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 June 30, 2019

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 August 9, 2019, the registrant had 66,042,966 shares of common stock, $0.001 par value per share, outstanding.

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Item 1. Financial Statements.

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In Thousands, Except Share Amounts)

	June 30, 2019	December 31, 2018*
Assets		
Current assets:		
Cash and cash equivalents	$ 265,072	$ 56,923
Short-term marketable securities	97,116	149,710
Related party receivable from collaboration	881	3,669
Prepaid expenses and other current assets	5,275	4,255
Total current assets	368,344	214,557
Property and equipment, net	22,172	23,893
Restricted cash	2,249	2,249
Deferred IPO costs	—	2,292
Other non-current assets	3,938	3,094
Total assets	$ 396,703	$ 246,085
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,164	$ 5,775
Accrued liabilities	15,292	14,003
Deferred rent, current	2,756	2,683
Deferred revenue, current	17,441	19,025
Total current liabilities	38,653	41,486
Deferred rent, non-current	10,843	12,221
Deferred revenue, non-current	—	3,942
Early exercise stock option liability	1,077	1,559
Convertible preferred stock warrant liability	—	198
Total liabilities	50,573	59,406
Commitments and contingencies (Note 7)		
Convertible preferred stock, $0.001 par value; 96,268,206 shares authorized as of June 30, 2019 and December 31, 2018; zero and 47,267,466 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively; aggregate liquidation preference of $0 and $277,774 at June 30, 2019 and December 31, 2018, respectively	—	294,874
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 129,000,000 shares authorized as of June 30, 2019 and December 31, 2018; 66,039,310 and 6,937,890 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	66	7
Additional paid-in capital	515,248	39,258
Accumulated other comprehensive gain (loss)	102	(267)
Accumulated deficit	(169,286)	(147,193)
Total equity (deficit)	346,130	(108,195)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 396,703	$ 246,085

*The condensed consolidated balance sheet as of December 31, 2018 has been derived from the audited financial statements as of that date.

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

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In Thousands, Except Share and Per Share Amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Related party revenue	$ 25,341	$ 22,118	$ 50,893	$ 40,731
Operating expenses:				
Research and development	28,819	22,846	58,346	42,300
General and administrative	6,229	3,458	11,596	7,332
Total operating expenses	35,048	26,304	69,942	49,632
Loss from operations	(9,707)	(4,186)	(19,049)	(8,901)
Interest income	2,044	891	3,154	1,643
Other income (expense), net	(6)	95	(42)	117
Net loss	$ (7,669)	$ (3,200)	$ (15,937)	$ (7,141)
Net loss per common share, basic and diluted	$ (0.13)	$ (0.52)	$ (0.47)	$ (1.16)
Weighted average shares used to compute net loss per common share, basic and diluted	61,044,450	6,200,143	34,078,099	6,163,425

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net Loss	$ (7,669)	$ (3,200)	$ (15,937)	$ (7,141)
Other comprehensive gain (loss), net of tax:				
Net unrealized gain (loss) on available-for-sale marketable securities	147	156	369	(67)
Total comprehensive loss	$ (7,522)	$ (3,044)	$ (15,568)	$ (7,208)

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In	Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity(Deficit)
Balance at December 31, 2018	47,267	$ 294,874	6,733	$ 7	$ 39,258	$ (267)	$ (147,193)	$ (108,195)
Issuance of common stock to participants in 401(k) Plan	—	—	8	—	98	—	—	98
Vesting of common stock from early exercises	—	—	34	—	237	—	—	237
Issuance of common stock upon exercise of stock options	—	—	80	—	279	—	—	279
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)
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
Conversion of Series A, B, C, D, E convertible preferred stock to common stock	(47,283)	(295,072)	47,283	47	295,025	—	—	295,072
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

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2017	47,267	$ 294,874	6,105	$ 6	$ 26,147	$ (431)	$ (146,700)	$ (120,978)
Vesting of common stock from early exercises	—	—	35	—	108	—	—	108
Issuance of common stock upon exercise of stock options	—	—	35	—	71	—	—	71
Repurchase of common stock	—	—	(23)	—	(185)	—	—	(185)
Stock-based compensation expense	—	—	—	—	2,179	—	—	2,179
Changes in unrealized loss on available-for-sale securities	—	—	—	—	—	(223)	—	(223)
Net loss	—	—	—	—	—	—	(3,941)	(3,941)
Balance at March 31, 2018	47,267	$ 294,874	6,152	$ 6	$ 28,320	$ (654)	(150,641)	$ (122,969)
Issuance of common stock to participants in 401(k) Plan	—	—	11	—	—	—	—	—
Vesting of common stock from early exercises	—	—	31	—	108	—	—	108
Issuance of common stock upon exercise of stock options	—	—	81	1	163	—	—	164
Stock-based compensation expense	—	—	—	—	2,292	—	—	2,292
Changes in unrealized gain on available-for-sale securities	—	—	—	—	—	156	—	156
Net loss	—	—	—	—	—	—	(3,200)	(3,200)
Balance at June 30, 2018	47,267	$ 294,874	6,275	$ 7	$ 30,883	$ (498)	(153,841)	$ (123,449)

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

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

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (15,937)	$ (7,141)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	3,896	3,453
Amortization of discount on marketable securities	(803)	(171)
Stock-based compensation expenses	6,276	4,476
Early exercised stock options	—	7
Other non-cash expenses	98	—
Changes in operating assets and liabilities		
Receivable from related party collaboration	2,788	—
Prepaid expenses and other assets	(1,864)	(428)
Accounts payable	(2,511)	2,056
Accrued expenses and other liabilities	1,167	(415)
Deferred rent	(1,305)	(652)
Deferred revenue	(11,682)	(9,939)
Net cash used in operating activities	(19,877)	(8,754)
Cash flows from investing activities		
Purchase of marketable securities	(75,224)	(70,245)
Proceeds from sales and maturities of marketable securities	128,990	97,332
Purchase of property and equipment	(2,275)	(5,063)
Net cash provided by investing activities	51,491	22,024
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	510	234
Repurchase of common stock	—	(185)
Net cash provided by financing activities	176,535	49
Net increase in cash and cash equivalents	208,149	13,319
Cash, cash equivalents, and restricted cash at beginning of period	59,172	27,842
Cash, cash equivalents, and restricted cash at end of period	$ 267,321	$ 41,161
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	482	216
Cost of property and equipment in accounts payable and accrued liabilities	128	456
Deferred IPO costs in accounts payable and accrued liabilities	30	—

The accompanying notes are an integral part of these 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 research-driven, clinical-stage biopharmaceutical company committed to discovering and developing first-in-class therapeutics for major diseases with an initial focus on cardio-metabolic and liver diseases. The Company's current portfolio is composed of seven product candidates (NGM282 (aldafermin), NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621) focused on non-alcoholic steatohepatitis, or NASH, diabetes, obesity, oncology and age-related macular degeneration, or AMD.

The Company was incorporated in Delaware on December 20, 2007 and its headquarters are located at 333 Oyster Point Blvd., South San Francisco, California 94080. The Company operates in one business segment.

Stock Split

On March 22, 2019, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock on a two-for-one basis (the "Reverse Stock Split"). In connection with the Reverse Stock Split, the conversion ratio for the Company's outstanding convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. The par value of the common stock was not adjusted as a result of the Reverse Stock Split. All references to common stock, options to purchase common stock, early exercised options, share data, per share data, convertible preferred stock (to the extent presented on an as-converted to common stock basis) and related information contained in these condensed consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Initial Public Offering

On April 3, 2019, the Company's registration statement on Form S-1 was declared effective by the United States Securities and Exchange Commission ("SEC") for its initial public offering ("IPO") of its common stock. The Company's shares of common stock started trading on the Nasdaq Select Global Market on April 4, 2019 and the transaction closed on April 8, 2019. In connection with the IPO, the Company sold an aggregate of 7,521,394 shares of common stock, which included 6,666,667 shares of common stock and 854,727 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares, at a public offering price of $16.00 per share. The aggregate net proceeds received by the Company from the offering were $107.8 million, net of underwriting discounts, commissions and offering expenses of $4.1 million, of which $2.3 million were paid in 2018. Upon the closing of the IPO, 47,283,839 shares of the Company's outstanding convertible preferred stock were automatically converted to common stock on a 1:1 basis and the related carrying amount of $295.1 million was reclassified to common stock and additional paid-in capital within stockholders' equity (deficit).

Concurrent with the completion of the IPO, the Company also issued 4,121,683 shares of its common stock to Merck Sharp & Dohme Corp. ("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 the Company's outstanding shares of common stock (Note 6).

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, 2018, included in the Company's final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, on April 4, 2019 ("the Prospectus"). 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 the Company 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, stock-based compensation, research and development periods under multiple element agreements, the valuation of convertible preferred stock warrants, the fair value of convertible preferred and common stock, contract manufacturing accruals, clinical trial accruals and revenue 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 six months ended June 30, 2019, the Company incurred net losses of $7.7 million and $15.9 million, respectively, compared to net losses of $3.2 million and $7.1 million for the three and six months ended June 30, 2018, respectively. As of June 30, 2019, the Company had an accumulated deficit of $169.3 million and does not expect to experience positive cash flows from operations in the near future. The Company had $362.2 million of cash, cash equivalents and marketable securities as of June 30, 2019, and therefore the Company expects that its cash and cash equivalents and marketable securities will be sufficient to fund its operations for a period of at least one year from the date these unaudited condensed consolidated financial statements are filed with the SEC. To fully implement the Company's business plan and fund its operations, the Company may raise capital through the issuance of equity securities or debt financings, collaborations, strategic alliances and licensing arrangements, government or other third-party funding or a combination of these.

Deferred Initial Public Offering Costs

Costs incurred in connection with the IPO primarily consisted of direct incremental legal, printing and accounting fees. IPO costs were capitalized as incurred and offset against proceeds upon completion of the IPO. As of June 30, 2019 and December 31, 2018, deferred IPO costs included on the accompanying condensed consolidated balance sheets were zero and $2.3 million, respectively.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, 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. 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.

Cash and Cash Equivalents

Cash and cash equivalents are stated at fair value. Cash equivalents are related to securities having 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 June 30, 2019 and December 31, 2018, cash and cash equivalents consisted of bank deposits and investments in money market funds.

Marketable Securities

The appropriate classification of the Company's marketable securities is determined at the time of purchase and such designations are re-evaluated at each balance sheet date. All of the Company's securities are considered as available-for-sale and carried at estimated fair values and reported in cash equivalents, 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 (deficit). Other income (expense), net, includes interest, amortization of purchase premiums and accretion of purchase discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method.

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

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 7).

Concentration of Credit and Other Risks

Cash and cash equivalents and marketable securities from the Company's available-for-sale and marketable security portfolio potentially subject the Company to concentrations of credit risk. The Company is invested in money market funds and marketable securities through custodial relationships with major U.S. and Australian banks. Under its investment policy, the Company limits amounts invested in such securities by credit rating, maturity, industry group, investment type and issuer, except for securities issued by the U.S. government.

Related party receivables from collaborations (Notes 5 and 6) are typically unsecured. Accordingly, the Company may be exposed to credit risk generally associated with its current collaboration agreement ("Collaboration Agreement") with Merck and any future collaboration agreements with other collaboration partners. 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 six months ended June 30, 2019 and 2018.

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

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized as the amount by which the carrying amount of the asset exceeds the estimated fair value of the asset. As of June 30, 2019 and December 31, 2018, no revision to the remaining useful lives or write-down of long-lived assets was required.

Income Taxes

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

Convertible Preferred Stock Warrant

Freestanding warrants to purchase the Company's convertible preferred stock were classified as a liability on the condensed consolidated balance sheet at December 31, 2018 as the underlying shares of convertible preferred stock were contingently redeemable, which could have obligated the Company to transfer assets at some point in the future to settle the warrants. The convertible preferred stock warrants are recorded as a liability and subject to remeasurement at each balance sheet date, with changes in estimated fair value recorded in the Company's consolidated statements of operations as a component of total other income (expense), net. On February 3, 2019, all convertible preferred stock warrants were automatically exercised on a net basis into 16,380 shares of Series A convertible preferred stock at a fair value of $0.2 million. As of June 30, 2019, there were no convertible preferred stock warrants outstanding.

Revenue Recognition

On January 1, 2019, the Company adopted Accounting Standards Update ("ASU") 2014-09, Revenue from Contracts with Customers, and subsequent amendments (ASC 606), using the modified retrospective transition method applied to those contracts that were not completed as of January 1, 2019. ASC 606 supersedes all prior revenue recognition guidance. Results for operating periods beginning after January 1, 2019 are presented under ASC 606, while prior period amounts have not been adjusted and continue to be reported in accordance with previous accounting rules under Accounting Standards Codification Topic 605, Revenue Recognition ("ASC 605").

The core principle in 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. 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 customer, 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 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 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 customer 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 SSP. In instances where 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 customer'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.

Prior to the adoption of ASC 606, the Company's revenue from collaboration agreements was recognized when the Company determined that persuasive evidence of an arrangement exists, services had been rendered, the price was fixed or determinable and collectability was reasonably assured. The Company would record amounts received prior to satisfying the above revenue recognition criteria as deferred revenue until all applicable revenue recognition criteria were met. Revenue allocated to research activities was generally recognized in the period the services were performed, and revenue allocated to licenses was generally recognized on a straight-line basis over the contractual term. Allocations to non-contingent elements were based on the relative selling price of each element using vendor-specific objective evidence or third-party evidence, where available. In the absence of either of these measures, the Company used the best estimate of selling price for that deliverable.

The most significant change to the Company's policies upon the adoption of ASC 606 is the estimation of an arrangement's total transaction price, which would include any variable consideration and the recognition of that transaction price based on a cost-based input method that requires significant estimates to determine, at each reporting period, the percentage of completion based on the estimated total effort required to complete the project and the total transaction price. Given the differences in revenue recognition policies, the revenue recognized in prior years is not strictly comparable to revenue recorded in the quarter ending June 30, 2019 or in future periods (see Recently Adopted Accounting Pronouncements).

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 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 information it receives from internal personnel and 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 that will be 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 service in exchange for the award, which is generally the vesting period of each award. Subsequent to the adoption of ASU 2018-07, Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, 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 service 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 differ from estimates.

Foreign Currency Transactions

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

The Company is subject to foreign currency risk with respect to its clinical and manufacturing contracts denominated in currencies other than the U.S. dollar, primarily British Pounds, Swiss Francs 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 six months ended June 30, 2019, the difference between comprehensive loss and net loss consisted of changes in net unrealized gain on marketable securities of $0.1 million and $0.4 million, respectively. The difference between comprehensive loss and net loss included changes in net unrealized gain on marketable securities of $0.2 million and net unrealized loss on marketable securities of $0.1 million for the three and six months ended June 30, 2018, respectively.

Net Loss per Common Share

Basic net loss per common share is calculated by dividing net loss by the weighted-average number of common 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 common share is computed giving effect to all potentially dilutive common shares, including common stock issuable upon exercise of stock options, and unvested restricted common stock and stock units. As the Company had net losses for the three and six months ended June 30, 2019 and 2018, all potential common shares were determined to be anti-dilutive.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	$ (7,669)	$ (3,200)	$ (15,937)	$ (7,141)
Denominator:				
Weighted-average number of common shares used in calculating net income per share—basic and diluted	61,044,450	6,200,143	34,078,099	6,163,425
Net loss per share—basic and diluted	$ (0.13)	$ (0.52)	$ (0.47)	$ (1.16)

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

	June 30,	
	2019	2018
Convertible preferred stock	—	47,267,466
Options to purchase common stock	11,417,124	9,699,102
Warrants to purchase convertible preferred stock	—	19,637
Shares committed under ESPP	406,200	—
Total	11,823,324	56,986,205

Segment and Geographical Information

The Company operates in one segment. Substantially all of the Company's long-lived assets are based in the United States. Long-lived assets are primarily comprised of property and equipment. For the three and six months ended June 30, 2019 and 2018, the Company's revenues were entirely within the United States based upon the location of the customers.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by us 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), we meet the definition of an emerging growth company, and have 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 June 2018, the FASB issued ASU 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Non-Employee Share-Based Payment Accounting as part of the FASB simplification initiative. The new standard expands the scope of Topic 718, allowing the Company to apply the requirements of Topic 718 to certain non-employee awards issued in exchange for the acquisition of goods and services from non-employees. ASU 2018-07 is intended to supersede Subtopic 505-50, Equity-Based Payments to Non-Employees and is effective for the Company for fiscal years beginning after December 15, 2019. Effective January 1, 2019, the Company early adopted this ASU using the modified retrospective transition method in which all previously issued equity-classified share-based payment awards to non-employees were remeasured at fair value as of the adoption date. Newly issued equity-classified share-based payments awards to non-employees are measured at fair value as of grant date. The adoption of this ASU did not have a material impact on the Company's condensed consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230) – Restricted Cash, to clarify the presentation of the change in restricted cash on the statement of cash flows. The new standard clarifies the FASB's position that changes to restricted cash are not reflective of an entity's operating, investing or financing activities, and therefore should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The ASU is effective for fiscal years beginning after December 15, 2018. The Company elected to early adopt this ASU using the retrospective transition method to each period presented having no effect within the classification of its condensed consolidated statements of cash flows due to there being no changes in the Company's restricted cash balances for any of the years presented.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (ASC 606), which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. ASU 2014-09 replaced existing revenue recognition guidance and permits the use of either the full retrospective or modified retrospective transition method. Additionally, in March 2016, the FASB issued ASU 2016-08, Revenue from Contracts with Customers (ASC 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which clarifies the implementation guidance on principal versus agent considerations in ASU 2014-09. In April 2016, the FASB issued ASU 2016-10, Revenue from Contracts with Customers (ASC 606): Identifying Performance Obligations and Licensing, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU 2016-12, Revenue from Contracts with Customers (ASC 606): Narrow-Scope Improvements and Practical Expedients, which relates to disclosures of remaining performance

obligations, as well as other amendments to guidance on collectability, non-cash consideration and the presentation of sales and other similar taxes collected from customers. For the Company, these standards (collectively, ASC 606) have the same effective date and transition date of January 1, 2019.

The Company adopted ASC 606 on January 1, 2019, using the modified retrospective transition method and, therefore, evaluated its contract with Merck under ASC 606. The Company recorded adjustments upon the adoption of ASC 606 as a result of the Company concluding that licenses and research and development services promised in the agreement are a single combined performance obligation. This determination impacts the timing of recognition of both the non-refundable upfront fee and the payments related to the services. Under previous guidance, the upfront fee was recognized ratably over the contract term, and fees related to the services were recognized in the period the services were performed. Under ASC 606, revenue for the single performance obligation is recognized over time using a cost-based input method to measure progress toward completion of the single combined performance obligation. The adoption of ASC 606 impacted the Company's contract liabilities and accumulated deficit balance as of January 1, 2019 as follows (in thousands):

	December 31, 2018	Adjustments due to the Adoption of ASC 606	January 1, 2019
Deferred revenue, current	$ 19,025	$ 5,171	$ 24,196
Deferred revenue, noncurrent	3,942	985	4,927
Accumulated deficit	(147,193)	(6,156)	(153,349)

The impact of the adoption of ASC 606 on the condensed consolidated balance sheet as of June 30, 2019, condensed consolidated statement of operations and cash flows for the six months ended June 30, 2019 was as follows (in thousands):

	June 30, 2019		
	Amount Under ASC 605	Adjustments	As Reported Under ASC 606
Deferred revenue, current	$ 13,287	$ 4,154	$ 17,441
Accumulated deficit	(165,132)	(4,154)	(169,286)

	Three Months Ended June 30, 2019		
	Amount Under ASC 605	Adjustments	As Reported Under ASC 606
Related party revenue	$ 24,331	$ 1,010	$ 25,341
Loss from operations	(10,717)	1,010	(9,707)
Net loss	(8,679)	1,010	(7,669)
Net loss per common share, basic and diluted	(0.14)		(0.13)

	Six Months Ended June 30, 2019		
	Amount Under ASC 605	Adjustments	As Reported Under ASC 606
Related party revenue	$ 48,891	$ 2,002	$ 50,893
Loss from operations	(21,051)	$ 2,002	(19,049)
Net loss	(17,939)	$ 2,002	(15,937)
Net loss per common share, basic and diluted	(0.53)		(0.47)

	Six Months Ended June 30, 2019		
	Amount Under ASC 605	Adjustments	As Reported Under ASC 606
Cash flows from operating activities:			
Net loss	$ (17,939)	$ 2,002	$ (15,937)
Changes in operating assets and liabilities:			
Deferred revenue	(9,680)	(2,002)	(11,682)

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 all assets and liabilities arising from leases on the balance sheet, 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 lease assets and liabilities. In March 2018, the FASB approved an alternative transition method to the modified retrospective approach, which eliminates the requirement to restate prior period financial statements and allows the cumulative effect of the retrospective allocation to be recorded as an adjustment to the opening balance of retained earnings at the date of adoption. The Company is currently assessing the timing of adoption and the impact that the adoption of ASU 2016-02 will have on its condensed consolidated financial statements and related disclosures.

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. This ASU modifies the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement 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. This ASU 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 it 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. This ASU will be effective for the Company for fiscal years and interim periods within those fiscal years, beginning after December 15, 2019. The Company is currently assessing the impact of this ASU 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 then 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, presentation and disclosure requirements. This ASU 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. This ASU will be effective for the Company for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. The Company is currently assessing the impact of this ASU on its 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 guidance amended guidance on reporting credit losses for assets held at amortized cost basis and available-for-sale debt securities. For available-for-sale debt securities, credit losses will be presented as an allowance rather than as a write-down. This standard is effective for the Company's fiscal year beginning after December 31, 2020. 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 and related disclosures.

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 on marketable securities other-than-temporary declines in market value. 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 June 30, 2019				
Money market funds	$ 265,326	$ —	$ —	$ 265,326
Corporate and agency bonds	52,453	68	—	52,521
Commercial paper	12,665	—	—	12,665
U.S. government agencies securities	31,896	34	—	31,930
Total	$ 362,340	$ 102	—	$ 362,442
Classified as:				
Cash and cash equivalents				$ 265,326
Short-term marketable securities (amortized cost of $97,014)				97,116
Total cash equivalents and marketable securities				$ 362,442

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
As of December 31, 2018				
Money market funds	$ 34,983	$ —	$ —	$ 34,983
Corporate and agency bonds	68,323	—	(241)	68,082
Commercial paper	17,904	—	—	17,904
U.S. government agencies securities	63,751	—	(26)	63,725
Total	$ 184,961	$ —	$ (267)	$ 184,694
Classified as:				
Cash and cash equivalents				$ 34,984
Short-term marketable securities (amortized cost of $149,978)				149,710
Total cash equivalents and marketable securities				$ 184,694

Cash and cash equivalents in the table above excludes payments in transit of $0.3 million as of June 30, 2019 and cash on deposit with banks of $21.9 million as of December 31, 2018.

As of June 30, 2019 and December 31, 2018, the Company's marketable securities had remaining contractual maturities less than one year.

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 June 30, 2019 and December 31, 2018 (in thousands):

	Fair Value Measurements			
As of June 30, 2019	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds	$ 265,326	$ —	$ —	$ 265,326
Corporate and agency bonds	—	52,521	—	52,521
Commercial paper	—	12,665	—	12,665
U.S. government agencies securities	—	31,930	—	31,930
	$ 265,326	$ 97,116	$ —	$ 362,442

	Fair Value Measurements			
As of December 31, 2018	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Money market funds	$ 34,983	$ —	$ —	$ 34,983
Corporate and agency bonds	—	68,082	—	68,082
Commercial paper	—	17,904	—	17,904
U.S. government agencies securities	—	63,725	—	63,725
	$ 34,983	$ 149,711	$ —	$ 184,694
Liabilities:				
Convertible preferred stock warrant liability	$ —	$ —	$ 198	$ 198
	$ —	$ —	$ 198	$ 198

There were no transfers of assets or liabilities between the fair value measurement levels during the six months ended June 30, 2019 and year ended December 31, 2018.

The following table provides a summary of changes in the fair value of the Company's convertible preferred stock warrant liability (in thousands):

Fair Value Using Level 3 Inputs	Amounts
Balance at December 31, 2017	$ 121
Change in fair value of warrant liability included in other income (expense), net	—
Balance at June 30, 2018	$ 121
Balance at December 31, 2018	$ 198
Net exercise of preferred stock warrant to Series A preferred stock	(198)
Balance at June 30, 2019	$ —

The original estimated fair value of approximately $28,000 related to the convertible preferred stock warrants, issued in February 2009 in conjunction with entering into a loan and security agreement with a lender, was measured upon issuance using the Black-Scholes option-pricing model. The Company did not record any gains or losses related to the change in estimated fair value of the warrant liabilities for the six months ended June 30, 2018. On February 3, 2019, all of the warrants were automatically exercised on a net basis into shares of Series A preferred stock. Therefore, the Company did not record any changes in the estimated fair value of the warrant liabilities for the six months ended June 30, 2019. There were no convertible preferred stock warrants outstanding as of June 30, 2019.

4. Balance Sheet Components

Property and Equipment

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

	June 30, 2019	December 31, 2018
Computer equipment	$ 1,131	$ 1,123
Laboratory equipment and office furniture	20,939	18,977
Leasehold improvements	25,741	25,314
Construction in process	416	679
Total property and equipment, gross	48,227	46,093
Less: accumulated depreciation and amortization	(26,055)	(22,200)
Total property and equipment, net	$ 22,172	$ 23,893

Depreciation expense for the three and six months ended June 30, 2019 was approximately $1.9 million and $3.9 million, respectively. For the three and six months ended June 30, 2018, depreciation expense was $1.7 million and $3.5 million, respectively.

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2019	December 31, 2018
Accrued expenses	$ 2,073	$ 2,595
Clinical trials and research and development costs	7,188	4,844
Personnel-related costs	3,579	4,148
Manufacturing costs	2,452	2,416
Total accrued liabilities	$ 15,292	$ 14,003

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 and has a non-cancellable five-year term running through March 16, 2020. The agreement included an exclusive worldwide license to our GDF15 receptor agonist program. On March 15, 2019, Merck exercised its option to extend the research phase of the collaboration through March 16, 2022. Merck terminated its license to the GDF15 receptor agonist program effective May 31, 2019. The collaboration also includes a broad, multiyear drug discovery and early development program financially supported by Merck but scientifically directed by the Company with input from Merck. The Company determines the scientific direction and areas of therapeutic interest, with input from Merck, and is primarily responsible for the conduct of all research, preclinical and early clinical development activities, through human proof of concept. 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 will fund 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 during the extended two year research period.

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 molecules that are directed against the same target in the same manner ("Optioned Program"). If Merck exercises its option, Merck will be responsible, at its own cost, for any further development and commercialization activities for compounds within that Optioned 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 milestones and royalties 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, then the Company is eligible to receive development and regulatory milestone payments upon the achievement of specific clinical development or regulatory events with respect to the licensed compound indications in the United States, the European Union and Japan of up to an aggregate of $449.0 million. 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.

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 under the research phase and about which the Company has generated unique biological insights (Small Molecule Program). 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 the Company's license, 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 those small molecule products.

The research and early development program has an initial term of five years, until March 16, 2020. On March 15, 2019, Merck exercised its option to extend the research phase of the collaboration through March 16, 2022. In connection with this extension, Merck agreed to continue to fund the Company's research and development efforts during the two-year extension period at the same levels as during the initial term and, in lieu of a $20.0 million extension fee that would have otherwise been payable to the Company, Merck will make additional payments totaling up to $20.0 million in support of the Company's research and development program activities across 2021 and the first quarter of 2022. Under the terms of the 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.

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 up to three years, which we call the tail period, by agreeing to pay all its internal and external costs for related work, 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 as of January 1, 2019 and June 30, 2019. 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 ("R&D") and commercialization of small molecule compounds; (iii) performance of R&D services for five years; (iv) two options to extend performance of the R&D 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 R&D services, resulting in these items being combined into a single performance obligation.

The Company considered whether the options created material rights in the contract and concluded that the fee attached to the exercise of such options approximated the standalone selling price of the promised goods or services included in the options. Therefore, the options do not give rise to material rights, are not performance obligations in the Collaboration Agreement and, if and when exercised, will be accounted for as separate arrangements under ASC 606.

The transaction price consists of the $94.0 million upfront fee and the potential 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 are 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 are 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 Collaboration Agreement is comprised of the up-front payment and the ongoing R&D reimbursements.

Any fees associated with options, including upfront fees, funding fees, milestones, etc. are not included in the transaction price as they are associated with options that are not material rights and, thus, are not performance obligations within the Collaboration Agreement. This includes the $20.0 million license fee associated with Merck's exercise of its option on NGM313. That amount was recognized in the period of exercise (i.e., fourth quarter of 2018) as the Company has no further obligations related to that license. Merck exercised its option on the NGM313 compound and paid the Company the $20.0 million option exercise fee in November 2018. The Phase 3 clinical study for NGM313 has not begun, and the Company has not made an election as to whether it will participate in cost and profit share or receive milestone and royalty payments. The amounts do not impact the estimated transaction price associated with the single performance obligation identified in the Collaboration Agreement.

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 measure proportional performance and 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 ("FTE") 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.

On May 31, 2019, Merck terminated its license to the GDF15 receptor agonist program. The Collaboration Agreement R&D services are not affected by the GDF15 receptor agonist program license termination and are expected to continue through the remainder of the research program term.

As of June 30, 2019 and December 31, 2018, deferred revenue related to the single performance obligation in the Collaboration Agreement was $17.4 million and $23.0 million, respectively. Of the amount recognized for the adoption of ASC 606 in the reporting period ended June 30, 2019, $6.2 million was in deferred revenue at the end of the prior reporting period. As of December 31, 2018, $3.7 million was due from Merck under the Collaboration Agreement. To date, the Company has recognized revenue of approximately $315.9 million related to the single performance obligation in the Collaboration Agreement.

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. In addition, during the period that ends on the earlier of the end of the initial five-year research term, termination of the Collaboration Agreement or the date on which Merck's ownership of the Company's securities drops below 5%, Merck has agreed to vote its shares in favor of the Company's nominees to the board of directors, increases in the authorized capital stock of the Company and amendments to the Company's equity plans approved by the board of directors, in each case as recommended by the chairman of the Company's board of directors. Merck has also agreed, during the period of the initial five-year research phase, not to sell any of its shares of the Company's capital stock (subject to certain limited exceptions).

The Company is also eligible to receive additional payments specific to Merck opting into an Optioned Program. Each Optioned Program is eligible to receive a one-time payment of $20.0 million upon Merck's exercise of its one-time option to obtain an exclusive, worldwide license to a compound following its completion of a human proof-of-concept study. In addition, if the Company does not opt into the cost and profit sharing option, then 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 compounds for the first three indications in the United States, the European Union and Japan.

A break out 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

Summary of Collaboration Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Related party revenue	$ 25,341	$ 22,118	$ 50,893	$ 40,731

The Company recognized collaboration and license revenue under the Collaboration Agreement of $25.3 million and $50.9 million for the three and six months ended June 30, 2019, respectively, of which $5.7 million and $11.4 million was recognized from the upfront license fee by applying the cost-based input measure of revenue recognition in those periods, respectively. The Company recognized collaboration and license revenue under the Collaboration Agreement of $22.1 million and $40.7 million for the three and six months ended June 30, 2018, respectively, of which $4.7 million and $9.4 million was the amortization of upfront license fee, respectively, with the remaining balance related to research and development services reimbursed by Merck provided under the Collaboration Agreement.

The Company is also eligible to receive commercial milestone payments of up to $125.0 million payable for each licensed product. In addition, the Company is eligible to receive royalties at ascending low-double digit to mid-teen percentage rates, depending on the level of net sales Merck achieves worldwide for each licensed compound.

Contract Assets and Liabilities

Changes in contract liabilities under ASC 606 were as follows (in thousands):

	Amounts
Balance at December 31, 2018	$ 22,967
Adoption of ASC 606	6,156
Balance at January 1, 2019	29,123
Revenue recognized included in the contract liability balance at the beginning of the period	(11,682)
Balance at June 30, 2019	$ 17,441

There were no contract assets for all the periods presented.

6. Related Party Transactions

Revenues from related parties refer to the Collaboration Agreement with Merck. For the three and six months ended June 30, 2019, the Company recognized related party revenues of $25.3 million and $50.9 million, respectively. For the three and six months ended June 30, 2018, the Company recorded related party revenue of $22.1 million and $40.7 million, respectively. As of June 30, 2019 and December 31, 2018, the Company had deferred revenue from related party collaboration agreements of $17.4 million and $23.0 million, respectively.

Other related party transactions include the Company's assignment of its operating lease of 630 Gateway to Merck (Note 7) and the Company's private placement with Merck that occurred concurrently with the Company's IPO (Note 1).

7. Commitments and Contingencies

Operating Lease and Lease Guarantee

In September 2009, the Company entered into an operating lease for a corporate office space and laboratory facility at 630 Gateway Blvd, in South San Francisco, California (630 Gateway) for approximately 50,000 square feet, as amended in June 2014 (2014 Lease Amendment), 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 a new operating lease for its corporate office space and laboratory facility at 333 Oyster Point Blvd, South San Francisco, California (333 Oyster Point) for approximately 122,000 square feet that expires in December 2023. The lease provided a tenant improvement allowance of $15.2 million that the Company used in 2016 towards $22.3 million in total leasehold improvements that are amortized over the lease term of seven years.

The 333 Oyster Point lease agreement required a letter of credit in the amount of $2.3 million as a security deposit to the lease, which the Company has recorded as non-current restricted cash on the condensed consolidated balance sheets. The Company has the right to reduce the letter of credit amount by $0.4 million on each of the third anniversary and fourth anniversary of the rent commencement date.

In July 2016, the Company assigned its operating lease of 630 Gateway to Merck, as part of 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 June 30, 2019 due to the short duration of the remaining lease term through November 2020, and Merck's credit rating of AA/A1 and subsequent investment in tenant improvements to the facility. As of June 30, 2019 and 2018, the remaining lease payment obligations that are due for 630 Gateway were approximately $2.9 million and $4.8 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 the quarters ended June 30, 2019 and 2018 and $1.1 million for the six months ended June 30, 2019 and 2018.

Future minimum payments under the unassigned lease obligations described above are as follows as of June 30, 2019 (in thousands):

Year Ending December 31,		
2019	$	2,461
2020		4,995
2021		5,141
2022		5,294
2023		5,455
Total	$	23,346

Indemnification

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

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

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

8. Convertible Preferred Stock

The Company has elected to follow the SEC staff's guidance (included in ASC 480-10-S99, SEC Materials) when evaluating the classification of its shares within the condensed consolidated balance sheets. A liquidation, winding up, change in control, or sale of substantially all assets of the Company could constitute a redemption event. Although the majority of the Company's preferred stock is not mandatorily or currently redeemable, a liquidation or winding up of the Company could constitute an event outside its control. Therefore, all shares of convertible preferred stock have been presented outside the permanent equity for all periods presented due to being contingently redeemable.

Convertible preferred stock at December 31, 2018, consisted of the following (in thousands):

	Shares		Issuance Price per Share	Aggregate Liquidation Value	Aggregate Carrying Value
	Authorized	Outstanding			
Series A	13,295	13,275	$ 2.00	26,550	$ 26,462
Series B	11,078	11,078	5.00	55,389	55,148
Series C	8,328	8,328	6.00	49,970	49,887
Series D	6,600	5,753	10.00	57,530	57,461
Series E	8,833	8,833	12.00	88,335	105,916
	48,134	47,267		$ 277,774	$ 294,874

In March 2015, the Company amended and restated its certificate of incorporation in conjunction with the Series E convertible preferred stock offering. Prior to the conversion of the convertible preferred stock upon closing of the IPO, the significant rights and obligations of the Company's convertible preferred stock were as follows:

Voting Rights: Each holder of convertible preferred stock is entitled to the number of votes equal to the number of shares of common stock into which such shares of convertible preferred stock are convertible. In the event the preferred stockholders control a majority of the board of directors through direct representation on the board of directors or through other rights, the stockholders can approve redemption of the preferred stock.

Dividends: Each holder of convertible preferred stock is entitled to receive non-cumulative dividends at the rate of 8% per annum for each share of convertible preferred stock outstanding, when, as and if declared by the board of directors. These dividends are payable in preference to common stock dividends. To date, the Company has not declared or paid any dividends.

Liquidation: In the event of any liquidation, dissolution or winding-up of the Company, each holder of convertible preferred stock is entitled to receive payment out of the assets of the Company legally available for distribution for each share of convertible preferred stock held by the holder of an amount per share of preferred stock equal to the original issue price plus all declared and unpaid dividends on the convertible preferred stock, with the exception that the holder of the Series E convertible preferred stock will only be eligible to receive an amount equal to $10.00 per share plus all declared and unpaid dividends on the convertible preferred stock. In the event that the available funds and assets are insufficient for full payment to the holders of convertible preferred stock on a per-share basis as outlined above, the entire assets and funds of the Company legally available for distribution shall be distributed ratably among the holders of convertible preferred stock in proportion to the full amount to which they would otherwise be respectively entitled. Upon completion of the distribution of assets as set forth above, all of the remaining assets, if any, shall be distributed ratably among the holders of common stock.

Conversion: Each share of convertible preferred stock was converted to shares of common stock at a ratio of 1:1 upon the closing of the Company's IPO. The Company's outstanding shares of convertible preferred stock converted into 47,283,839 shares of common stock (Note 1). As of June 30, 2019, the Company does not have any convertible preferred stock issued or outstanding.

9. Stockholders' Equity (Deficit)

Common Stock

As of June 30, 2019 and December 31, 2018, the Company had 66,039,310 and 6,937,890 shares of common stock outstanding, respectively, which included shares subject to repurchase of 140,005 and 205,108, respectively, as a result of early exercise of stock options not yet vested. As of June 30, 2019 and December 31, 2018, the Company reserved shares of common stock for issuance as follows:

	June 30, 2019	December 31, 2018
Conversion of convertible preferred stock	—	47,267,466
Common stock options outstanding	11,417,124	9,806,689
Common stock options available for grant	349,401	2,125,875
Warrant to purchase convertible preferred stock	—	19,637
401(k) Matching Plan	28,274	36,751
ESPP shares available for purchase	1,000,000	—
Total	12,794,799	59,256,418

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 within four years and are exercisable from the grant date until ten years after the date of grant. Vesting of certain employee options may be accelerated in the event of a change in control of the Company. As of June 30, 2019, 17,874,624 shares of common stock had been authorized for issuance under the 2018 Plan. The Company's 2008 Equity Incentive Plan (the 2008 Plan) expired at the beginning of 2018.

Stock options are governed by stock option agreements between the Company and recipients of stock options. The board of directors exercises reasonable judgment and considers a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including the Company's stage of development; progress of its research and development efforts; the rights, preferences and privileges of its convertible preferred stock relative to those of its common stock; equity market conditions affecting comparable companies; and the lack of marketability of our common stock. The exercise price of each option shall not be less than 100% of the fair market value of the common stock subject to the option on the date the option is granted. A 10% or greater stockholder shall not be granted an incentive stock option unless the exercise price of such option is at least 110% of the fair value of the common stock on the date of grant and the option is not exercisable after the expiration of five years from the grant date. Options become exercisable and expire as determined by the Compensation Committee, provided that the term of incentive stock options may not exceed ten years from the date of grant for options granted to those other than 10% stockholders.

Stock Option Activity

A summary of the outstanding stock options 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, 2018	2,125,875	9,806,689	$ 5.86	6.62	$ 105,226
Additional shares reserved					
Options granted	(1,898,251)	1,898,251	12.42		
Options exercised	—	(166,039)	3.24		
Options cancelled	121,777	(121,777)	8.72		
Balances at June 30, 2019	349,401	11,417,124	$ 6.96	6.63	$ 87,792
Vested and expected to vest at June 30, 2019		11,284,854	6.91	6.61	87,261
Outstanding and exercisable at June 30, 2019		11,417,124	$ 6.96	6.63	$ 87,792

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, as determined by the board of directors.

The weighted-average grant date fair value of stock options granted during the six months ended June 30, 2019 and 2018 was $7.82 and $4.93 per share, respectively. The intrinsic value of stock options exercised was $1.7 million and $0.7 million for the six months ended June 30, 2019 and 2018, respectively. Because of the Company's net operating losses, the Company did not realize any tax benefits from stock-based payment arrangements for the three and six months ended June 30, 2019 and 2018.

Early Exercise of Stock Options

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

As of June 30, 2019, there were 140,005 shares of common stock outstanding subject to the Company's right of repurchase at prices ranging from $7.64 to $8.14 per share. At December 31, 2018, there were 205,108 shares of common stock outstanding subject to the Company's right of repurchase at prices ranging from $4.00 to $8.14 per share. As of June 30, 2019 and December 31, 2018, the Company recorded $1.1 million and $1.6 million, respectively, as early exercise stock option liabilities associated with shares issued with repurchase rights.

Employee Stock-Based Compensation Expense

Employee and director stock-based compensation expense for the three and six months ended June 30, 2019 and 2018, 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 to employees and directors for the three and six months ended June 30, 2019 and 2018, which was allocated as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Research and development	$ 2,151	$ 1,294	$ 3,563	$ 2,633
General and administrative	1,482	891	2,643	1,795
Total stock-based compensation expense	$ 3,633	$ 2,185	$ 6,206	$ 4,428

Valuation Assumptions

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes option-pricing model requires the Company to make certain estimates and assumptions, including assumptions related to the expected price volatility of the Company's stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company's stock.

The fair value of stock option awards granted to employees was estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted-average valuation assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Risk-free interest rate	2.19%	2.75%	2.44%	2.59%
Expected term of options (in years)	5.76	6.25	6.17	6.25
Expected stock price volatility	65.47%	70.09%	64.92%	70.81%
Forfeiture rate	2.26%	11.94%	2.18%	5.46%
Expected dividends	—	—	—	—

The weighted-average valuation assumptions were determined as follows:

Expected Stock Price Volatility: The expected volatility is based on the historical volatility of the stock of similar entities within the Company's industry over periods commensurate with the Company's expected term assumption.

Expected Term of Options: The expected term of options represents the period of time options are expected to be outstanding. The expected term of the options granted is derived using the "simplified" method (that is, estimating the expected term as the midpoint between the vesting date and the end of the contractual term for each option).

Risk-Free Interest Rate: The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

Expected Annual Dividends: The Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend.

Forfeiture Rate: The forfeiture rate represents the percentage of unvested stock options the Company expects will not vest, and, therefore, should not be expensed. The Company estimates forfeiture rates based on historical stock option grants and cancellations.

As of June 30, 2019, there was approximately $26.3 million in total unrecognized compensation expense, net of estimated forfeitures, related to unvested options granted to employees and directors under the 2008 and 2018 Plans. The expense is expected to be recognized over a weighted-average period of 2.74 years.

Stock Options Granted to Non-employees

The Company grants stock options to non-employees in exchange for services performed for the Company. The Company granted 22,500 options to non-employees during the three and six months ended June 30, 2019 and did not grant any options during the three and six months ended June 30, 2018. Stock-based compensation expense related to stock-based payment awards to non-employees for the three and six months ended June 30, 2019 was $39,000 and $70,000, respectively. Stock-based compensation expense related to stock-based payment awards to non-employees for the three and six months ended June 30, 2018 was $23,000 and $48,000, respectively. As of June 30, 2019 and December 31, 2018, non-employee stock options to purchase 30,315 and 16,042 shares, respectively, remained unvested.

The fair value of stock option awards granted to non-employees was estimated at the date of grant using a Black-Scholes option-pricing model with the following weighted-average valuation assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Risk-free interest rate	2.26%	—	2.26%	—
Expected term of options (in years)	6.00	—	6.00	—
Expected stock price volatility	65.77%	—	65.77%	—
Expected dividends	—	—	—	—

2019 Employee Stock Purchase Plan

In March 2019, the Company adopted the 2019 ESPP. The Company reserved 1,000,000 shares of common stock pursuant to purchase rights granted to the Company's employees. The 2019 ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1 of each calendar year, beginning January 1, 2020, by the least of (1) 1.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (2) 1,000,000 shares or (3) a number determined by our board of directors that is less than (1) and (2).

Under the 2019 ESPP, eligible employees are granted options to purchase shares of our common stock through payroll deductions that cannot exceed 15% of each employee's salary. The 2019 ESPP provides for a 24-month offering period, which includes four six-month purchase periods. At the end of each purchase period, eligible employees are permitted to purchase shares of common stock at the lower of 85% of fair market value at the beginning of the offering period or fair market value at the end of the purchase period. The 2019 ESPP is considered a compensatory plan and the Company recorded stock-based compensation expense of $0.5 million for the three months ended June 30, 2019. As of June 30, 2019, no shares of common stock were issued under the 2019 ESPP.

The fair value of the rights granted to employees under the 2019 ESPP was estimated at the date of offer using a Black-Scholes option-pricing model with the following weighted-average valuation assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Risk-free interest rate	1.90%	—	1.90%	—
Expected term of options (in years)	1.24	—	1.24	—
Expected stock price volatility	59.79%	—	59.79%	—
Expected dividends	—	—	—	—

10. Income Taxes

The Company has a history of losses, and expects to record a loss in 2019. Additionally, the net deferred tax assets have been fully offset by a valuation allowance against our net operating loss carryforwards. Therefore, the Company has not recorded a provision for income taxes.

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

The following discussion and analysis should be read in conjunction with the audited consolidated financial statements and notes for the year ended December 31, 2018, included in the Company's final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, on April 4, 2019 (the "Prospectus"), and other financial information appearing 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, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. 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 clinical-stage biopharmaceutical company developing novel therapeutics based on our scientific understanding of key biological pathways underlying cardio-metabolic, liver, oncologic and ophthalmic diseases. These diseases are among the largest unmet medical needs globally and 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 seven product candidates, six of which have entered clinical testing. 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, or NASH, in mid-2019. In an ongoing Phase 2 clinical trial, aldafermin has demonstrated the ability to rapidly improve NASH and reverse liver fibrosis at 12 weeks. Our other programs are in Phase 1 clinical or preclinical testing; some of these programs are subject to our Merck collaboration as described below.

In February 2015, we entered into a five-year research collaboration, product development and license agreement with Merck Sharp & Dohme Corp., or Merck, that allows us to develop multiple product candidates in parallel without bearing substantially greater costs or incurring significantly greater risk compared to developing candidates on our own. Through June 30, 2019, Merck had paid us $378.7 million, of which $20.0 million was to license NGM313 and related compounds and $358.7 million was upfront payment and reimbursement of research and development expenses. On March 15, 2019, Merck exercised its option to extend 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 during the two-year extension period and, in lieu of a $20.0 million extension fee payable to us, during such two year extension period, Merck will 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 an IPO issuing an aggregate of 7,521,394 shares of common stock, which included 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. As a result of the IPO, we received approximately $107.8 million in net proceeds, after deducting underwriting discounts, commissions and offering expenses of $4.1 million, of which $2.3 million was paid in 2018. As of June 30, 2019, we offset the deferred offering costs against the net proceeds received from the sale of common stock. At the closing of the IPO, 47,283,839 shares of outstanding convertible preferred stock were automatically converted to common stock on a 1:1 basis. Following the IPO, there were no shares of preferred stock outstanding. Concurrent with the completion of the IPO, we also issued 4,121,683 shares 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.

We have incurred net losses in each year since our inception. Our consolidated net losses were $7.7 million and $15.9 million for the three and six months ended June 30, 2019, respectively, compared to losses of $3.2 million and $7.1 million for the three and six months ended June 30, 2018, respectively. As of June 30, 2019, we had an accumulated deficit of $169.3 million, of which $4.2 million was an accumulated adjustment to retained earnings at January 1, 2019 for the Company's adoption of ASU 2014-09, Revenue from Contracts with Customers, and subsequent amendments ("ASC 606"), under the modified retrospective approach to adoption. 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 clinical trials and our expenses on other research and development activities.

Since inception, we have funded our operations primarily through the private placement of convertible preferred stock totaling $295.1 million, upfront license fees paid by collaboration partners of $123.0 million, our initial public offering with net proceeds of $107.8 million, a concurrent private placement of common stock to Merck for $65.9 million, the license of NGM313 and related compounds to Merck for $20.0 million and research and development service fees provided by collaboration partners of $284.6 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. Accordingly, to fund further operations we may need to raise capital. Until such time as we can generate meaningful revenue from product sales, if ever, we expect to finance our operating activities through public equity or debt financings, collaborations, strategic alliances and licensing arrangements, government or other third-party funding or a combination of these. We may not be able to secure additional funding on terms acceptable to us, or at all, and any failure to secure funding as and when needed could compromise our ability to execute on our business plan, which could materially and adversely affect our business, financial condition and results of operations. To the extent we obtain additional funding through product 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. Additionally, we currently utilize third-party clinical research organizations, or CROs, to carry out our clinical development and we do not have a sales organization.

Financial Operations Overview

Collaboration 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 with Merck. Merck is also a significant stockholder and, as such, collaboration revenue from Merck is referred to as related party revenue. We have not generated any revenue from commercial product sales to date. We receive research and development funding pursuant to our Collaboration Agreement with Merck, and we may also be entitled to receive additional milestone and other contingent payments upon the occurrence of specific events. Due to the nature of this Collaboration Agreement and the nonlinearity of the related revenue recognition, our revenue has fluctuated from period to period in the past and we expect that it will continue to fluctuate in future periods.

The following table summarizes the sources of our collaboration revenue for the three and six months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2019**	**2018**	**2019**	**2018**
Related party revenue				
Recognition of upfront fee	$ 5,710	$ 4,700	$ 11,402	$ 9,400
Collaboration service revenue	19,631	17,418	39,491	31,331
Total related party revenue	$ 25,341	$ 22,118	$ 50,893	$ 40,731

Research and Development Expenses

Research and development efforts relating to our product candidates include manufacturing drug substance, drug product and clinical trial material, conducting preclinical testing 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 acquiring and manufacturing drug substance, drug product and clinical trial materials.

Our clinical development efforts are focused on multiple programs. Our lead product candidate, aldafermin, is the subject of ongoing and planned Phase 2 clinical trials for NASH. We anticipate the majority of our financial resources outside of the Merck collaboration will be dedicated to the development of aldafermin for the foreseeable future, however, we may also devote financial resources to the development of our GDF15 receptor agonist program, or 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. Additionally, if our research and development expenses were to exceed the funding caps provided in our Collaboration Agreement with Merck, we could be required to devote our financial resources toward the development of those programs subject to the collaboration.

The aldafermin clinical trials we have initiated or plan to initiate include: (1) a 24-week expansion cohort of aldafermin (cohort 4) under our ongoing Phase 2 protocol as a double-blind, placebo-controlled study of once-daily 1 mg aldafermin for the treatment of patients with fibrosis stage F2 or F3 NASH, (2) a Phase 2b clinical trial of aldafermin in a double-blind, placebo-controlled format testing 0.3 mg, 1 mg and 3 mg daily doses of aldafermin for 24 weeks for the treatment of patients with fibrosis stage F2 or F3 NASH and (3) a Phase 2b clinical trial of aldafermin for the treatment of NASH patients with early cirrhosis (F4 stage fibrosis). Significant portions of our research and development resources are focused on these clinical trials and other work needed to prepare aldafermin for regulatory approval for the treatment of NASH, including manufacturing of clinical trial material and preparation for Phase 3 testing of aldafermin in NASH.

Our NGM313 product candidate has completed single ascending dose and multiple ascending dose 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, or NAFLD. Merck exercised its option to license the NGM313 program, and all future development expenses will be paid for by Merck 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.

We have initiated Phase 1 clinical trials for NGM120, NGM217 and NGM621, each of which is subject to reimbursement under our Merck collaboration up to the funding caps provided in the agreement. We recently completed a Phase 1 trial assessing the safety, tolerability and pharmacokinetics of NGM120. Later this year, we are planning to initiate a Phase 1a/1b clinical study with NGM120 in cancer patients to explore its potential to treat cancer anorexia-cachexia syndrome and, possibly, cancer. Merck has a one-time option to license NGM120 following completion of a proof-of-concept study in humans.

We are also conducting a Phase 1 clinical trial with NGM217 to assess safety and tolerability and to inform dose-range finding for future studies. Thereafter, we plan to commence a Phase 1b/2a proof-of-concept study in diabetic patients to assess the ability of the agent to increase insulin production by the pancreas. Merck has a one-time option to license NGM217 following completion of a proof-of-concept study in humans.

We initiated a Phase 1 clinical trial of NGM621 in the second half of 2019. We expect the Phase 1 clinical trial will assess the safety and tolerability of up to two intravitreal injections of NGM621 in patients with the dry form of age-related macular degeneration. Merck has the option to license NGM621 following completion of a proof-of-concept study in humans.

NGM386 and NGM395 comprise our GDF15 receptor agonist program and both were licensed to Merck at the inception of our collaboration. Substantially all of the related research and development expenses for these programs were borne directly by Merck under our Collaboration Agreement. Merck terminated its license to the GDF15 receptor agonist program, effective May 31, 2019, and we regained full rights to NGM386 and NGM395. We may incur further research and development expenses following our assessment of the suitability of this program for further development.

Our research and development expenses related to the development of aldafermin, NGM313, NGM120, NGM217 and NGM621 consist primarily of:

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

The following is a comparison of research and development expenses for the three and six months ended June 30, 2019 and 2018:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2019**	**2018**	**2019**	**2018**
External research and development expenses:				
Aldafermin (FGF19 analog)	$ 5,934	$ 2,730	$ 12,714	$ 5,393
NGM313 (FGFR1c/KLB agonist)	644	992	1,773	1,643
NGM386, NGM395 (GDF15 analogs)	416	746	373	743
NGM120 (GFRAL antagonist)	1,894	991	2,183	1,639
NGM217 (undisclosed)	263	515	443	1,241
NGM621 (undisclosed)	1,199	1,648	2,482	1,976
Total external research and development expenses	10,350	7,622	19,968	12,635
Internal and unallocated research and development expenses(1)	18,469	15,224	38,378	29,665
Total research and development expenses	$ 28,819	$ 22,846	$ 58,346	$ 42,300

(1) Internal and unallocated research and development expenses consist primarily of employee compensation, 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 or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- 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 could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another 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 enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation. 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 and potential commercialization of our product candidates. 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 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 Six Months Ended June 30, 2019 and 2018

The following table summarizes our results of operations for the three and six months ended June 30, 2019 and 2018:

	Three Months Ended June 30,			Six Months Ended June 30,		
(in thousands)	**2019**	**2018**	**Change ($)**	**2019**	**2018**	**Change ($)**
Related party revenue	$ 25,341	$ 22,118	$ 3,223	$ 50,893	$ 40,731	$ 10,162
Operating expenses:						
Research and development	28,819	22,846	5,973	58,346	42,300	16,046
General and administrative	6,229	3,458	2,771	11,596	7,332	4,264
Total operating expenses	35,048	26,304	8,744	69,942	49,632	20,310
Loss from operations	(9,707)	(4,186)	5,521	(19,049)	(8,901)	10,148
Interest income	2,044	891	1,153	3,154	1,643	1,511
Other income (expense), net	(6)	95	(101)	(42)	117	(159)
Net loss	$ (7,669)	$ (3,200)	$ 4,469	$ (15,937)	$ (7,141)	$ 8,796

Related Party Revenue. Related party revenue was $25.3 million and $22.1 million for the three months ended June 30, 2019 and 2018, respectively. The increase of $3.2 million in revenue was primarily due to $1.0 million recognized on the adoption of ASC 606, $1.2 million for increased reimbursable research personnel costs and $1.0 million for increased reimbursable research and development costs.

For the six months ended June 30, 2019 and 2018, related party revenue was $50.9 million and $40.7 million, respectively. The increase of $10.2 million in revenue was primarily due to $2.0 million recognized on the adoption of ASC 606, $2.9 million for increased reimbursable research personnel costs, $5.1 million increase in reimbursable research and development costs and $0.3 million for increased costs associated with maintaining our intellectual property rights.

Research and Development Expenses. Research and development expenses were $28.8 million and $22.8 million for the three months ended June 30, 2019 and 2018, respectively. The increase in research and development expenses of $6.0 million was primarily attributable to an increase of $3.2 million in unallocated research and development expenses primarily related to hiring and personnel-related expenses and early research testing and $4.1 million in external expenses primarily related to clinical trials and CRO costs for our aldafermin and NGM120 programs. These increases were partially offset by a decrease of $1.3 million in other program external expenses resulting from timing of clinical trial activities and lower manufacturing costs of clinical materials.

For the six months ended June 30, 2019 and 2018, research and development expenses were $58.3 million and $42.3 million, respectively. The increase in research and development expenses of $16.0 million was primarily attributable to an increase of $8.7 million in unallocated research and development expenses primarily related to hiring and personnel-related expenses and early research testing, $3.0 million for the acquisition of clinical trial materials and $5.5 million in external expenses primarily related to clinical trial and CRO costs for aldafermin, NGM120 and NGM621 programs. These increases were partially offset by a decrease of $1.2 million in other program external expenses resulting from timing of clinical trial activities and lower manufacturing costs of clinical materials. 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 borne by our collaborator, such as aldafermin and, possibly, NGM386 and NGM395, advance in clinical development.

General and Administrative Expenses. General and administrative expenses were $6.2 million and $3.5 million for the three months ended June 30, 2019 and 2018, respectively. The increase in general and administrative expenses of $2.7 million was primarily due to an increase of $1.3 million in personnel-related expenses, $0.6 million for legal and accounting expenses and $0.8 million for consulting expenses.

For the six months ended June 30, 2019 and 2018, general and administrative expenses were $11.6 million and $7.3 million, respectively. The increase in general and administrative expenses of $4.3 million was primarily due to an increase of $1.8 million in personnel-related expenses, $1.5 million for legal and accounting expenses and $1.0 million for consulting expenses. We anticipate general and administrative expenses will increase with expansion of support resources.

Interest Income. Income was $2.0 million and $0.9 million for the three months ended June 30, 2019 and 2018, respectively and $3.2 million and $1.6 million for the six months ended June 30, 2019 and 2018, respectively. The increase in interest income was primarily attributable to higher yields on our available-for-sale marketable securities and an increase in our cash and investments balance subsequent to the completion of our IPO in April 2019.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operating activities since our inception. As of June 30, 2019, our operations have been financed primarily through the private placement of convertible preferred stock totaling $295.1 million, upfront license fees paid by collaboration partners of $123.0 million, the license of NGM313 and related compounds to Merck for $20.0 million and research and development service fees provided by collaboration partners of $284.6 million. In April 2019, we completed our IPO and issued an aggregate of 7,521,394 shares of common stock, which included 6,666,667 shares of common shares and 854,727 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares, at an offering price of $16.00 per share. We received $107.8 million, net of underwriting discounts, commissions and offering expenses. We concurrently completed a private placement of 4,121,683 common shares to Merck at a price of $16.00 per share, for proceeds of $65.9 million. As of June 30, 2019, we had cash and cash equivalents of $265.1 million, short-term marketable securities of $97.1 million, working capital (excluding deferred revenue) of $347.1 million and an accumulated deficit of $169.3 million, compared to cash and cash equivalents of $56.9 million, short-term marketable securities of $149.7 million, working capital (excluding deferred revenue) of $192.1 million and an accumulated deficit of $147.2 million at December 31, 2018.

We anticipate that we will continue to incur net losses for the foreseeable future as we continue the development of our product candidates, expand our corporate infrastructure, including the costs associated with becoming a public company, and conduct pre-commercialization activities. We will require substantial additional capital to achieve our development and commercialization goals for aldafermin, for any Merck licensed programs that we opt to co-develop for any programs that Merck does not opt to develop and that we choose to develop and for any programs for which Merck elects to terminate its license, including NGM386 and NGM395, for which Merck has terminated its license and that we are considering whether to advance pending study results. If our Merck collaboration were to be terminated, we could require significant additional capital in order to proceed with development and commercialization of our product candidates, or we may require additional partnering in order to help fund such development and commercialization. We plan to continue to fund our operations and capital funding needs through public or private equity or debt financings, government or other third-party funding, collaborations, strategic alliances and licensing arrangements or a combination of these. The sale of convertible debt or additional equity 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 assure you that financing will be available in the amounts we need or on terms acceptable to us, 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 suspend or curtail planned programs. Any of these actions could materially harm our business, results of operations and future prospects.

We believe that our existing cash and cash equivalents, along with amounts available to us under our Collaboration Agreement with Merck will be sufficient to meet our anticipated cash requirements for at least the next 12 months. 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.

Cash Flows

The following table shows a summary of our cash flows for the six months ended June 30, 2019 and 2018 (in thousands):

	Six Months Ended June 30,	
(in thousands)	**2019**	**2018**
Net cash provided by (used in):		
Operating activities	$ (19,877)	$ (8,754)
Investing activities	51,491	22,024
Financing activities	176,535	49
Net increase in cash and cash equivalents	$ 208,149	$ 13,319

Cash Used in Operating Activities

During the six months ended June 30, 2019, cash used in operating activities was $19.9 million, which consisted of a net loss of $15.9 million, adjusted for non-cash charges of $9.4 million and cash used through changes in operating assets and liabilities of $13.4 million. The non-cash charges consisted primarily of stock-based compensation expense of $6.3 million and depreciation expense of $3.9 million. The change in operating assets and liabilities was primarily due to a decrease in accounts receivable from related party collaboration revenue of $2.8 million, increase in prepaid expenses and other current assets of $1.9 million, decrease in accounts payable of $2.5 million, increase in accrued expenses and other liabilities of $1.2 million and decreases in deferred rent and deferred revenue of $1.3 million and $11.7 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.

During the six months ended June 30, 2018, cash used in operating activities was $8.8 million, which consisted of a net loss of $7.1 million, adjusted for non-cash charges of $7.8 million and cash used through changes in operating assets and liabilities of $9.4 million. The non-cash charges consisted primarily of stock-based compensation expense of $4.5 million and depreciation expense of $3.5 million. The change in operating assets and liabilities was primarily due to a decrease in deferred revenue of $9.9 million due to the recognition of upfront license fees from Merck and the timing of advance payments from Merck related to the reimbursement of costs associated with research and development activities. This was partially offset by an increase in accounts payable of $2.1 million.

Cash Provided by Investing Activities

During the six months ended June 30, 2019, cash provided by investing activities was $51.5 million, which consisted of $129.0 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 $2.3 million.

During the six months ended June 30, 2018, cash provided by investing activities was $22.0 million, which consisted of $97.3 million in proceeds from the maturities of marketable securities, partially offset by purchases of marketable securities of $70.2 million and purchases of property and equipment of $5.1 million.

Cash Provided by Financing Activities

During the six months ended June 30, 2019, cash provided by financing activities was $176.5 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 $0.5 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.

During the six months ended June 30, 2018, cash provided by financing activities was $49,000, which consisted of proceeds from the issuance of common stock upon the exercise of previously granted stock options of $0.2 million less repurchases of common stock of $0.2 million.

Off-Balance Sheet Arrangements

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

Contractual Obligations

Our principal obligations consist of the operating lease for our facilities and non-cancelable purchase commitments with contract manufacturers or service providers. The following table sets out, as of June 30, 2019, our contractual obligations due by period (in thousands):

	Payments due by period				
	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years	Total
Contractual obligations:					
Operating lease obligations(1)	$ 4,922	$ 15,656	$ 2,768	$ —	$ 23,346
Total contractual obligations	$ 4,922	$ 15,656	$ 2,768	$ —	$ 23,346

(1) Consists of our corporate headquarters lease encompassing approximately 122,000 square feet of office and laboratory space that expires in December 2023.

We enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical studies and other services and products for operating purposes that are cancelable at any time by us, generally upon 30 days' prior written notice. These payments are not included in this table of contractual obligations.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, low single-digit royalties and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our consolidated balance sheets or in the contractual obligations table above.

Quantitative and Qualitative Disclosures about Market Risk

Our cash, cash equivalents and marketable securities as of June 30, 2019 consisted of readily available checking and money market funds, as well as available-for-sale securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operations. We believe that our exposure to interest rate risks is not significant and that a hypothetical 10% movement in market interest rates would not have a significant impact on the total value of our portfolio or our interest income. We do not believe that our cash, cash equivalents or marketable securities have significant risk of default or illiquidity. While we believe our cash, cash equivalents and marketable securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash, cash equivalents and marketable securities at one or more financial institutions that are in excess of federally insured limits.

We are also exposed to market risk related to changes in foreign currency exchange rates, mainly relating to our Australian subsidiary. In addition, we contract with vendors that are located in Asia and Europe, and the payments under such contracts are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these agreements. We do not currently hedge our foreign currency exchange rate risk. As of June 30, 2019 and December 31, 2018, our liabilities denominated in foreign currencies were not material. A 10% increase or decrease in current exchange rates would not have a material effect on our financial results.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our condensed consolidated financial statements, as well as revenue and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. 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.

Our significant accounting policies are described in Note 2 to our condensed consolidated financial statements appearing elsewhere in this quarterly report. We believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Revenue Recognition

On January 1, 2019, we adopted ASU 2014-09, Revenue from Contracts with Customers, and subsequent amendments (ASC 606), using the modified retrospective transition method applied to those contracts that were not completed as of January 1, 2019. ASC 606 supersedes all prior revenue recognition guidance. Results for operating periods beginning after January 1, 2019 are presented under ASC 606, while prior period amounts have not been adjusted and continue to be reported in accordance with previous accounting rules under Accounting Standards Codification Topic 605, Revenue Recognition ("ASC 605").

The core principle in 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. We apply 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) we satisfy a performance obligation.

All of our revenue to date has been generated from our collaboration agreements. The terms of these agreements generally require us to provide (i) license options for our 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.

We assess whether the promises in our arrangements, including any options provided to the customer, 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 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 variable consideration related to the performance of research and development services. We typically submit a budget for the research and development services to the customer 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 SSP. In instances where 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. We utilize judgment to assess the nature of our 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. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Our 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, we evaluate whether the milestones are considered probable of being achieved and estimate 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 our or our customer'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, we re-evaluate the probability of achievement of each such milestone and any related constraint and, if necessary, adjust our 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.

Prior to the adoption of ASC 606, our revenue from collaboration agreements was recognized when we determined that persuasive evidence of an arrangement exists, services had been rendered, the price was fixed or determinable and collectability was reasonably assured. We would record amounts received prior to satisfying the above revenue recognition criteria as deferred revenue until all applicable revenue recognition criteria were met. Revenue allocated to research activities was generally recognized in the period the services were performed, and revenue allocated to licenses was generally recognized on a straight-line basis over the contractual term. Allocations to non-contingent elements were based on the relative selling price of each element using vendor-specific objective evidence or third-party evidence, where available. In the absence of either of these measures, we used the best estimate of selling price for that deliverable.

The most significant change to our policies upon the adoption of ASC 606 is the estimation of an arrangement's total transaction price, which would include any variable consideration and the recognition of that transaction price based on a cost-based input method that requires significant estimates to determine, at each reporting period, the percentage of completion based on the estimated total effort required to complete the project and the total transaction price. Given the differences in revenue recognition policies, the revenue recognized in prior years is not strictly comparable to revenue recorded in the quarter ending June 30, 2019 or in future periods (see Recently Adopted Accounting Pronouncements in the condensed consolidated financial statements).

Accrued Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue expenses, the largest of which are research and development expenses. This process involves:

- communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost;
- estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and
- periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to contract research organizations in connection with preclinical studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to contract manufacturing organizations in connection with the production of clinical trial materials; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical trials on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical study milestones. Our service providers generally invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses after a reporting period. However, due to the nature of estimates, we cannot assure that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

Stock-Based Compensation

Stock-based compensation expense represents the grant date fair value of employee stock option grants and rights to acquire stock granted under our 2019 ESPP, recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures.

Subsequent to the adoption of ASU 2018-07, Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, 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 requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures.

We calculate the fair value of stock-based compensation awards using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model requires the use of subjective assumptions, including stock price volatility, the expected life of stock options, risk free interest rate and the fair value of the underlying common stock on the date of grant. Our key assumptions are:

- ***Expected Stock Price Volatility:*** The expected volatility is based on the historical volatility of the stock of similar entities within our industry over periods commensurate with our expected term assumption.
- ***Expected Term of Options:*** The expected term of options represents the period of time options are expected to be outstanding. The expected term of the options granted is derived using the “simplified” method (that is, estimating the expected term as the mid-point between the vesting date and the end of the contractual term for each option).
- ***Risk-free Interest Rate:*** We base the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.
- ***Expected Annual Dividends:*** The estimate for annual dividends is zero because we have not historically paid dividends, and do not expect to pay dividends for the foreseeable future.

We recorded stock-based compensation expense related to employees, directors and nonemployees of $3.7 million and $6.3 million for the three and six months ended June 30, 2019, respectively compared to $2.2 million and $4.5 million for the three and six months ended June 30, 2018. As of June 30, 2019, we had unrecognized stock-based compensation cost related to options granted to employees and directors of $26.3 million, net of forfeitures, which is expected to be recognized as expense over approximately 2.74 years.

Historically, the fair value of the common stock underlying our share-based awards was estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, timely valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Given the absence of a public trading market for our common stock historically, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including our stage of development; progress of our research and development efforts; the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock; equity market conditions affecting comparable public companies; and the lack of marketability of our common stock.

We have utilized the probability-weighted expected return method, or PWERM, alone or in combination with the option pricing method, or OPM, as a hybrid method, or Hybrid Method, each an accepted valuation method under the AICPA Practice Guide, for determining the fair value of our common stock. The PWERM is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of expected future equity values for the common stock, under various possible future liquidity event scenarios, in light of the rights and preferences of each class and series of stock, discounted for a lack of marketability. The OPM values each equity class by creating a series of call options on the equity value, with exercise prices based on the liquidation preferences, participation rights and strike prices of derivatives. The Hybrid Method is appropriate for a company expecting a near term liquidity event, but where, due to market or other factors, the likelihood of completing the liquidity event is uncertain. The Hybrid Method considers a company’s going concern nature, stage of development and the company’s ability to forecast near and long-term future liquidity scenarios. In connection with our preparation for filing a registration statement with the SEC, we evaluated whether or not in retrospect the valuation of our common stock as of the date of each option grant over the previous 12 months was appropriate for accounting purposes.

The dates of our contemporaneous valuations have not always coincided with the dates of our stock option grants. In determining the exercise prices of the stock options, our board of directors considered, among other things, the most recent contemporaneous valuations of our common stock and our assessment of additional objective and subjective factors we believed were relevant as of the grant date. The additional factors considered when determining any changes in fair value between the most recent contemporaneous valuation and the grant dates included our stage of research and development, our operating and financial performance and current business conditions.

After our IPO, the fair market value of each share of underlying common stock is determined based on the closing price of our common stock as reported by the Nasdaq Global Select Market on the date of grant.

JOBS Act Accounting Election

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies may delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards would otherwise apply to private companies.

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition time to comply with new or revised accounting standards as applicable to public companies. We have elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earlier to occur of (1) (a) December 31, 2024, (b) the last day of the fiscal year in which our annual gross revenue is $1.07 billion or more, or (c) the date on which we are deemed to be a "large accelerated filer," under the rules of the SEC, which means the market value of our equity securities that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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 six months ended June 30, 2019, as compared to the recent accounting pronouncements described in our audited consolidated financial statements and notes for the year ended December 31, 2018, included in the Company's final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, on April 4, 2019, that are of significance or potential significance to us.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business, primarily related to interest rate and foreign currency sensitivities.

Interest Rate Sensitivity

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and marketable securities of $362.2 million as of June 30, 2019, which consisted primarily of money market funds and marketable securities, largely composed of investment grade, short to intermediate term fixed income securities.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and short-term duration, according to our board-approved investment charter. Our investments are subject to interest rate risk and could fall in value if market interest rates increase. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our condensed consolidated financial statements.

Foreign Currency Sensitivity

The majority of our transactions occur in U.S. dollars. However, we do have certain transactions that are denominated in currencies other than the U.S. dollar, primarily Australian dollars, British Pounds, Swiss Francs and the Euro, and we therefore are subject to foreign exchange risk. The fluctuation in the value of the U.S. dollar against other currencies affects the reported amounts of expenses, assets and liabilities associated with a limited number of manufacturing, preclinical and clinical activities. A hypothetical 10% change in foreign currency exchange rates during any of the periods presented would not have had a material impact on our condensed consolidated financial statements.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of June 30, 2019, management, with the participation of our Chief Executive Officer and acting 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 Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and acting 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 acting Chief Financial Officer concluded that, as of June 30, 2019, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended June 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Our business involves significant risks, some of which are described below. You should carefully consider the following risks, as well as the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock.

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 clinical-stage biopharmaceutical company that was incorporated in December 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. Our net loss was $0.5 million and $14.2 million for the years ended December 31, 2018 and 2017, respectively. For the three and six months ended June 30, 2019, we also incurred net losses of $7.7 million and $15.9 million, respectively, compared to net losses incurred for three and six months ended June 30, 2018 of $3.2 million and $7.1 million, respectively. As of June 30, 2019, we had an accumulated deficit of $169.3 million.

We have spent, and expect to continue to spend, significant resources to fund research and development of, and seek regulatory approvals for, our product candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, preclinical testing and clinical trial 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. 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.

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

Over the past two years, substantially all of our revenue was from our collaboration partner, Merck. We will require substantial additional capital to achieve our development and commercialization goals for aldafermin, for any Merck licensed programs that we opt to co-develop and for any programs that Merck does not opt to license and that we choose to develop, such as NGM386 and/or NGM395, for which Merck terminated its license effective May 31, 2019 and for which we are considering advancement pending study results. Under the Merck collaboration, Merck provides us with reimbursement for research and development activities of up to $50 million per year, plus additional amounts up to agreed upon annual caps, if certain conditions are met; however, we may require additional funding to advance our research and development affairs on our planned timeline, or at all. If our Merck collaboration were to be terminated, or if the annual cap under the Merck collaboration is insufficient, we could require significant additional capital in order to proceed with development and commercialization of our product candidates, or we may require additional partnering in order to help fund such development and commercialization. Merck has exercised its option to extend the research and early development program through March 16, 2022 and has the right to extend it again through March 16, 2024. If adequate funds or partners are not available to us on a timely basis, on favorable terms or at all, we may be required to delay, limit, reduce or terminate our research and development efforts or other operations.

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, alone or with our partners, successfully completes clinical trials, receives regulatory approval and is successfully commercialized. As our product candidates are in early 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 and future partners' 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 and legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
- launch and commercialize future 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 post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for our or our partners' products, if any;
- 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 the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or if or when we will achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we decide, or are required by the FDA or foreign regulatory authorities, to perform studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, 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, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

We may 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 product candidates or develop new product candidates.

As a research and development company, our operations have consumed substantial amounts of cash since inception. 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 borne by our collaborator, such as aldafermin, NGM386 and NGM395, advance in clinical development. We believe that our existing cash, cash equivalents and short-term marketable securities and funding we expect to receive under our existing Collaboration Agreement and through our IPO, will fund our projected operating requirements for at least the next twelve months. Our forecast of the period of time through which our financial resources will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary 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, costs and results of preclinical tests and clinical trials for our product candidates and future product candidates we may develop;
- whether Merck exercises its option to license product candidates upon our completion of a proof-of-concept study in humans;
- whether Merck terminates the research collaboration (under pre-specified circumstances in the Collaboration Agreement) or terminates a program that is licensed;

- whether Merck exercises its remaining option to extend the research phase of its collaboration with us, which would trigger an extension payment to us;
- 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 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 of any patents or other intellectual property rights;
- the effect of competing technological and 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 our 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 technologies.

Unless and until we can generate a sufficient amount of revenue from our 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 terminated in certain circumstances. We expect to finance future cash needs through public or private equity or debt offerings or product collaborations. Additional capital may not be available in sufficient amounts or on reasonable terms, if at all. 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. 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 need to secure additional financing, such additional fundraising efforts may divert our management and research efforts from our day-to-day activities, which may adversely affect our ability to develop and commercialize future product candidates. If we do not raise additional capital, 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
- relinquish, or license on unfavorable terms, our rights to technologies or any product candidates that we otherwise would seek to develop or commercialize ourselves.

If we need to conduct additional fundraising activities, but are unable to do so, we may be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

To the extent we obtain additional funding through product 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. If we are unable to obtain additional funding on a timely basis, we may be required to curtail or terminate some or all of our development programs or product candidates.

We plan to use current year operating losses and our federal and state net operating loss, or NOL, carryforwards to offset taxable income from revenue generated from operations, including corporate collaborations. However, our ability to use NOL carryforwards 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 NOL carryforwards to offset income that would otherwise be taxable. However, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, the amount of benefits from our NOL carryforwards may be impaired or limited if we incur a cumulative ownership change of more than 50%, as interpreted by the U.S. Internal Revenue Service, over a three-year period. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of our initial public offering and subsequent shifts in our stock ownership, some of which are outside our control. As a result, our use of federal NOL carryforwards could be limited. State NOL carryforwards may be similarly limited. Any such disallowances may result in greater tax liabilities than we would incur in the absence of such a limitation 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 and 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 and extensive regulatory approval processes implemented by the FDA and similar regulatory bodies in other countries. The approval process is typically lengthy and expensive, and approval is never certain. We or our collaborator, if any, may delay, suspend or terminate clinical trials 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 institutional review boards or other governing entities at clinical sites selected for participation in our clinical trials;
- delays in enrolling participants into clinical 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 NASH that issued in 2018 and 2019 and from the EMA that issued in 2018;
- the need to repeat clinical trials as a result of inconclusive or negative results or poorly executed testing or changes in required endpoints by the FDA or comparable foreign authorities;
- insufficient supply or deficient quality of product candidate materials or other materials necessary to conduct our clinical trials;
- unfavorable FDA 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 the 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 active, 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 receive 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 future product candidates, we or our partners must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Preclinical studies and clinical trials are expensive, will 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, NGM120, and NGM386 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 effective or safe 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 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 acceptable to the FDA in our trials. 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 our product treatments and the average exposure time in the 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 partners to develop drugs that are effective and safe in humans, we will not have a viable business.

The Phase 2 clinical trial of aldafermin that has produced NASH histology data is ongoing, and the clinical data produced to date is preliminary and has not been subjected to quality control procedures.

We have ongoing, Phase 2 clinical trials of aldafermin in NASH. Until the 24-week cohort of the aldafermin Phase 2 clinical trial is completed, we are unable to perform typical quality control procedures on the data produced in this trial to ensure its accuracy. While we believe the data available to date is accurate, until such time as the final quality control procedures are performed it should be regarded as preliminary. Differences between preliminary data and final data may lead us to make different operational decisions regarding or incur additional expenses for the development of aldafermin than we otherwise would if final data was available. Additionally, our business and prospects depend on the development of this program, and, if final data is less promising than the preliminary data suggests, our business and prospects could be adversely affected.

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. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. To date, some of our clinical trials have involved small patient populations and, because of the small sample size in such trials, 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 is 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 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 drug candidates for approval in the United States requires filing an IND application and reaching agreement with the FDA on clinical protocols, finding appropriate clinical sites and clinical investigators, securing approvals for such studies from the institutional review board at each such site, manufacturing clinical quantities of drug candidates and supplying drug product to clinical sites. Currently, we have multiple active INDs with the FDA in the United States, including for aldafermin for NASH and primary biliary cholangitis, or PBC, for NGM621 for geographic atrophy secondary to age-related macular degeneration and for NGM120 for treatment of solid tumors and pancreatic cancer, and an active Clinical Trial Authorisation in the United Kingdom from the Medicines and Healthcare Products Regulatory Agency for NGM217 for diabetes.

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. We do not know whether any other 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 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 unsuccessful completion of clinical development include:

- delays in reaching agreement on acceptable terms with prospective contract research organizations, or 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 of the product candidates to the clinical sites;
- 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;
- delays in patient enrollment;
- delays in patients completing a trial or returning for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to side effects or disease progression;
- demonstration of a significant adverse safety or tolerability signal limiting the utility of the therapeutic 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 from our clinical trials 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 partners' inability to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenue or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

If 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;
- the number and location of clinical sites we enroll;
- competition with other companies for clinical 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, and 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 potential 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. 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;
- we tend to identify and select from our drug discovery efforts 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 collaboration partners may change their development profiles or plans for potential product candidates or abandon a therapeutic area or the development of a 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. Research programs to identify new product candidates require substantial technical, financial and human resources. 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 products.

To date, our product candidates have been manufactured by third-party manufacturers solely for preclinical studies and clinical trials. These manufacturers may not be able to scale production to the larger quantities required for large clinical trials and to commercialize our product candidates. We have entered into a Development and Manufacturing Services Agreement with Lonza Ltd. for the production of Phase 3 and commercial supplies of aldafermin. The process of manufacturing our products 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 may fail to qualify upon an audit by Merck under our Collaboration Agreement;
- 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, natural disasters, power failures, local political unrest and numerous other factors; and
- any adverse developments affecting 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 products. We may also have to record inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

Certain raw materials necessary for the manufacture of our product candidates under our current manufacturing process, such as reagents that support cell growth, are available only from a single supplier and have been purchased without a long-term supply agreement. For example, we have a non-exclusive license from Lonza Sales AG to use its glutamine synthetase gene expression system, available only from Lonza Sales AG, to manufacture and commercialize our proprietary products, including our product candidates that are currently subject to our collaboration with Merck. We do not have agreements in place that guarantee our supply or the price of these raw materials. 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 assure you 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 human 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 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, or PSC, and intervertebral discitis. In our completed Phase 1 and Phase 1b clinical trials of NGM313, there were two reported serious adverse events: 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, preliminary data indicate there were three reported serious adverse events: renal colic, bipolar disorder and panic attack, all of which were deemed by the investigators to be unrelated to treatment with NGM120 or placebo.

Significant increases in serum levels of low density lipoprotein, or 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. While the impact of these drug-induced changes in cholesterol are unknown, we believe that concomitant statin use, along with aldafermin's triglyceride lowering and high density lipoprotein, or HDL, cholesterol elevating properties, will provide an overall neutral to positive impact on patients' cardiovascular health. 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.

One subject in the aldafermin Phase 2 clinical trial in type 2 diabetes developed antibodies against aldafermin that appear to cross-react with FGF19. This patient did not demonstrate any biochemical or clinical safety concerns while in the study, and we have not identified any safety concerns while monitoring the subject following the study. Six of the 36 subjects in the aldafermin Phase 2 extension clinical trial in PBC were confirmed to have antibodies against aldafermin. These subjects have not demonstrated any biochemical or clinical safety signals that were different from observations in subjects that did not generate antibodies against aldafermin. However, future results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In such an event, we could 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 or 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 a modified version of FGF19, a human hormone 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, or CAC, 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 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, or BLA. As a result of such incomplete information or due to incorrect analysis by us, we may select a cost and profit share program that later proves to have less commercial potential than an alternative, or none at all, or may pass on a cost and profit sharing program that proves commercially successful.

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team, especially Dr. Jin-Long Chen, and our scientific advisors or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer. The departure of Dr. Chen within the next several years would permit Merck to shift the focus under our Collaboration Agreement to concentrate on the development of later-stage product candidates.

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. We are dependent on the members of our management team and our scientific advisors for our business success. An important element of our strategy is to take advantage of the research and development expertise of our current management and to utilize the expertise of our scientific advisors in the cardio-metabolic, liver, oncologic and ophthalmic disease fields. We currently have employment letter agreements with all of our executive officers. Our employment agreements with our executive officers are terminable by them without notice and some provide for severance and change in control benefits. The loss of any one of our executive officers or key scientific consultants, 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. Prior to March 17, 2020, the departure of Dr. Chen as our employee or director of our research (other than on account of his employment by Merck) would give Merck the right to shift the focus of its research and development funding to concentrate on the development of later-stage product candidates, but Merck would not have the right to terminate or otherwise alter the conduct of the collaboration.

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, scientific, administrative and commercial 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 commercialization of our product candidates. In particular, we have experienced a very competitive hiring environment in the San Francisco Bay Area, where we are headquartered. 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, formulation supplier, manufacturing, clinical research organization 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 intend to conduct research programs in a range of therapeutic areas, but 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 Merck 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 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, reporting systems and operational, financial and management controls. 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 technology 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 technologies, 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, 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, Amgen, Can-Fite, Cirius, CymaBay, Enanta, Galectin, Galmed, Genfit, Gilead, Intercept, Inventiva, Madrigal, MannKind, MediciNova, Metacrine, Nalpropion, Terns, Viking, Vivus and Zafgen, 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 cardio-metabolic disorders, liver, oncologic and ophthalmic diseases will increase. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical testing 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. Many of our competitors have established distribution channels for 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 from Gilead; OCA, an FXR agonist, from Intercept; MGL-3196, a beta-thyroid hormone receptor agonist from Madrigal; pegbelfermin, PEGylated FGF21, from Bristol-Myers Squibb; AKR-001, an Fc conjugated FGF21 from Akero; elobixibat, an IBAT-inhibitor from Albireo; a Galectin-3 inhibitor from Galectin; a synthetic conjugate of cholic acid and arachidic acid from Galmed; an FXR agonist from Metacrine; FXR agonists from Novartis; semaglutide, a GLP-1 analog from Novo Nordisk; a mitochondrial pyruvate complex modulator from Cirius; a PPAR delta agonist from CymaBay; and a PPAR alpha/delta agonist from Genfit. 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; Thiazolidinediones (TZDs); Alpha-glucosidase inhibitors (AGIs); Dipeptidyl peptidase 4 (DPP4) inhibitors; Glucagon-like peptide-1 (GLP-1)

analogues; SGLT2 inhibitors; and Insulins, including injectable and inhaled versions. Further competition could arise from products currently in development, including: 11 beta HSD (Incyte, Japan Tobacco, Roche); GPR40 (Connexios, Takeda); and oral GLP-1 mimetics (Novo Nordisk). Some of these programs have been 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, pharmaceutical companies and others in the medical community. Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, 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. We cannot be certain that third-party payors will sufficiently reimburse sales of our products, or otherwise enable us to sell our products at profitable prices. Similar concerns could also limit the reimbursement amounts that health insurers or government agencies in other countries are prepared to pay for our products. In many regions, including Europe, Japan and Canada, where we may market our products, either directly or with our collaborators, the pricing of prescription drugs is controlled by the government or regulatory agencies. Regulatory agencies in these 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. 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 in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities;
- the relative convenience and ease of administration;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- 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 by these physicians 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. 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. 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 ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. 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 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 of 2010, or, collectively, the Affordable Care Act, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and congressional challenges to certain aspects of the Affordable Care Act. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. The U.S. House of Representatives passed legislation known as the American Health Care Act of 2017. More recently, the Senate Republicans introduced and then updated a bill to replace the Affordable Care Act known as the Better Care Reconciliation Act of 2017. The Senate Republicans also introduced legislation to repeal the Affordable Care Act without companion legislation to replace it, and a “skinny” version of the Better Care Reconciliation Act of 2017.

Each of these measures was rejected by the full Senate. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act’s individual mandate to carry health insurance and delaying the implementation of certain Affordable Care Act - mandated fees. Congress will likely consider other legislation to replace elements of the Affordable Care Act. In December 2018, a United States District Court judge in Texas ruled that the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While this U.S. District Court judge, as well as the Trump administration and Centers for Medicare and Medicaid Services, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011 was enacted, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2025 unless Congress takes additional action. Recently, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, 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. For example, the Trump administration released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. 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 in 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. 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. 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.

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 centers are located outside of the United States. Furthermore, if we or our collaborator succeeds in developing any products, we intend to market them in the European Union and other jurisdictions in addition to the United States. If approved, we or our 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 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;
- 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 in 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, 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 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, 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 future arrangements with 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 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 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 of 1996, or HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, also imposes obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, 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 Affordable Care Act 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 U.S. Department of Health and Human Services 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 U.S. Department of Health and Human Services ownership and investment interests held by physicians (as defined above) and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; 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, 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 could disrupt the operations of our 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. The contract manufacturing organization that is the sole supplier of clinical drug substance of NGM313, NGM120, NGM217, NGM621, NGM386 and NGM395, is located in a region that has experienced recent political unrest.

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 and consultants may fail and are vulnerable to damage from computer viruses and unauthorized access. While we have not, to our knowledge, experienced any such 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. 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 resulted in an integrity loss of certain clinical sample data for aldafermin that may result in material costs to recover or reproduce the data. 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 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 European Union in connection with our business, including in connection with conducting clinical trials in the European Union. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the European Union. The collection and use of personal health data in the European Union is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679), or the 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

European Union 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.

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 these product candidates.

In February 2015, we entered into a collaboration with Merck focused on the discovery, development and commercialization of biologics, including NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621 but excluding aldafermin. In November 2018, Merck exercised its option to license NGM313. Merck's license to the GDF15 receptor agonist program, including NGM386 and NGM395, was terminated effective May 31, 2019. On March 15, 2019, Merck exercised its option to extend the collaboration for an additional two years, from March 17, 2020 through March 16, 2022. The collaboration involves a complex allocation of rights, provides for substantial research and development support, provides for additional payments upon Merck's election to extend the term of the research program 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, including whether Merck exercises its option to license additional product candidates or terminates its license to a 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, NGM386 and NGM395. 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 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 will be 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, Merck might opt not to exercise its option to acquire a license to a product candidate that has generated proof-of-concept data, or Merck may opt to terminate its license to a program, as it did for NGM386 and NGM395.
- 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. For example, under our agreement with Merck, it is possible for Merck to terminate the NGM313 program and any program for which we have not exercised our cost and profit sharing option upon prior written notice or terminate any program for which we have exercised our cost and profit sharing option upon prior written notice, without triggering a termination of the remainder of the collaboration arrangement.

- 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 our collaboration arrangement 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, terminate or shift the focus of its research and development funding, any of which would materially and adversely affect our business.

Under our Collaboration Agreement with Merck, Merck has the right to terminate all or part of the agreement at certain times and under certain circumstances. Merck may terminate the research and early development program effective March 17, 2022 by providing notice to us prior to March 17, 2021. Merck may 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. Prior to March 17, 2020, the departure of Dr. Chen as our employee or director of our research (other than on account of his employment by Merck) gives rise to the right of Merck to shift the focus of the research and development funding provided by Merck to concentrate on the development of later-stage product candidates, but Merck would not have the right to terminate or otherwise alter the conduct of the collaboration. After the current term of the collaboration or, if Merck again exercises its option to extend the term, after such extension period, Merck may terminate the overall agreement for convenience upon written notice and subject to certain limitations.

Subject to certain limitations, Merck may partially terminate the agreement for convenience as it relates to NGM313 or any future optioned program. Merck terminated its license to the GDF15 receptor agonist program effective May 31, 2019. Merck may also terminate the agreement as it relates to its rights to research and develop small molecule compounds. It may also terminate the agreement with respect to a specific optioned program, such as NGM313, 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 optioned 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 could impede our ability to fund and complete our research and development programs, which would materially and adversely affect our business.

We may not be able to obtain and maintain the third party relationships 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, clinical research organizations, 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 substance and drug product and to market, sell and distribute any products we successfully develop. Any problems we experience with any of these third parties could delay the development, commercialization and manufacturing of our 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, NGM386, NGM395, NGM217, NGM120 and NGM621 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 optioned 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 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, 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 and our collaborator expect to expend substantial management time and effort to enter into relationships with third parties and, if we or our collaborator 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, preclinical and clinical development and manufacturing of our programs and, therefore, enter into these relationships with less information than if these third parties were in the United States and 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, NGM386 and NGM395, 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 similar regulatory authorities outside the United States, 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 technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

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 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, 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 curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on 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 testing, 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 contract research organizations, clinical data management organizations, medical institutions, consultants and clinical investigators, to conduct our clinical trials and certain aspects of our research and preclinical testing. 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 current Good Clinical Practices, 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.

We also expect to rely on other 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.

We contract with third parties for the manufacture of our product candidates for preclinical testing and expect to continue to do so for clinical trials and for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or medicines or that such supply will not be available to us 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 testing and for commercial supply of any of these product candidates for which we or our collaborator obtains marketing approval. To date, we have obtained materials for aldafermin, NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621 for our preclinical and clinical testing from third-party manufacturers. Other than for a long-term supply agreement with Lonza for aldafermin, 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 or to do so on acceptable terms. 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;
- 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 current Good Manufacturing Practices, or cGMP, regulations 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 for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or medicines may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis.

Risks Related to Regulatory Approvals

None of our product candidates has received regulatory approvals. 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. 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 clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any 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 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 of our product candidates to support the submission and filing of a biologics license application, or 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 our commercialization plans, or we may decide to abandon the development program for other reasons. If we were to 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.

We have received orphan drug status for aldafermin for PBC in the United States and for PBC and PSC in the European Union. The FDA grants orphan drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States and fewer than five in 10,000 individuals in the European Union. Typically, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or the European Medicines Agency, or EMA, from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and 10 years in the European Union. The European Union exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Although we have obtained orphan drug status for aldafermin for PBC and PSC, that exclusivity may not effectively protect the candidate from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior, in that it is shown to be safer, more effective or makes a major contribution to patient care. Any inability to secure orphan drug designation or the exclusivity benefits of this designation could have an adverse impact on our ability to develop and commercialize our product candidates. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Obtaining orphan drug designation may not provide us with a material commercial advantage.

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. 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 for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the BLA. Fast Track designation does not change the standards for product approval.

Although aldafermin has received Fast Track designation from the FDA for PBC and NASH, we may not necessarily experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. 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 European Union 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 and standards. 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 recall 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, refuse to permit the import or export of products or require us to initiate a product recall.

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, the Department of Justice, the Department of Health and Human Services' 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 False Claims Act, 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 False Claims Act 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 will depend in significant part on our and our current or future licensors', licensees' or collaborators' ability to establish and maintain adequate protection of our intellectual property covering the product candidates we plan to develop, and the ability to develop these product candidates and commercialize the products resulting therefrom, without infringing the intellectual property rights of others. In addition to taking other steps to protect our intellectual property, we have applied for, and intend to continue to apply for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. We have filed numerous patent applications both in the United States and in certain foreign jurisdictions to obtain patent rights to inventions we have discovered, with claims directed to compositions of matter, methods of use, formulations, combination therapy and other technologies relating to our product candidates. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, whether the claims of the patents will exclude others from making, using or selling our product candidates or products that are substantially similar to our product candidates. In countries where we have not and do not seek patent protection, third parties may be able to manufacture and sell our product candidates without our permission, and we may not be able to stop them from doing so.

With respect to patent rights, we do not know whether any of the pending patent applications for any of our product candidates will result in the issuance of patents that effectively protect our technologies, processes and product candidates, or if any of our issued patents or our current or future licensors', licensees' or collaborators' issued patents will effectively prevent others from commercializing competitive technologies, processes and products. Publications 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 the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our current or future licensors, licensees or collaborators were the first to file for patent protection of such inventions.

Any changes we make to our product candidates, including aldafermin, NGM313, NGM120, NGM621, NGM386 and NGM395 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 the half-life extended variant of FGF19 that we are developing, NGM313, NGM120, NGM621, NGM386 and NGM395 or any of our other product candidates.

We do not currently own or have a license to any issued patents that cover our NGM217 or NGM621 product candidates, although they are disclosed and claimed in our pending U.S. provisional, U.S. non-provisional and/or Patent Cooperation Treaty ("PCT") applications. The patent landscape surrounding NGM217 and NGM621 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.

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. Moreover, 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 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.

Similar to other biotechnology companies, our patent position is generally highly uncertain and involves complex legal and factual questions. 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 and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our current or future licensors', licensees' or collaborators' pending and future patent applications 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. 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. Our and our current or future licensors', licensees' or collaborators' 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.

Furthermore, 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 a patent are not enforceable for their full scope, but are instead 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.

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 protective or effective as that in the United States and we may, therefore, be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States. Whether filed in the United States or abroad, our patent applications may be challenged or may fail to result in issued patents.

In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing or commercializing competing products. Furthermore, others may independently develop or commercialize similar or alternative technologies or drugs, or design around our patents. Our patents may be challenged, invalidated, circumvented or narrowed, or fail to provide us with any competitive advantages. In many foreign countries, patent applications and/or issued patents, or parts thereof, must be translated into the native language. If our patent applications or issued patents are translated incorrectly, they may not adequately cover our technologies; in some countries, it may not be possible to rectify an incorrect translation, which may result in patent protection that does not adequately cover our technologies in those countries.

Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States are less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and certain state laws in the United States. Consequently, we and our collaborator may not be able to prevent third parties from practicing our and our collaborator's inventions in all countries outside the United States, or from selling or importing products made using our and our collaborator's inventions in and into the United States or other jurisdictions. Competitors may use our and our collaborator's technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our collaborator have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and our and our collaborator's patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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 and our collaborator to stop the infringement of our and our collaborator's patents or the marketing of competing products in violation of our and our collaborator's proprietary rights, generally. Proceedings to enforce our and our collaborator's patent rights in foreign jurisdictions could result in substantial costs and divert our and our collaborator's efforts and attention from other aspects of our business, could put our and our collaborator's patents at risk of being invalidated or interpreted narrowly, could place our and our collaborator's patent applications at risk of not issuing and could provoke third parties to assert claims against us or our collaborator. We or our collaborator may not prevail in any lawsuits that we or our collaborator initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

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. In addition, 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. In those countries, we and our collaborator may have limited remedies if patents are infringed or if we or our collaborator are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Accordingly, our and our collaborator's efforts 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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance 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, in some cases, be cured 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 collaborator 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 technology, 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 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 would weaken our and our collaborator's ability to obtain new patents or to enforce existing patents and patents we and our collaborator may obtain in the future.

Patent reform laws, such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, as well as changes in how patent laws are interpreted, could increase the uncertainties and costs surrounding the prosecution of our and our collaborator's patent applications and the enforcement or defense of our or our collaborator's issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the filing and prosecution strategies associated with patent applications, including a change from a "first-to-invent" to a "first-inventor-to-file" patent system, and may also affect patent prosecution and litigation, such as by allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the "first-inventor-to-file" provisions, became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our collaborator's patent applications and the enforcement or defense of our or our collaborator's issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

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 cardio-metabolic disease, NASH, oncology and ophthalmic fields, and there are issued third-party patents and published third-party patent applications in these fields. The patent landscape around our aldafermin, NGM313, NGM217, NGM120, NGM621, NGM386 and NGM395 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 aldafermin, NGM313, NGM217, NGM120, NGM621, NGM386 and NGM395 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 depending on 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 several 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 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 our or our collaborator's patents or misappropriate or otherwise violate our or our collaborator's intellectual property rights. In the future, we or our collaborator may initiate legal proceedings to enforce or defend our or our collaborator's intellectual property rights, to protect our or our collaborator's trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us or our collaborator to challenge the validity or scope of intellectual property rights we own, control or to which we have rights. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of our or our collaborator's patents, requiring us or our collaborator to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time-consuming and many of our or our collaborator's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our collaborator can. Accordingly, despite our or our collaborator's efforts, we or our collaborator 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. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we or our collaborator 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 is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our or our collaborator's patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our collaborator's 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-party pre-issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, *inter partes* review or interference proceedings, or other pre-issuance or post-grant proceedings or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us or our collaborator, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our or our collaborator's patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, allow third parties to commercialize our technology or product candidates and compete directly with us, without payment to us, or could require us or our collaborator to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our product candidates without infringing third-party patent rights. Our business could be harmed if the prevailing party does not offer us or our collaborator a license on commercially reasonable terms, or at all. Even if we or our collaborator obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our collaborator. In addition, if the breadth or strength of protection provided by our or our collaborator's patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, many foreign jurisdictions have rules of discovery that are different than those in the United States and that may make defending or enforcing our or our collaborator's patents extremely difficult. There could also 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 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 intellectual property rights controlled by third parties, 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 the ability of our collaborator 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. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us or our collaborator alleging that we or our collaborator infringe their intellectual property rights or we or our collaborator may initiate legal proceedings against third parties 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 and time-consuming and many of our or our collaborator's adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our collaborator can.

For example, through our European representative, we filed an opposition in the European Patent Office ("EPO"), to a patent granted to St. Vincent's Hospital Sydney Limited, or St. Vincent's, claiming the use of MIC-1, also known as GDF15, in the treatment of obesity. In the first instance proceedings, the Opposition Division at the EPO upheld the patent as granted. We have appealed this decision to the Board of Appeals at the EPO, and the patentee filed its reply to our grounds for appeal in November 2018. Although there are uncertainties regarding EPO appeal timelines, summons to oral proceedings will likely issue towards the end of 2019, and oral proceedings are likely to be scheduled six to twelve months thereafter. The St. Vincent's patent as granted is currently scheduled to expire in April 2025. Even should the patent be upheld on appeal, we do not believe that NGM386 and/or NGM395 would be commercially launched until after expiration of the patent. In addition, we have filed an opposition in the EPO to a patent granted to Amgen Inc., or Amgen, claiming the use of GDF15 polypeptides for the treatment of several metabolic disorders. At the first instance proceedings, the Opposition Division at the EPO maintained the patent in amended form, with claims not including obesity, an indication for which we are presently pursuing regulatory approval for NGM386 and NGM395. We plan to appeal the decision to maintain the patent to the Board of Appeals at the EPO. The Amgen patent as granted is currently scheduled to expire in April 2032. If these patents have not expired, or are not ultimately deemed invalid in appeals stemming from the opposition proceedings, and/or our non-infringement positions are not upheld, and these patents are successfully

asserted against us in a European country court proceeding after the approval of either of our NGM386 or NGM395 product candidates for the treatment of obesity in Europe, then we may be required to obtain licenses to such patents in order to commercialize our GDF15 program product candidates, and there can be no assurance that such licenses would be available on commercially reasonable terms, or at all.

Additionally, in November 2018, we filed an opposition in the EPO to a patent granted to Genentech, Inc., or Genentech, claiming the use of an anti-KLB agonist antibody for treating diabetes mellitus or insulin resistance. We are one of two opponents challenging the Genentech patent as granted on numerous grounds, including lack of novelty and inventive step, insufficiency and claiming subject matter that extends beyond the application as originally filed. Genentech filed its response to opposition in April 2019. The EPO's summons to oral proceedings is expected in the third quarter of 2019. The Genentech patent is currently scheduled to expire in April 2028. If the Genentech patent is not invalidated in the opposition proceedings and appeals, has not expired and/or our non-infringement positions are not upheld, and this patent is successfully asserted against us or our collaborator in a European country court proceeding after the approval of our NGM313 product candidate for the treatment of diabetes and/or NASH in Europe, then we and/or our collaborator may be required to obtain a license to this patent in order to commercialize our NGM313 product candidate, and there can be no assurance that such license would be available on commercially reasonable terms, or at all. An unfavorable outcome in any such proceeding could require us or our collaborator to cease using the related technology or developing or commercializing our product candidates, or to attempt to license rights to it from the prevailing party, which may not be available on commercially reasonable terms, or at all.

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 and/or patentability of our product candidates. In general, such searches are conducted based on keywords, 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 such 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 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 above, or any appeals stemming therefrom. As to pending third-party applications, we cannot predict with any certainty which claims will issue, if any, or the scope of such issued claims. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability and the ability of our collaborator to commercialize any product candidates we may develop and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If any such third-party patents (including those that may issue from such applications) were successfully asserted against us or our collaborator or other commercialization partners and we were unable to successfully challenge the validity or enforceability of any such asserted patents, then we or our collaborator and other commercialization partners may be prevented from commercializing our product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results.

We may be subject to claims by third parties asserting that our employees or we have misappropriated a third party's 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. Some 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 these 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, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel 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.

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

If we breach any license agreement related to our product candidates, we could lose the ability to continue the development and commercialization of our product candidates.

Our commercial success depends upon our ability, and the ability of our licensors and collaborator, to develop, manufacture, market and sell our product candidates and use our and our collaborator's 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 licenses that are important to our business and 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 a license agreement with Lonza Sales under which we license cell lines used to produce our product candidates that are currently subject to our collaboration with Merck. We require Lonza Sales' prior consent to grant sub-licenses under this agreement and therefore Lonza Sales 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 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.

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 you 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.

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 technology 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 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 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 stock has been and may continue to be volatile, and you could lose all or part of your investment.

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 any non-renewal, termination or other change in our relationship with Merck;
- the success of competitive products or technologies;
- 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. Broad market and industry factors 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. A stockholder lawsuit could also divert the time and attention of our management. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

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

Our common stock is currently listed on the Nasdaq Global Select Market, or Nasdaq, under the symbol "NGM" and trades on that market. We cannot assure you that an active trading market for our common stock will be sustained. Accordingly, we cannot assure you of 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. Merck has granted a proxy to the chairman of our board of directors to vote Merck’s shares in favor of any action recommended and approved by our board of directors, subject to certain exceptions. 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.

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 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 shareholder vote to approve compensation of certain executive officers) and the "say on golden parachute" provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Act and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer; and
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation.

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.

Although we are still evaluating the JOBS Act, we currently intend to take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an "emerging growth company." We have elected to avail ourselves of this exemption and, therefore, 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 rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations. In addition, our independent registered public accounting firm will not be 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," which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an "emerging growth company," we may elect not to provide you with 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, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

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 of 2002 and the Dodd-Frank Wall Street Reform and Protection 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 may 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 may 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 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.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by The Nasdaq Global Select Market, the SEC or other regulatory authorities. In addition, our common stock may not be able to remain listed on The Nasdaq Global Select Market or any other securities exchange.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Substantially all of the shares of our common stock not sold in our initial public offering will be available for sale in the public market beginning after the end of the 180th day after the date of our initial public offering following the expiration of lock-up agreements, subject, in the case of our affiliates, to the conditions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. 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 will be available for sale in the public market beginning on March 17, 2020.

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.

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.

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 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 our research and early development program 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 optioned by Merck. Merck has also granted a proxy to the chairman of our board of directors to vote Merck’s shares in favor of any action recommended and approved by our board of directors, subject to certain exceptions.

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 claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Our amended and restated certificate of incorporation provides further that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. These choice of 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. If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business. For example, in December 2018 the Court of Chancery of the State of Delaware determined that the exclusive forum provision of federal district courts of the United States for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court. If this ultimate adjudication were to occur, the federal district court exclusive forum provision in our amended and restated certificate of incorporation would no longer be applicable.

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

Since April 1, 2019 we have made sales of the following unregistered securities:

(1) In April 2019, we issued and sold 4,121,683 shares (the Private Placement Shares) of our common stock at a price per share of $16.00 to Merck in a private placement that occurred concurrently with the closing of our initial public offering. The aggregate cash purchase price of the Private Placement Shares was $65.9 million.

The issuances and sales of the securities listed in (1) above was deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act, as a transaction by an issuer not involving a public offering.

Use of Proceeds from our Initial Public Offering of Common Stock

In April 2019, our Registration Statement on Form S-1 (No. 333-227608) was declared effective by the SEC pursuant to which we issued and sold an aggregate of 7,521,394 shares of common stock (inclusive of 6,666,667 shares of common stock and 854,727 shares of common stock pursuant to the underwriters' exercise of their over-allotment option) at a public offering price of $16.00 per share for aggregate net cash proceeds of $107.8 million, after deducting underwriting discounts, commissions and offering costs. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The sale and issuance of 6,666,667 shares in the IPO closed on April 8, 2019 and the sale of 854,727 additional shares pursuant to the underwriters' over-allotment option closed on May 7, 2019. Goldman Sachs & Co. LLC, Citigroup Global Markets Inc. and Cowen and Company, LLC acted as joint book-running managers for the offering.

There has been no material change in the planned use of proceeds from our initial public offering from that described in the Prospectus.

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.

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

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 and Acting 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 Acting 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.

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: August 12, 2019

By: /s/ David J. Woodhouse, Ph.D.
David J. Woodhouse, Ph.D.
Chief Executive Officer, Acting 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 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. I am 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. 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: August 12, 2019

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

Exhibit 32.1

CERTIFICATIONS 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 and Acting Chief Financial Officer of NGM Biopharmaceuticals, Inc. (the "Company") hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2019, 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: August 12, 2019

In Witness Whereof, the undersigned has set his hands hereto as of the twelfth day of August, 2019.

/s/ David J. Woodhouse, Ph.D.
David J. Woodhouse, Ph.D.
Chief Executive Officer and Acting Chief 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."