabetes, these products would face competition from currently approved and marketed products, including: biguanides; sulfonylureas; TZDs; alpha-glucosidase inhibitors (AGIs); dipeptidyl peptidase 4 (DPP4) inhibitors; glucagon-like peptide-1 (GLP-1) analogues; SGLT2 inhibitors; oral GLP-1 mimetics; and insulins, including injectable and inhaled versions. Further competition could arise from products currently in development, including: 11 beta HSD (Incyte, Japan Tobacco, Roche); and GPR40 (Connexios, Takeda). Some of these programs have advanced further in clinical development than our product candidates and could receive approval before our product candidates are approved, if they are approved at all.

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 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.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. 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 regulatory 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, the “ACA”) was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There remain 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 will likely 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. In March 2020, the Supreme Court of the United States agreed to hear the appeal of this decision. It is unclear how such litigation and other efforts to challenge, repeal, or replace the ACA will impact the ACA or our business.

Other legislative changes that have affected or may affect our industry include the Budget Control Act of 2011 which has triggered automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 unless Congress takes additional action. Recently, there has also been increasing executive, legislative and enforcement interest in the United States with respect to drug pricing practices. There have been several recent U.S. congressional inquiries and proposed bills 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 as a result of the recent presidential election. 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 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 materials 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;
- certain expenses, including, among others, expenses for travel, translation and insurance; 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 obtains 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 ("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 ("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 (" 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 relationships with physician assistants, nurse practitioners, 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 former facility was subject to 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 the operations of our current facility. 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 complete 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. Our sole supplier of clinical drug substance for NGM313, NGM120, NGM621, NGM395 and NGM707 is located in a region that has experienced recent political unrest.

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. Based on guidance issued by federal, state and local authorities, we transitioned to a remote work environment for a vast majority of our employees in March 2020, while maintaining essential in-person laboratory functions in order to advance key research and development initiatives, supported by the implementation of updated onsite safety procedures. In June 2020, following updated guidance issued by federal, state and local authorities, we re-opened our laboratory facilities for research activities 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. These and 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 impact 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 an unwillingness to travel to sites for required screening and clinical trial visits and procedures. In this regard, we have experienced, from to time, a slower pace of clinical site initiation and enrollment than anticipated in certain of our clinical trials, including the ALPINE 4 and CATALINA 2 trials, 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 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 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 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 could also 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 regulatory 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, 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. 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. In particular, some of our suppliers of certain materials used in the production of our drug products are located in Europe. In this regard, any manufacturing supply interruption of aldafermin, which is currently manufactured by Lonza at facilities in Switzerland, or our other product candidates, which are currently manufactured at a facility in Lithuania, could adversely affect our ability to conduct ongoing and future clinical trials of aldafermin and our other product candidates. For example, 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 materials 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 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 Sales AG 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, the potential Phase 3 testing of aldafermin which could materially and adversely affect our business. In any event, if the evolving effects of the COVID-19 pandemic 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.

In addition, while the potential economic impact brought 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 or to exercise its remaining option to extend the research phase of the collaboration beyond March 16, 2022.

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. In addition, to the extent the evolving effects of the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this *"Risk Factors"* section.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Similar to other companies in our industry, we face substantial cybersecurity risk. Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors, collaborators and consultants may fail and are vulnerable to damage from computer viruses and unauthorized access. While we have not, to our knowledge, experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss 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 similar events relating to their computer systems could also have a material adverse effect on our business.

As a result of the ongoing COVID-19 pandemic, certain functional areas of our workforce remain in a remote work environment, which imposes additional risks to our business, including increased risk associated with working outside our corporate network security protection boundaries, increased risk of industrial espionage, phishing and other cybersecurity attacks and the increased risk of unauthorized dissemination of sensitive personal information or proprietary confidential information, any of which could have a material adverse effect on our business. Despite our efforts to increase security and authentication measures, we have experienced an overall increase in cybersecurity incidents, none of which have caused disruption to our business or resulted in a material security breach. However, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations.

In 2017, a security breach of the internal computer systems of our collaborator, Merck, caused material damage to its operations, but did not affect our internal operations. In June 2019, a vendor that conducted bioanalytical services for some of our aldafermin clinical trials was affected by a ransomware attack that resulted in a significant disruption to its IT systems. This cybersecurity incident at our vendor did not result in an integrity loss of certain clinical sample data for aldafermin, as verified by independent vendors. However, to the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material costs, be exposed to liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be hindered or delayed.

European data collection is governed by restrictive regulations governing the collection, use, processing and cross-border transfer of personal information.

We may collect, process, use or transfer personal information from individuals located in the EU in connection with our business, including in connection with conducting clinical trials 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 health data in the EU are governed by the provisions of the General Data Protection Regulation ((EU) 2016/679) ("GDPR"). This legislation imposes requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside of the European Economic Area, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the EU may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations.

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 parties to the transfer have implemented specific safeguards to protect the transferred personal information. One of the primary safeguards allowing United States companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the United States Department of Commerce. However, the Court of Justice of the EU recently invalidated the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the United States or most other countries. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Although we rely primarily on individuals' explicit consent to transfer their personal information from Europe to the United States and other countries, in certain cases we have relied or may rely on the Standard Contractual Clauses. Authorities in the United Kingdom and Switzerland, whose data protection laws are similar to those of the EU, may similarly invalidate use of the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield, respectively, as mechanisms for lawful personal information transfers from those countries to the United States. As such, 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 processing personal information from Europe. 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. 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.

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 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.

In February 2015, we entered into a collaboration with Merck focused on the discovery, development and commercialization of biologics, excluding aldafermin, and including a license to our GDF15 receptor agonist program product candidates, NGM386 and NGM395. In November 2018, Merck exercised its option to license NGM313. In 2019, Merck exercised its option to extend the research phase of the collaboration for an additional two years, from March 17, 2020 through March 16, 2022, and terminated its license to the GDF15 receptor agonist program.

The Merck collaboration involves a complex allocation of rights, provides for substantial research and development support, provides for additional payments upon Merck's election, if exercised in its unilateral discretion, to further extend the term of the research program 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. We cannot predict the success of the collaboration, whether Merck will exercise its remaining option to extend the research phase of the collaboration or whether Merck will exercise its option to license additional product candidates or whether Merck will terminate its license to a licensed program.

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. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. 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 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, under our agreement with Merck, it is possible for Merck to unilaterally terminate the NGM313 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 arrangement. In addition, Merck might opt not to exercise its option 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 to one or more medicines 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. For example, Merck has the first right to maintain or defend our intellectual property rights under the Collaboration Agreement with respect to certain licensed programs and, although we may have the right to assume the maintenance and defense of our intellectual property rights if Merck does not, our ability to do so may be compromised by Merck's actions.

- 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 agreement 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.

Under certain circumstances, Merck may unilaterally terminate its annual funding of our research and development program, or terminate or shift the focus of its research and development funding, any of which would materially and adversely affect our business.

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 may unilaterally terminate the research phase of the collaboration program effective March 17, 2022 by providing notice to us prior to March 17, 2021. Merck may also unilaterally terminate its annual funding of the research program prior to March 17, 2022 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 of the collaboration, 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 NGM313 or any future licensed program. For example, Merck terminated its license to our GDF15 receptor 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, terminates the Collaboration Agreement, decides not to further extend the research phase of the collaboration or shifts the focus of its research and development funding, it would delay or preclude our ability complete our research and development programs, which would materially and adversely affect our business. For example, if Merck elects not to exercise its remaining option to extend the research phase of the collaboration beyond March 16, 2022, which Merck may unilaterally elect to do at its sole discretion, we would require significant additional capital in order to proceed with development and commercialization of any product candidates that had been subject to the Merck collaboration but Merck decides not to proceed with after termination of the research phase, or we will need to enter into additional collaboration or license agreements in order to fund such development and commercialization, which may not be possible, or we may be required to delay, scale back or discontinue development of such product candidates.

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, CROs, clinical investigators, manufacturers and other third parties to support our discovery efforts, to formulate product candidates, to conduct clinical trials for some or all of our product candidates, 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.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including 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 its own business priorities, at a time that is costly or damaging to us.

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 larger quantities. We intend to use third-party manufacturers for commercial quantities of aldafermin, NGM120, NGM621, NGM395 and NGM707, to the extent we advance these product candidates, and will rely on Merck to determine whether to utilize a third-party manufacturer or internal manufacturing capacity for NGM313 and other licensed product candidates. Our or our collaborator's manufacturers may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or efficient manner, or at all. If we or our collaborator are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate. Our or our collaborator's failure or the failure of third-party manufacturers to comply with the FDA's current Good Manufacturing Practices ("cGMP") and to pass inspections of the manufacturing facilities by the FDA or other regulatory agencies could seriously harm our business.

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 investigators, manufacturers 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.

We expect 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, substantial capital will be paid to third parties in these relationships. 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. 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, 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. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of intellectual property, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. Potential collaborators may also consider alternative product candidates or intellectual property for similar indications that may be available for collaboration and whether such an alternative collaboration could be more attractive than the one with us for our product candidate.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. For example, under 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 NGM313 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.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

We rely on third parties to conduct our clinical trials and some aspects of our research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely on, and expect to continue to rely on, third parties, such as CROs, clinical data management organizations, medical institutions, consultants and clinical investigators, to conduct our clinical trials and certain aspects of our research and preclinical studies. Any of these third parties may terminate their engagements with us at any time. If we 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.

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. Moreover, the FDA requires us to comply with standards, commonly referred to as cGCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. 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 this regard, we cannot guarantee that these third parties will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic or otherwise.

We also expect to rely on third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our medicines, producing additional losses and depriving us of potential product revenue.

In addition, we rely on these third parties to provide accurate financial information related to our research and development activities and if any inaccurate financial information were provided by these third parties, our results of operations could be adversely impacted.

We contract with third parties for the manufacture of our product candidates for preclinical and clinical studies and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or that such supply will not be available to us on our requested timeline or at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of our product candidates for preclinical and clinical studies and for commercial supply of any of these product candidates for which we or our collaborator obtains marketing approval. To date, we have obtained aldafermin, NGM313, NGM120, NGM621, NGM395 and NGM707 for preclinical and clinical studies from third-party manufacturers. Other than our supply agreement with Lonza for aldafermin drug substance, we do not have a long-term supply agreement with any third-party manufacturer.

We may be unable to establish any agreements with third-party manufacturers on acceptable terms or at all. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the possible breach of the manufacturing agreement by the third party or the failure to supply product on the timelines and at the cost agreed to;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting.

Third-party manufacturers may not be able to comply with cGMP or similar regulatory requirements outside the United States. Our failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or medicines, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

Any medicines that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing our product candidates.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. In this regard, remote work policies and quarantines, shelter-in-place and similar government orders related to the COVID-19 pandemic 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. In particular, some of our suppliers of certain materials used in the production of our drug products are located in Europe. For example, any manufacturing supply interruption of aldafermin, which is currently manufactured by Lonza at facilities in Switzerland, or our other product candidates, which are currently manufactured at a facility in Lithuania, could adversely affect our ability to conduct ongoing and future clinical trials of aldafermin and our other product candidates. We do not currently have arrangements in place for redundant supply for bulk drug substances or drug product. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer, if possible. Although there may be potential alternative manufacturers who could manufacture our product candidates, we would incur additional costs and experience delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or any future products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. Refer also to the risk factor entitled "*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.*"

Risks Related to Regulatory Approvals

None of our product candidates has received regulatory approval. If we are unable to obtain regulatory approvals to market one or more of our product candidates, our business will be adversely affected.

We do not expect our product candidates to be commercially available for several years, if at all. Our product candidates are subject to strict regulation by regulatory authorities in the United States and in other countries. We cannot market any product candidate until we have completed all necessary preclinical studies and clinical trials and have obtained the necessary regulatory approvals. The approval process is typically lengthy and expensive, and approval is never certain. We do not know whether regulatory agencies will grant approval for any of our product candidates. Even if we complete preclinical studies and clinical trials successfully, we may not be able to obtain regulatory approvals or we may not receive approvals to make claims about our products that we believe to be necessary to effectively market our products. Data obtained from preclinical studies and clinical trials is subject to varying interpretations that could delay, limit or prevent regulatory approval, and failure to comply with regulatory requirements or inadequate manufacturing processes are examples of other problems that could prevent approval. In addition, we may encounter delays or rejections due to additional government regulation from future legislation, administrative action or changes in the policies of the FDA or comparable foreign regulatory authorities. Even if the FDA or a comparable foreign regulatory authority approves a product, the approval will be limited to those indications covered in the approval.

The regulatory approval processes of the FDA and comparable foreign regulatory 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. The time required to obtain approval from the FDA and comparable foreign regulatory 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 regulatory 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 regulatory 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; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory 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. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the BLA. Fast Track designation does not change the standards for product approval.

Although aldafermin has received Fast Track designation from the FDA for NASH and PBC, 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 announced that it had received a complete response letter regarding its New Drug Application for OCA for the treatment of NASH, in which the FDA indicated that it had determined that the predicted benefit of OCA 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.

Further, access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for aldafermin or any other product candidate that we are developing or may develop.

Our failure to obtain regulatory 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 regulatory 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 regulatory 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. Also, regulatory approval for any of our product candidates may be withdrawn if we fail to comply with regulatory requirements, if problems occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of any of our product candidates by regulatory 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 obtained regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory 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 regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory 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 products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory 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 regulatory 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 also 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, and we could be subject to costly and damaging product liability claims.

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, regulatory 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 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 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. However, patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by third parties. 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. The patent examination process may require us or our current or future licensors, licensees or collaborators to narrow the scope of the claims of pending and future patent applications, which would limit the scope of patent protection that is obtained, if any. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. In recent years, these areas have been the subject of much litigation in the industry. As a result, 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.

Success in obtaining and maintaining patents and other intellectual property rights may depend upon being the first to make a particular invention or being the first inventor to file a patent application on that invention. However, the publication of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all until they are issued as a patent. Therefore, 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 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.

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 product candidate, although it is disclosed and claimed in our pending U.S. provisional application(s). The patent landscape surrounding NGM621 and NGM707 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, including aldafermin, NGM313, NGM120, NGM621, NGM395 and NGM707, 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, NGM313, NGM120, NGM621, NGM395 and NGM707 or any of our other product candidates.

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

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. Thus, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our inventions or technologies, or from developing or commercializing competing products.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world is prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. Competitors may use our technology and that of our current or future licensors, licensees or collaborators in jurisdictions where we have not obtained patent protection to develop their own products and, in some cases, may export otherwise infringing products to territories where we and our collaborator have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent that competition.

The requirements for patentability differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. Europe and other countries impose limitations on inventions related to methods for treating the human body. Differences in national law and practice may limit the breadth and strength of any patents obtained by us or our current or future licensors, licensees or collaborators.

India, certain countries in Europe, and certain developing countries, including Thailand, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Additionally, many countries limit the enforceability of patents against government agencies or government contractors. We or our licensors, licensees or collaborators may have limited remedies if patents are infringed or if compelled to grant a license to a third party, which could materially diminish the value of those patents and could limit our potential revenue opportunities. 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.

Patent applications, issued patents and/or parts thereof must be translated into the native language in many foreign countries. If our patent applications or issued patents are translated incorrectly, they may not adequately cover our products, product candidates, or other technologies and it may not be possible to rectify an incorrect translation.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals. This could make it difficult for us or our current or future licensors, licensees or collaborators to stop the infringement of the patents or the marketing of competing products in violation of the patent or other proprietary rights. Proceedings to enforce patent rights in foreign jurisdictions could result in substantial costs and divert the attention of us or our current or future licensors, licensees or collaborators from other aspects of our business, could put the patents at risk of being invalidated or interpreted narrowly, could place the patent applications at risk of not issuing, and/or could provoke third parties to assert claims against us or our current or future licensors, licensees or collaborators. We or our current or future licensors, licensees or collaborators may not prevail in any lawsuits that are initiated and the damages or other remedies awarded, if any, may not be commercially meaningful.

The duration of our intellectual property rights is limited.

Patents generally have a term of 20 years from the earliest effective filing date of the application that first discloses the claimed invention or an obvious variant thereof. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after the resulting products are commercialized. As a result, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours and we may need to rely solely on regulatory or similar protections, if they are available.

We expect to seek extensions of patent terms for our issued patents, where available. In the United States, this includes under the Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product's approval date. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. During the period of patent term extension, the claims of the patent are not enforceable over their full scope, but instead are limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, any period during which we have the right to exclusively market our product will be shorter than we would otherwise expect, and our competitors may obtain approval of and launch products earlier than might otherwise be the case.

Non-compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies could adversely affect our patent protection.

Periodic maintenance and annuity fees on issued United States patents and most foreign patent applications and patents must be paid to the U.S. Patent and Trademark Office ("USPTO") and foreign patent agencies, respectively, in order to maintain such patents and patent applications. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application, examination and issuance processes. While an inadvertent lapse can be cured, in some cases, by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or our current or future licensors, licensees or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market with similar or identical products or technologies, which would have a material adverse effect on our business, financial condition and results of operations.

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

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property rights, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. The U.S. Supreme Court and the United States Court of Appeals for the Federal Circuit have ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances, weakening the rights of patent owners in certain situations or ruling that certain subject matter is not eligible for patent protection. In addition to increasing uncertainty with regard to our and our collaborator's ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts, the USPTO and equivalent bodies in foreign jurisdictions, 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.

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 aldafermin, NGM313, NGM120, NGM621, NGM395 and NGM707 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 a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidates, which would have a material adverse effect on our business, financial condition and results of operations. Moreover, even if we obtain licenses to such intellectual property, but subsequently fail to meet our obligations under our license agreements, or such license agreements are terminated for any other reason, we may lose our rights to in-licensed technologies.

The licensing or acquisition of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, 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 which event 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 under which we license cell lines 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.

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 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. 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.

Our commercial success depends upon our ability and that of our current or future licensors, licensees or collaborators to develop, manufacture, market and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. 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. 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.

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.

We perform searches of patent and scientific databases in order to identify documents that may be of potential relevance to the freedom-to-operate of our product candidates. Such searches generally are conducted based on keywords, amino acid and nucleic acid sequences, inventors/authors and assignees/entities to capture U.S. and European patents and patent applications, PCT publications and scientific journal articles. There can be no assurance that these searches will identify all potentially relevant patents or patent applications, and the failure to identify any such patents or patent applications could have a material adverse effect on the commercialization of our product candidates.

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 aldafermin, NGM313, NGM120, NGM621, NGM395 and NGM707 product candidates. We are not aware of any facts that would lead us to conclude that the valid and enforceable claims of any third-party patents would reasonably be interpreted to encompass our product candidates, unless we are unsuccessful in our opposition of any of the granted European patents that are discussed below, or any appeals stemming therefrom. As to pending third-party applications, we cannot predict with any certainty the claims that will issue, if any, or the scope of such issued claims.

We filed an opposition in the European Patent Office ("EPO") against a patent, granted to St. Vincent's Hospital Sydney Limited ("St. Vincent's"), claiming the use of MIC-1, also known as GDF15, for the treatment of obesity. The Opposition Division of the EPO upheld the patent as granted in the first instance proceedings. We appealed this decision to the Board of Appeals but subsequently withdrew from the opposition. The opposition proceedings were terminated with the patent being maintained. We may not be able to commercially launch NGM395 in Europe for the treatment of obesity without a license from St. Vincent's or until after the patent's expiration, which is currently scheduled for April 2025. There is no assurance that such a license, if necessary, can be obtained from St. Vincent's on commercially reasonable terms, or at all.

We filed an opposition in the EPO against a patent, granted to Amgen, claiming the use of GDF15 polypeptides for the treatment of several metabolic disorders, including obesity. At the first instance proceedings, the Opposition Division of the EPO maintained the patent in view of amendments to the patent and statements by Amgen disclaiming the treatment of obesity. We appealed to the Board of Appeals at the EPO the Opposition Division's decision to maintain the Amgen patent. Should the patent be upheld on appeal or should we decide not to pursue the appeal, we may not be able to commercially launch NGM395 in Europe for the treatment of any metabolic orders encompassed by the claims without a license from Amgen or until after the patent's expiration, which is currently scheduled for April 2032. There is no assurance that such a license, if necessary, can be obtained from Amgen on commercially reasonable terms, or at all.

We filed an opposition in the EPO against a patent, granted to Genentech, Inc., claiming the use of an anti-KLB agonistic antibody for the treatment of diabetes mellitus or insulin resistance. The opposition is now terminated and the patent has been revoked in its entirety.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely substantially on trade secrets in our activities, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our proprietary information and there may be no adequate remedy available for such breach of an agreement. We cannot assure that our proprietary information will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Third parties may initiate legal proceedings against us alleging that we or our employees have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at universities or at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Most of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, 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. Litigation may be necessary to defend against these claims. If we fail in prosecuting or defending any such claims, we may lose valuable intellectual property rights or personnel, pay monetary damages, and/or sustain other damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

We may be subject to claims challenging the inventorship of our patents and other intellectual property or otherwise be unable to secure ownership of our intellectual property.

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 and other claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products and product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technologies that are not covered by the claims of the patents that we license or may own in the future;

- we, or our current or future licensors, licensees or collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we license or may own in the future;

- we, or our current or future licensors, licensees or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;

- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;

- issued patents to which we hold rights may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may not develop additional proprietary technologies that are patentable;

- the patents of others may harm our business; and

- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 $23.95 on June 17, 2020 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 Merck's failure to exercise its remaining unilateral option to extend the research phase of the collaboration, any termination of the collaboration, or other change in our relationship with Merck;
- 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;
- 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 significant 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 The Column Group and Merck, and their respective affiliates beneficially own a significant 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 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 (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 (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 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 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. GAAP 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 September 30, 2020, the average daily trading volume for our common stock on the Nasdaq Global Select Market was only 290,811 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. Shares issued to Merck in the private placement that occurred concurrently with our IPO became available for sale in the public market beginning on March 17, 2020, subject to the condition of Rule 144 under the Securities Act.

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 (“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 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 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 of America 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 Internal Revenue Service 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 increase even more 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 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. The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. A limited number of analysts are currently covering our company. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline. Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds from our IPO of Common Stock

There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on April 4, 2019.

Repurchase of Shares of Company Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

+ Filed herewith.

* The certifications attached as Exhibit 32.1 accompany 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: November 12, 2020

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

Date: November 12, 2020

By: /s/ Siobhan Nolan Mangini
Siobhan Nolan Mangini
Chief Financial Officer

Exhibit 31.1

CERTIFICATIONS OF PERIODIC REPORT UNDER 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: November 12, 2020

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

Exhibit 31.2

CERTIFICATIONS OF PERIODIC REPORT UNDER 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: November 12, 2020

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

Exhibit 32.1

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

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

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2020, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: November 12, 2020

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 12th day of November, 2020.

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

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

"This certification accompanies the 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."